TITLE 1. ADMINISTRATION

PART 15. TEXAS HEALTH AND HUMAN SERVICES COMMISSION

CHAPTER 354. MEDICAID HEALTH SERVICES

SUBCHAPTER A. PURCHASED HEALTH SERVICES

DIVISION 11. GENERAL ADMINISTRATION

1 TAC §354.1149

The Executive Commissioner of the Texas Health and Human Services Commission (HHSC) proposes an amendment to §354.1149, concerning Exclusions and Limitations.

BACKGROUND AND PURPOSE

The purpose of the proposal is to align Texas Medicaid coverage of vaccines for adults with federal requirements in section 11405 of the Inflation Reduction Act (IRA) of 2022 (Public Law 117-169). On June 27, 2023, the Centers for Medicare & Medicaid Services issued guidance on its interpretation of the amendments to the Social Security Act made by the IRA to require Medicaid programs to cover vaccines and their administration, provided that the vaccine is approved by the U.S. Food and Drug Administration (FDA) for use by adult populations and is administered in accordance with recommendations of the Advisory Committee on Immunization Practices (ACIP), effective October 1, 2023. States are directed to add coverage for all ACIP-recommended vaccines for adults, including vaccines solely for travel to or from foreign countries. As a result, the Texas Health and Human Services Commission (HHSC) is removing the exclusion of all FDA-approved and ACIP-recommended vaccines used solely for occupation and/or travel as Medicaid benefits for the adult population.

SECTION-BY-SECTION SUMMARY

The proposed amendment to §354.1149 removes the exclusion in subsection (a)(9) of the rule for immunizations specifically for travel to or from foreign countries. This change is consistent with the requirements of the IRA of 2022. The proposed amendment renumbers the remaining paragraphs in subsection (a) and makes minor editing changes.

FISCAL NOTE

Trey Wood, HHSC Chief Financial Officer, has determined that for each year of the first five years that the rule will be in effect, there will be an estimated additional cost to state government as a result of enforcing and administering the rule as proposed. Enforcing or administering the rule does not have foreseeable implications relating to costs or revenues of local government.

The effect on state government for each year of the first five years the proposed rule is in effect is an estimated cost of $9,405 for all funds in fiscal year (FY) 2025, $9,305 in FY 2026, $9,207 in FY 2027, $9,108 in FY 2028, and $9,012 in FY 2029.

GOVERNMENT GROWTH IMPACT STATEMENT

HHSC has determined that during the first five years the rule will be in effect:

(1) the proposed rule will not create or eliminate a government program;

(2) implementation of the proposed rule will not affect the number of HHSC employee positions;

(3) implementation of the proposed rule will require an increase in future legislative appropriations;

(4) the proposed rule will not affect fees paid to HHSC;

(5) the proposed rule will not create a new regulation;

(6) the proposed rule will expand existing regulation;

(7) the proposed rule will not change the number of individuals subject to the rule; and

(8) HHSC has insufficient information to determine the proposed rule's effect on the state's economy.

SMALL BUSINESS, MICRO-BUSINESS, AND RURAL COMMUNITY IMPACT ANALYSIS

Trey Wood has also determined that there will be no adverse economic effect on small businesses, microbusinesses, or rural communities because participation in providing the immunizations described in the proposed rule is optional.

LOCAL EMPLOYMENT IMPACT

The proposed rule will not affect a local economy.

COSTS TO REGULATED PERSONS

Texas Government Code §2001.0045 does not apply to this rule because the rule is necessary to protect the health, safety, and welfare of the residents of Texas; does not impose a cost on regulated persons; and is necessary to comply with federal law.

PUBLIC BENEFIT AND COSTS

Emily Zalkovsky, State Medicaid Director, has determined that for each year of the first five years the rule is in effect, Texas Medicaid clients will have the option of receiving a wider array of vaccines helping to improve the quality of life for many.

Trey Wood has also determined that for the first five years the rule is in effect, there are no anticipated economic costs to per-

sons who are required to comply with the proposed rules because the proposed rule is optional for facilities to provide the covered immunizations and the proposed rule will provide Medicaid coverage to adult recipients for the additional immunizations.

TAKINGS IMPACT ASSESSMENT

HHSC has determined that the proposal does not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, does not constitute a taking under Texas Government Code §2007.043.

PUBLIC COMMENT

Written comments on the proposal may be submitted to Rules Coordination Office, P.O. Box 13247, Mail Code 4102, Austin, Texas 78711-3247, or street address 701 W. 51st Street, Austin, Texas 78751; or emailed to HHSRulesCoordinationOffice@hhs.texas.gov.

To be considered, comments must be submitted no later than 31 days after the date of this issue of the *Texas Register.* Comments must be (1) postmarked or shipped before the last day of the comment period; (2) hand-delivered before 5:00 p.m. on the last working day of the comment period; or (3) emailed before midnight on the last day of the comment period. If last day to submit comments falls on a holiday, comments must be postmarked, shipped, or emailed before midnight on the following business day to be accepted. When emailing comments, please indicate "Comments on Proposed Rule 24R026" in the subject line.

STATUTORY AUTHORITY

The amendment is authorized by Texas Government Code §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of services by the health and human services agencies; Texas Government Code §531.033, which provides the Executive Commissioner of HHSC with broad rulemaking authority; and Texas Human Resources Code §32.021, which provides HHSC with the authority to administer the federal medical assistance program in Texas and to adopt rules and standards for program administration.

The amendment affects Texas Government Code §531.0055.

§354.1149. Exclusions and Limitations.

(a) Notwithstanding any other provision of this subchapter, Medicaid services or supplies that are not medically necessary will not be considered for Medicaid reimbursement. The following benefit exclusions and limitations are applicable under the Medicaid program for services provided under this subchapter. They do not apply to Medicaid services provided through the Texas Health Steps Comprehensive Care Program. Additional exclusions and limitations are listed in the Texas Medicaid Provider Procedures Manual. The following benefits are not included in the Texas Medicaid Program:

(1) services provided to any individual who is an inmate in a public institution (except as a patient in a medical institution approved for participation in the Medicaid program), or is a patient in:

(A) the hospital or nursing sections of facilities for persons with intellectual and developmental disabilities; or

(B) an institution for mental disease if the patient is between the ages of 22 and 64;

(2) special shoes or other supportive devices for the feet and ambulation aids (except as provided for in the home health services program);

(3) any services provided by military medical facilities, except:

(A) those military hospitals enrolled to provide inpatient emergency services;

(B) Veterans Administration facilities; or

(C) United States Public Health Service hospitals;

(4) care and treatment related to any condition covered by workers' compensation laws;

(5) care, treatment, or other services by a doctor of dentistry unless:

(A) the recipient's dental diagnosis is causally related to a life-threatening medical condition; or

(B) the treatment is specifically authorized by the Health and Human Services Commission (HHSC) or its designee;

(6) any care or services to the extent that a benefit is paid or payable under Medicare;

(7) any services or supplies provided to an individual before the effective date of designation by HHSC as an eligible recipient or after the effective date of denial as an eligible recipient except orthodontic services that are authorized and initiated while the recipient is eligible for Medicaid may be continued for 36 months after a recipient is no longer Medicaid eligible;

(8) any services or supplies provided in connection with cosmetic surgery except as required for the prompt repair of accidental injury or for improvement of the functioning of a malformed body member;

~~[(9) immunizations specifically for travel to or from foreign countries. Immunizations included on the immunization schedule approved by the Advisory Committee on Immunization Practices (ACIP) are a benefit unless an immunization is specifically excluded by HHSC;]~~

(9) [~~(10)~~] any services provided by an immediate relative of the eligible recipient or member of the eligible recipient's household except for personal care services;

(10) [~~(11)~~] custodial care;

(11) [~~(12)~~] any services or supplies provided outside of the United States, except for Medicare deductible and coinsurance amounts subject to the limits specified in §354.1143 of this division [~~title~~] (relating to Coordination of Medicaid with Medicare Parts A, B, and C);

(12) [~~(13)~~] any services or supplies not provided for in this chapter;

(13) [~~(14)~~] any services or supplies not provided for in this chapter for:

(A) the treatment of flat foot conditions and the prescription of supportive devices therefor;

(B) the treatment of subluxations of the foot; or

(C) routine foot care (including the cutting or removal of corns, warts, or calluses, the trimming of nails, and other routine hygiene care);

(14) [~~(15)~~] any medical and remedial care, services, and supplies provided to a hospital inpatient after total hospitalization-related expenditures under the Medicaid Program reach $200,000 per recipient, per 12-month benefit period unless the services are exempted by subparagraphs (A) - (C) of this paragraph. For the purposes of this limit, "12-month benefit period" means 12 consecutive months beginning November 1 of each year and ending October 31 of the next year. The limit applies to hospitalization-related services while the recipient is a hospital inpatient regardless of where the services are provided, how soon within the 12-month period the limit is reached, and how many hospital stays are involved. For the purposes of this limit, HHSC or its designee processes and pays claims, if payable, based on the sequential date of service. The services exempted from the $200,000 limit are:

(A) covered benefits under §354.1175 of this division [~~title~~] (relating to Organ Transplants);

(B) care, services, and supplies otherwise authorized by HHSC; and

(C) physician services as allowed by Title XIX laws and regulations and state law; and

(15) [~~(16)~~] any services or supplies that are experimental or investigational.

(b) Outpatient Behavioral Health Services. Benefits to an individual for the diagnosis or treatment of mental disease, psychoneurotic, and personality disorders while not confined as an inpatient in a hospital are limited to 30 visits to enrolled practitioners per calendar year. This utilization control limitation may be exceeded when prior authorized on a case-by-case-basis.

(c) Private Room Facilities. Private room facilities are not a benefit unless a facility submits a physician's certification of medical necessity to HHSC or its designee certifying that one of the following conditions is met:

(1) the recipient, based on a medical opinion, has a critical or contagious illness;

(2) the eligible recipient's condition results in undue disturbance to other patients; or

(3) the need for care is emergent and lower cost facilities are not immediately available.

(d) Institutional Care. Separate payments are not made for services and supplies in an institution where the reimbursement formula and vendor payment include such services or supplies as a part of the institutional care.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on May 29, 2024.

TRD-202402393
Karen Ray
Chief Counsel
Texas Health and Human Services Commission
Earliest possible date of adoption: July 14, 2024
For further information, please call: (512) 438-4651

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CHAPTER 371. MEDICAID AND OTHER HEALTH AND HUMAN SERVICES FRAUD AND ABUSE PROGRAM INTEGRITY

SUBCHAPTER G. ADMINISTRATIVE ACTIONS AND SANCTIONS

DIVISION 3. ADMINISTRATIVE ACTIONS AND SANCTIONS

1 TAC §371.1721

The Executive Commissioner of the Texas Health and Human Services Commission (HHSC), on behalf of the Office of Inspector General (OIG), proposes in the Texas Administrative Code (TAC), Title 1, Part 15, Chapter 371, Subchapter G, Division 3, new §371.1721, concerning Recoupment of Overpayments Identified by Inspection.

BACKGROUND AND PURPOSE

The purpose of the proposal is to describe the OIG's inspection procedures related to records requests, inspection processes, notices, final reports, and due process.

Texas Government Code Section 531.102 authorizes the OIG to conduct inspections related to the provision and delivery of all health and human services in Texas to identify fraud, waste, or abuse.

SECTION-BY-SECTION SUMMARY

The proposed new §371.1721(a) summarizes OIG's performance of inspections, including the recovery of overpayments when identified during an inspection.

The proposed new §371.1721(b) describes the procedures related to an inspection records request, including the time deadline required to submit records in response to a records request. The proposed new §371.1721(b) also states that failure to timely produce requested records may result in an OIG enforcement action.

The proposed new §371.1721(c) describes the standards OIG inspections follow, the time scope, notice prior to the start of an inspection, and the opportunity to submit documentation to address an inspection finding. A person, as defined in §371.1 of this chapter, is subject to an OIG inspection.

The proposed new §371.1721(d) specifies the notices OIG sends during an inspection, consisting of the draft inspection report and final inspection report.

The proposed new §371.1721(e) outlines the contents of an inspection final report, including a management response, if any, and any recommendations, findings, or overpayment amounts.

The proposed new §371.1721(f) describes the due process provided to a person subject to an OIG inspection, including the requirements for requesting an administrative hearing at the HHSC Appeals Division.

The proposed new §371.1721(g) specifies the timing and circumstances under which results of an OIG inspection become final.

FISCAL NOTE

Trey Wood, HHSC Chief Financial Officer, has determined that for each year of the first five years that the rule will be in effect, there will be an estimated reduction in cost to state government

as a result of enforcing and administering the rule as proposed. The effect on state government for each year of the first five years the proposed rule is in effect is an estimated reduction in cost for all funds of $100,000 in fiscal year (FY) 2025, $100,000 in FY 2026, $100,000 in FY 2027, $100,000 in FY 2028, and $100,000 in FY 2029. The estimate for FY 2025 may vary depending on the rule implementation date.

GOVERNMENT GROWTH IMPACT STATEMENT

HHSC has determined that during the first five years that the rule will be in effect:

(1) the proposed rule will not create or eliminate a government program;

(2) implementation of the proposed rule will not affect the number of HHSC employee positions;

(3) implementation of the proposed rule will result in no assumed change in future legislative appropriations;

(4) the proposed rule will not affect fees paid to HHSC;

(5) the proposed rule will create a new regulation;

(6) the proposed rule will not expand, limit, or repeal existing regulations;

(7) the proposed rule will not change the number of individuals subject to the rule; and

(8) the proposed rule will not affect the state's economy.

SMALL BUSINESS, MICRO-BUSINESS, AND RURAL COMMUNITY IMPACT ANALYSIS

Trey Wood has also determined that there will be no adverse economic effect on small businesses, micro-businesses, or rural communities. The rule does not impose any additional costs on small businesses, micro-businesses, or rural communities that are required to comply with the rules.

LOCAL EMPLOYMENT IMPACT

The proposed rule will not affect a local economy.

COSTS TO REGULATED PERSONS

Texas Government Code §2001.0045 does not apply to this new rule because it does not impose a cost on regulated persons; is necessary to receive a source of federal funds or comply with federal law; and is necessary to implement legislation that does not specifically state that §2001.0045 applies to the rule.

PUBLIC BENEFIT AND COSTS

Kacy VerColen, OIG Chief of Audits and Inspections, has determined that for each year of the first five years the rule is in effect, the public benefit will be the identification and inspection of fraud, waste, and abuse, in the provision and delivery of health and human services in the state of Texas.

Trey Wood has also determined that for the first five years the rule is in effect, there are no anticipated economic costs to persons who are required to comply with the proposed rule because an overpayment recovery is a returning of funds that should have never been received, not a cost to the business.

TAKINGS IMPACT ASSESSMENT

OIG has determined that the proposal does not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, does not constitute a taking under Texas Government Code §2007.043.

PUBLIC COMMENT

Written comments on the proposal may be submitted to HHS Office of Inspector General - Chief Counsel Division, P.O. Box 85200, Austin, Texas 78708, or street address 4601 W. Guadalupe Street, Austin, Texas 78751-3146; or by email to IG_Rules_Comments_Inbox@hhsc.state.tx.us.

To be considered, comments must be submitted no later than 31 days after the date of this issue of the *Texas Register.* Comments must be (1) postmarked or shipped before the last day of the comment period; (2) hand-delivered before 5:00 p.m. on the last working day of the comment period; or (3) emailed before midnight on the last day of the comment period. If the last day to submit comments falls on a holiday, comments must be postmarked, shipped, or emailed before midnight on the following business day to be accepted. When emailing comments, please indicate "Comments on Proposed Rule 23R031" in the subject line.

STATUTORY AUTHORITY

The proposed new rule is authorized by Texas Government Code §531.0055(e), which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of services by the health and human services system; Texas Government Code §531.102(a), which grants the OIG the responsibility for the prevention, detection, audit, inspection, review, and investigation of fraud, waste, and abuse in the provision and delivery of all health and human services in the state, including services through any state-administered health or human services program that is wholly or partly federally funded, and which provides the OIG with the authority to obtain any information or technology necessary to enable it to meet its responsibilities; Texas Government Code §531.102(a-2), which requires the Executive Commissioner of HHSC to work in consultation with the Office of the Inspector General to adopt rules necessary to implement a power or duty of the office; Texas Government Code §531.102(x), which requires the Executive Commissioner of HHSC, in consultation with the Office of Inspector General, to adopt rules establishing criteria for determining enforcement and punitive actions with regard to a provider who has violated state law, program rules, or the provider's Medicaid provider agreement; Texas Government Code §531.033, which requires the Executive Commissioner of HHSC to adopt rules necessary to carry out the commission's duties under Chapter 531; Texas Human Resources Code §32.021 and Texas Government Code §531.021(a), which provide HHSC with the authority to administer the federal medical assistance (Medicaid) program in Texas, to administer Medicaid funds, and to adopt rules necessary for the proper and efficient regulations of the Medicaid program; Texas Government Code §531.1131(e), which requires the Executive Commissioner of HHSC to adopt rules necessary to implement §531.1131, including rules establishing due process procedures that must be followed by managed care organizations when engaging in payment recovery efforts as provided by Section 531.1131; and Texas Human Resources Code §32.039, which provides authority to assess administrative penalties and damages and provides due process for persons potentially subject to damages and penalties.

The proposed new rule affects Texas Government Code §531.0055 and Texas Human Resources Code Chapter 32.

§371.1721. Recoupment of Overpayments Identified by Inspection.

(a) Introduction. The OIG conducts inspections related to the provision and delivery of all health and human services in the state. The OIG may recover an overpayment identified in an inspection.

(b) Records.

(1) A person who receives a request for records and documentation for an OIG inspection must provide the records and documentation to the OIG within the time period requested by the OIG or 10 calendar days from the date of receipt of the request, whichever is later, except when OIG determines an element of surprise is critical to the inspection objective. When an element of surprise is critical, the person must provide the records and documentation to OIG when requested.

(2) When requested, a person subject to an OIG inspection must submit a signed and notarized OIG-approved records affidavit that properly authenticates the records provided to OIG as business records pursuant to Texas Rules of Evidence Rule 803(6) and Rule 902(10).

(3) Failure to produce requested records and affidavits may result in an OIG enforcement action under this chapter.

(c) Inspection procedures. During an inspection, the OIG:

(1) follows the Quality Standards for Inspection and Evaluation adopted by the Council of the Inspectors General on Integrity and Efficiency;

(2) limits the scope covered to a five year period;

(3) notifies the person subject to an inspection in writing of the impending inspection not later than the seventh calendar day before the first day of the site visit, if any, except when the OIG determines an element of surprise is critical to the inspection objective; and

(4) permits the person subject to an inspection to produce documentation to address any finding found during an inspection by the date specified by the OIG.

(d) Notice.

(1) Draft inspection report. The OIG delivers the draft inspection report to the person subject to the inspection after field work is completed.

(2) Final inspection report. The OIG delivers a final inspection report to the person subject to the inspection.

(3) Electronic mail. OIG notices may be sent by electronic mail.

(e) Final report. The final inspection report includes:

(1) a statement of compliance with the Quality Standards for Inspection and Evaluation;

(2) the management response, if provided, which may be summarized; and

(3) any recommendations, findings, or overpayment amount.

(f) Management response; overpayments; and due process.

(1) Draft inspection report. A person who is the subject of a draft inspection report may provide a written management response. The OIG must receive the written management response by the date specified by the OIG. The OIG may revise the draft inspection report as needed to incorporate management responses, if provided, or other relevant considerations; or the OIG may issue a final report.

(2) Final inspection report. A person who receives a final inspection report that includes an overpayment amount must:

(A) pay the overpayment amount no later than 60 calendar days after receipt of the final inspection report;

(B) timely request and execute a final payment plan agreement approved by the OIG; or

(C) make a timely request to the OIG for an administrative hearing at the HHSC Appeals Division.

(3) Request for payment plan agreement. A request for a final payment plan agreement must be in writing and received by the OIG no later than 15 calendar days after receipt of the final inspection report.

(4) Request for administrative hearing appeal. A request for an appeal must be in writing and received by the OIG no later than 15 calendar days after receipt of the final inspection report. The request must:

(A) be signed by the person or the person's attorney;

(B) specify the issues, findings, or legal authority being challenged and the basis for each challenge;

(C) for inspection findings that are not being challenged, state whether the person will remit payment no later than 60 calendar days after receipt of the final inspection report or seek a payment plan agreement; and

(D) include a copy of the final inspection report.

(5) Administrative hearing appeal. Upon timely receipt of a written request for appeal that meets the requirements in paragraph (4) of this subsection, the OIG notifies the HHSC Appeals Division of the person's hearing request. The appeal then proceeds pursuant to Chapter 357, Subchapter I of this title (relating to Hearings Under the Administrative Procedure Act).

(g) Scope and effect.

(1) A final inspection report becomes final and unappealable 30 calendar days after the person's receipt of the final inspection report, unless the OIG has received a timely and complete request for an appeal.

(2) If the person has timely and completely requested an appeal, the contested amount of the overpayment becomes final 30 calendar days after the person receives written notice of the appeal results. Recovery of any overpayments at issue on appeal is not initiated until the appeal has been finally determined.

(3) The effect of a final overpayment identified in a final inspection report is to create a final debt in favor of the State of Texas.

(4) Failure to pay a delinquent debt may result in OIG collection efforts or enforcement action under this chapter.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on May 29, 2024.

TRD-202402392
Karen Ray
Chief Counsel
Texas Health and Human Services Commission
Earliest possible date of adoption: July 14, 2024
For further information, please call: (512) 221-7320

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TITLE 4. AGRICULTURE

PART 2. TEXAS ANIMAL HEALTH COMMISSION

CHAPTER 51. ENTRY REQUIREMENTS

4 TAC §51.12

The Texas Animal Health Commission (Commission) proposes amendments to Title 4, Texas Administrative Code, Chapter 51 titled "Entry Requirements." Specifically, amendments to §51.12, regarding Sheep.

BACKGROUND AND PURPOSE

Scrapie is a fatal, degenerative disease affecting the central nervous systems of sheep and goats. It is classified as a transmissible spongiform encephalopathy (TSE), similar to BSE (bovine spongiform encephalopathy, or "mad cow disease") in cattle. Scrapie is believed to be caused by a prion, an infectious agent composed of protein, and is known for its long incubation period and eventual severe impact on the brain and spinal cord of affected animals. The disease is of significant concern in the sheep industry due to its impact on animal health and the resulting economic losses.

Research on the susceptibility of various sheep breeds to scrapie has shown that the difference in risk based on breed or type of sheep is too small to measure. However, it has been discovered that certain sheep that have historically had a higher prevalence of scrapie was likely due to management during lambing. The breeds of sheep that tend to lamb in small pens (jugs) lead to more exposure to the scrapie prion, unlike rambouillet sheep, which lamb in large pastures.

Nevertheless, general measures to prevent scrapie, such as selective breeding for resistance and adherence to strict biosecurity protocols, are relevant for all sheep breeds. There have been reports that individuals are seeking to circumvent USDA regulations to bring high-risk sheep into Texas, as well as spreading misinformation concerning the commission rules about scrapie. This proposed amendment is made in conjunction with proposed amendments to Chapter 60 of the Commission rules in an effort to clarify the Commission's rules and make every effort to reduce the incidence of and control the spread of scrapie in Texas.

SECTION-BY-SECTION DISCUSSION

Section 51.12 sets forth the requirements for sheep entering Texas. The proposed amendments require that all female breeding sheep and crossbred female breeding sheep originate from an Export Certified Flock or have documentation supporting that the animals are of the genotype RR at codon 171 or AA at codon 136 and QR at codon 171.

FISCAL NOTE

Ms. Jeanine Coggeshall, General Counsel for the Texas Animal Health Commission, determined that for each year of the first five years that the rule is in effect, enforcing or administering the proposed rules does not have foreseeable implications relating to costs or revenues of state or local governments. Commission employees will administer and enforce these rules as part of their current job duties and resources. Ms. Coggeshall also determined for the same period that there is no estimated increase or loss in revenue to the state or local government as a result of enforcing or administering the proposed amendments.

PUBLIC BENEFIT NOTE

Ms. Coggeshall determined that for each year of the first five years the rule is in effect, the anticipated public benefits are improved cooperation with local and state law enforcement to better enforce Commission entry requirements.

TAKINGS IMPACT ASSESSMENT

The Commission determined that the proposal does not restrict, limit, or impose a burden on an owner's rights to his or her private real property that would otherwise exist in the absence of government action. Therefore, the proposed rules are compliant with the Private Real Property Preservation Act in Texas Government Code §2007.043 and do not constitute a taking.

LOCAL EMPLOYMENT IMPACT STATEMENT

The Commission determined that the proposed rules would not impact local economies and, therefore, did not file a request for a local employment impact statement with the Texas Workforce Commission pursuant to Texas Government Code §2001.022.

REGULATORY ANALYSIS OF MAJOR ENVIRONMENTAL RULES

The Commission determined that this proposal is not a "major environmental rule" as defined by Government Code §2001.0225. "Major environmental rule" is defined to mean a rule the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or the public health and safety of a state or a sector of the state. This proposal is not specifically intended to protect the environment or reduce risks to human health from environmental exposure.

GOVERNMENT GROWTH IMPACT STATEMENT

In compliance with the requirements of Texas Government Code §2001.0221, the Commission prepared the following Government Growth Impact Statement. The Commission determined for each year of the first five years the proposed rule would be in effect, the proposed rule:

Will not create or eliminate a government program;

Will not require the creation or elimination of employee positions;

Will result in no assumed change in future legislative appropriations;

Will not affect fees paid to the Commission;

Will create new regulation;

Will expand existing regulations;

Will not change the number of individuals subject to the rule; and

Will not affect the state's economy.

SMALL BUSINESS, MICRO-BUSINESS, AND RURAL COMMUNITY IMPACT ANALYSIS

Ms. Coggeshall also determined that there will be no adverse economic effect on small businesses, micro-businesses, or rural communities pursuant to Texas Government Code, Chapter 2006. The rules do not impose any additional costs on small businesses, micro-businesses, or rural communities that are required to comply with the rules.

COSTS TO REGULATED PERSONS

The proposed amendments to Chapter 51 do not impose additional costs on regulated persons and are designed to better align Commission scrapie rules with the USDA's scrapie program and current science. The proposed rules do not otherwise impose a direct cost on a regulated person, state agency, a special district, or a local government within the state.

PUBLIC COMMENT

Written comments regarding the proposed amendments may be submitted to Amanda Bernhard, Texas Animal Health Commission, 2105 Kramer Lane, Austin, Texas 78758, by fax at (512) 719-0719 or by e-mail to comments@tahc.texas.gov. To be considered, comments must be received no later than thirty (30) days from the date of publication of this proposal in the *Texas Register.* When faxing or emailing comments, please indicate " Comments on Proposed Rule-Chapter 51, Entry Requirements" in the subject line.

STATUTORY AUTHORITY

The amendments are authorized by Texas Agriculture Code, Chapter 161.

Pursuant to §161.041, titled "Disease Control", the Commission shall protect all livestock, exotic livestock, domestic fowl, and exotic fowl from diseases the Commission determines require control or eradication. Pursuant to §161.041(b) the Commission may act to eradicate or control any disease or agent of transmission for any disease that affects livestock, exotic livestock, domestic fowl, or exotic fowl. The Commission may adopt any rules necessary to carry out the purposes of this subsection, including rules concerning testing, movement, inspection, and treatment.

Pursuant to §161.043, titled "Regulation of Exhibitions", the Commission may regulate the entry of livestock and may require certification of those animals as reasonably necessary to protect against communicable diseases.

Pursuant to §161.046, titled "Rules", the Commission may adopt rules as necessary for the administration and enforcement of this chapter.

Pursuant to §161.047, titled "Entry Power", a commissioner or veterinarian or inspector employed by the Commission may enter public or private property for the exercise of an authority or performance of a duty under Chapter 161.

Pursuant to §161.048, titled "Inspection of Shipment of Animals or Animal Product", the Commission may require testing, vaccination, or another epidemiologically sound procedure before or after animals are moved. An agent of the Commission is entitled to stop and inspect a shipment of animals or animal products being transported in this state to determine if the shipment originated from a quarantined area or herd; or determine if the shipment presents a danger to the public health or livestock industry through insect infestation or through a communicable or non-communicable disease.

Pursuant to §161.054, titled "Regulation of Movement of Animals; Exception", the Commission may by rule regulate the movement of animals, and may restrict the intrastate movement of animals even though the movement of the animals is unrestricted in interstate or international commerce. The Commission may require testing, vaccination, or another epidemiologically sound procedure before or after animals are moved.

Pursuant to §161.056(a), titled "Animal Identification Program", the Commission, to provide for disease control and enhance the ability to trace disease-infected animals or animals that have been exposed to disease, may develop and implement an animal identification program that is no more stringent than a federal animal disease traceability or other federal animal identification program. Section 161.056(d) authorizes the Commission to adopt rules to provide for an animal identification program more stringent than a federal program only for control of a specific animal disease or for animal emergency management.

Pursuant to §161.081, titled "Importation of Animals", the Commission by rule may provide the method for inspecting and testing animals before and after entry into the state of Texas. The Commission may create rules for the issuance and form of health certificates and entry permits.

No other statutes, articles, or codes are affected by this proposal.

§51.12. Sheep.

(a) (No change.)

(b) Scrapie.

(1) - (3) (No change.)

(4) All female breeding sheep [~~blackface ovine females~~] and all [~~blackface~~] crossbred female breeding sheep as defined by §60.1 of this title (relating to Definitions) [~~females~~] , except hair sheep, imported into the State of Texas for breeding purposes shall originate from an Export [~~a Scrapie~~] Certified [~~Free~~] Flock or have documentation supporting that the animals are of the genotype RR at codon 171 or AA at codon 136 and QR at codon 171.

(5) (No change.)

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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Jeanine Coggeshall
General Counsel
Texas Animal Health Commission
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For further information, please call: (512) 839-0511

CHAPTER 60. SCRAPIE

4 TAC §60.1

The Texas Animal Health Commission (Commission) proposes amendments to Title 4, Texas Administrative Code, Chapter 60 titled Scrapie.

BACKGROUND:

Scrapie is a fatal, degenerative disease affecting the central nervous systems of sheep and goats. It is classified as a transmissible spongiform encephalopathy (TSE), similar to BSE (bovine spongiform encephalopathy, or "mad cow disease") in cattle. Scrapie is believed to be caused by a prion, an infectious agent composed of protein, and is known for its long incubation period and eventual severe impact on the brain and spinal cord of affected animals. The disease is of significant concern in the sheep industry due to its impact on animal health and the resulting economic losses.

Research on the susceptibility of various sheep breeds to scrapie has shown that the difference in risk based on breed or type of sheep is too small to measure. However, it has been discovered that certain sheep that have historically had a higher prevalence of scrapie was likely due to management during lambing. The breeds of sheep that tend to lamb in small pens (jugs) lead to more exposure to the scrapie prion, unlike rambouillet sheep, which lamb in large pastures.

Nevertheless, general measures to prevent scrapie, such as selective breeding for resistance and adherence to strict biosecurity protocols, are relevant for all sheep breeds. There have been reports that individuals are seeking to circumvent USDA regulations to bring high-risk sheep into Texas, as well as spreading misinformation concerning the commission rules about scrapie. This proposed amendment is made in conjunction with proposed amendments to Chapter 51 of the Commission rules in an effort to clarify the Commission's rules and make every effort to reduce the incidence of and control the spread of scrapie in Texas.

SECTION BY SECTION DISCUSSION

The proposed amendments to Section 60.1(8) eliminate the definition for "Blackfaced Sheep" and reorganize the definition of "Breed Associations and Registries" to conform to alphabetical order.

The proposed amendments to Section 60.1(9) adds a definition for "Breeding Sheep."

FISCAL NOTE

Ms. Jeanine Coggeshall, General Counsel of the Texas Animal Health Commission, determined that for each year of the first five years the rules are in effect, there will be no additional fiscal implications for state or local government because current commission employees will administer and enforce these rules as part of their current job duties and resources. Ms. Coggeshall also determined for the same period that there is no estimated increase or loss in revenue to state or local government as a result of enforcing or administering the rule amendments.

PUBLIC BENEFIT NOTE

Ms. Coggeshall determined that for each year of the first five years the rules are in effect, the anticipated public benefit, due to enforcing the rules, will be to prevent higher risk sheep from potentially reintroducing scrapie to the state.

TAKINGS IMPACT ASSESSMENT

The Commission determined that the proposal does not restrict, limit, or impose a burden on an owner's rights to his or her private real property that would otherwise exist in the absence of government action. Instead, the proposed amendments relate to the handling of animals, including requirements concerning testing, movement, inspection, identification, reporting of disease, and treatment pursuant to 4 TAC §59.7. Therefore, the proposed rules are compliant with the Private Real Property Preservation Act in Texas Government Code §2007.043 and do not constitute a takings.

SMALL BUSINESS, MICRO-BUSINESS, AND RURAL COMMUNITY IMPACT ANALYIS

Ms. Coggeshall also determined that there will be no adverse economic effect on small businesses, micro-businesses, or rural communities. The rules do not impose any additional costs on small businesses, micro-businesses, or rural communities that are required to comply with the rules.

REGULATORY ANALYSIS OF MAJOR ENVIRONMENTAL RULES

The Commission determined that this proposal is not a "major environmental rule" as defined by Government Code §2001.0225. "Major environmental rule" is defined to mean a rule the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or the public health and safety of a state or a sector of the state. This proposal is not specifically intended to protect the environment or reduce risks to human health from environmental exposure.

LOCAL EMPLOYMENT IMPACT STATEMENT

The Commission determined that the proposed rules would not impact local economies and, therefore, did not file a request for a local employment impact statement with the Texas Workforce Commission pursuant to Texas Government Code §2001.022.

GOVERNMENT GROWTH IMPACT STATEMENT

In compliance with the requirements of Texas Government Code §2001.0221, the commission prepared the following Government Growth Impact Statement. The Commission determined for each year of the first five years the proposed rules would be in effect, the proposed rules:

Will not create or eliminate a government program;

Will not require the creation or elimination of employee positions;

Will result in no assumed change in future legislative appropriations;

Will not affect fees paid to the Commission;

Will create new regulation;

Will expand existing regulations;

Will not change the number of individuals subject to the rule; and

Will not affect the state's economy.

COSTS TO REGULATED PERSONS

The Commission determined there may be costs associated with requiring specific genotyping on all blackface ovine, as well as embryos and semen, because the Commission would take enforcement actions against those regulated persons who violate the entry requirements for blackface ovine. The current population of blackface ovine is only a fraction of the total ovine population, so the number of regulated persons this rule change would affect would not be significant.

The Commission also determined the proposed rules follow the legislative requirement that the commission shall protect all livestock from disease the Commission determines require control or eradication. Further, Government Code §2001.045, related to increasing costs to regulated persons, does not apply to this rule proposal to adopt a new reportable or actionable disease pursuant to Agriculture Code §161.041, the rules proposed here do not impose a direct cost on regulated persons, including a state agency, a special district, or a local government, within the state. Therefore, it is not necessary to repeal or amend any other existing rule.

REQUEST FOR COMMENT

Written comments regarding the proposed amendments may be submitted to Amanda Bernhard, Texas Animal Health Commission, 2105 Kramer Lane, Austin, Texas 78758, by fax to (512) 719-0719 or by email to comments@tahc.texas.gov. To be considered, comments must be received no later than thirty (30) days from the date of publication of this proposal in the *Texas Register.* When faxing or emailing comments, please indicate "Comments on Chapter 60-Scrapie " in the subject line.

STATUTORY AUTHORITY

The amendments are authorized by Texas Agriculture Code, Chapter 161.

Pursuant to §161.041, titled "Disease Control", the Commission shall protect all livestock, exotic livestock, domestic fowl, and exotic fowl from diseases the commission determines require control or eradication. Pursuant to §161.041(b) the commission may act to eradicate or control any disease or agent of transmission for any disease that affects livestock, exotic livestock, domestic fowl, or exotic fowl. The Commission may adopt any rules necessary to carry out the purposes of this subsection, including rules concerning testing, movement, inspection, and treatment.

Pursuant to §161.043, titled "Regulation of Exhibitions", the Commission may regulate the entry of livestock and may require certification of those animals as reasonably necessary to protect against communicable diseases.

Pursuant to §161.046, titled "Rules", the Commission may adopt rules as necessary for the administration and enforcement of this chapter.

Pursuant to §161.047, titled "Entry Power", a commissioner or veterinarian or inspector employed by the commission may enter public or private property for the exercise of an authority or performance of a duty under Chapter 161.

Pursuant to §161.048, titled "Inspection of Shipment of Animals or Animal Product", the Commission may require testing, vaccination, or another epidemiologically sound procedure before or after animals are moved. An agent of the Commission is entitled to stop and inspect a shipment of animals or animal products being transported in this state to determine if the shipment originated from a quarantined area or herd; or determine if the shipment presents a danger to the public health or livestock industry through insect infestation or through a communicable or non-communicable disease.

Pursuant to §161.054, titled "Regulation of Movement of Animals; Exception", the Commission may by rule regulate the movement of animals, and may restrict the intrastate movement of animals even though the movement of the animals is unrestricted in interstate or international commerce. The Commission may require testing, vaccination, or another epidemiologically sound procedure before or after animals are moved.

Pursuant to §161.056(a), titled "Animal Identification Program", the Commission, to provide for disease control and enhance the ability to trace disease-infected animals or animals that have been exposed to disease, may develop and implement an animal identification program that is no more stringent than a federal animal disease traceability or other federal animal identification program. Section 161.056(d) authorizes the Commission to adopt rules to provide for an animal identification program more stringent than a federal program only for control of a specific animal disease or for animal emergency management.

Pursuant to §161.081, titled "Importation of Animals", the Commission by rule may provide the method for inspecting and testing animals before and after entry into the state of Texas. The Commission may create rules for the issuance and form of health certificates and entry permits.

No other statutes, articles, or codes are affected by this proposal.

§60.1. Definitions.

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise:

(1) - (7) (No change.)

(8) Breed Associations and Registries--organizations that maintain the permanent records of ancestry or pedigrees of animals (including the animal's sire and dam), individual identification of animals, and/or ownership of animals. [~~Blackfaced Sheep--any purebred Suffolk, Hampshire, Shropshire, or cross thereof, any non-purebred sheep known to have Suffolk, Hampshire, or Shropshire ancestors, and any non-purebred wool sheep of unknown ancestry with a black face. Hair sheep with black or dark faces are not considered to be in this category.~~]

(9) Breeding Sheep--sexually intact sheep six months of age or older raised for the purpose of breeding. [~~Breed Associations and Registries--organizations that maintain the permanent records of ancestry or pedigrees of animals (including the animal's sire and dam), individual identification of animals, and/or ownership of animals.~~]

(10) - (57) (No change.)

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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Jeanine Coggeshall
General Counsel
Texas Animal Health Commission
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TITLE 10. COMMUNITY DEVELOPMENT

PART 8. TEXAS SPACE COMMISSION

CHAPTER 320. COMMISSION GOVERNANCE

SUBCHAPTER A. COMMISSION STANDARDS ON CONFLICTS OF INTEREST AND CODE OF CONDUCT

10 TAC §§320.1 - 320.7

The Texas Space Commission ("Commission") proposes new 10 TAC §§320.1 - 320.7, Subchapter A, concerning Commission Standards on Conflicts of Interest and Code Of Conduct.

EXPLANATION AND JUSTIFICATION OF THE RULES

In May 2023, the 88th Texas Legislature passed House Bill 3447, which, in part, created the Texas Space Commission, an agency administratively attached to the Office of the Governor. The Commission was established to strengthen Texas's proven leadership in civil, commercial, and military aerospace activity and to promote innovation in the fields of space exploration and com-

mercial aerospace opportunities. House Bill 3447 established a Board of Directors ("Board") to govern the Commission and directed the Board to adopt conflict-of-interest rules to govern members of the Board and Commission employees. In accordance with that directive, the Commission held its first meeting on May 8, 2024, and unanimously voted to propose the conflict of interest and code of conduct rules detailed in this rulemaking.

SECTION BY SECTION SUMMARY

Proposed new §320.1 specifies the intent of the Commission regarding the rules in Subchapter A.

Proposed new §320.2 establishes definitions the Commission and Board will utilize in undertaking its work.

Proposed new §320.3 establishes when Board members, Commission staff, and staff of the Office of the Governor providing administrative support to the Commission must recuse themselves. The rule also details the circumstances in which a person has a financial or professional interest in a matter. The rule also specifies who must receive notices when the person specified by the rules to receive notice also holds a conflict of interest.

Proposed new §320.4 details how Board members, Commission Executive Director, and other staff assisting the Commission must provide notice and disclose of the existence of a conflict. The rule also establishes that individuals who hold conflicts must recuse themselves. Proposed new §320.5 establishes that the requirement to recuse may be waived in exceptional circumstances and specifies what situations constitute exceptional circumstances.

Proposed new §320.6 establishes how failures to report conflicts of interests shall be reported and investigated.

Proposed new §320.7 establishes the code of conduct for all Board members, the Executive Director, and all other staff that supports the work of the Commission.

FISCAL NOTE

Gwen Griffin, Chair of the Texas Space Commission, has determined that the first five-year period the proposed rules are in effect, there will be no additional estimated cost, reduction of costs, or loss or increase in revenue to the state or local governments due to the enforcement or administration of the rules. Additionally, Chair Griffin has determined that enforcing or administering the rules does not have foreseeable implications relating to the costs or revenues of state or local government.

PUBLIC BENEFIT

Chair Griffin has determined for the first five-year period the proposed rules are in effect there will be a benefit to grant applicants and the general public because the rules will promote the fair and transparent administration of the grant programs entrusted to the Commission.

PROBABLE ECONOMIC COSTS

Chair Griffin has determined for the first five-year period the proposed rules are in effect, there will be no additional economic costs to persons required to comply with the proposed rules.

REGULATORY FLEXIBILITY ANALYSIS FOR SMALL AND MICRO-BUSINESSES AND RURAL COMMUNITIES.

Chair Griffin has determined that the proposed rules will have no adverse economic effect on small businesses, micro-businesses, or rural communities. Therefore, the Commission is not required to prepare a regulatory flexibility analysis pursuant to §2006.002, Texas Government Code.

LOCAL EMPLOYMENT IMPACT STATEMENT

Chair Griffin has determined that the proposed rules will not affect a local economy, so the Commission is not required to prepare a local employment impact statement under §2001.002, Texas Government Code.

GOVERNMENT GROWTH IMPACT STATEMENT

Chair Griffin has determined that during each year of the first five years in which the proposed rules are in effect, the rules:

1) will not create or eliminate government programs;

2) will not require the creation of new employee positions;

3) will not require an increase or decrease in future legislative appropriations to the Commission;

4) will not require an increase or decrease in fees paid to the Commission;

5) will create new regulations;

6) will not expand certain existing regulations, limit certain existing regulations, or repeal existing regulations;

7) will increase the number of individuals subject to the applicability of the rules; and

8) will positively affect the Texas economy.

TAKINGS IMPACT ASSESSMENT

Chair Griffin has determined that there are no private real property interests affected by the proposed rules. Thus, the Commission is not required to prepare a takings impact assessment pursuant to §2007.043, Texas Government Code.

REQUEST FOR PUBLIC COMMENTS

Comments on the proposed rules may be submitted to Joseph Behnke, Counsel for the Texas Space Commission, P.O. Box 12428, Austin, Texas 78701, or by email to joseph.behnke@gov.texas.gov with the subject line "Texas Space Commission Rules." The deadline for receipt of comments is 5:00 p.m., Central Time, on July 3, 2024, which is at least 30 days from the date of publication in the *Texas Register.*

STATUTORY AUTHORITY.

Section 482.401, Texas Government Code, authorizes the Commission to adopt conflict-of-interest rules to govern the members of the Board and Commission employees. Section 482.403, Texas Government Code, also requires the Commission to adopt rules governing the waiver of conflict-of-interest rules required under section 482.401, Texas Government Code, as well as the investigation and consequences of unreported conflicts of interest.

CROSS REFERENCE TO STATUTE

Chapter 482, Texas Government Code. No other statutes, articles, or codes are affected by the proposed rules.

§320.1. Intent.

It is the intent of the Texas Space Commission, its Board of Directors, Executive Director, Chief Compliance Officer, staff, and all parties affiliated with the Commission to provide applicants for funds from the Space Exploration and Aeronautics Research Fund a fair and unbiased, merit-based assessment free from conflicts of interests, impropriety, and self-dealing. This Subchapter provides requirements to avoid con-

flicts of interest and a code of conduct to be observed by those individuals involved in the application review process, the creation of contracts related to awards, and compliance and oversight matters.

§320.2. Definitions.

The words and terms used in this Chapter shall have the meanings provided below, unless the context clearly indicates otherwise.

(1) Board--The Board of Directors established under Section 482.105, Texas Government Code, to govern the Texas Space Commission.

(2) Chair--The presiding officer of the Board.

(3) Executive Director--The executive director of the Texas Space Commission, hired by the Board under Section 482.106(a), Texas Government Code.

(4) General Counsel--The General Counsel Division of the Office of the Governor.

(5) Second Degree of Affinity or Consanguinity--A spouse, parent, child, grandparent, grandchild, or sibling, or the spouse of each of those respective relatives, of a member of the Board. Stepfamily members (e.g., stepbrother, stepmother, etc.) are considered consanguineous relatives.

(6) Space Exploration and Aeronautics Research Fund or Fund--The fund established by Section 482.301, Texas Government Code, created as a trust fund outside the treasury with the Texas Comptroller of Public Accounts and administered by the Commission.

(7) Texas Space Commission or Commission--The body governed by the Board and established under Section 482.101, Texas Government Code, to strengthen Texas's proven leadership in civil, commercial, and military aerospace activity and to promote innovation in the fields of space exploration and commercial aerospace opportunities, including the integration of space, aeronautics, and aviation industries into the economy of this state.

(8) Vice-chair--The officer of the Board empowered to fulfill the duties of the Chair in the Chair's absence from or inability to participate during a meeting of the Board.

§320.3. Conflicts of Interest.

(a) A member of the Board, the Executive Director, the Chief Compliance Office, or staff of the Texas Space Commission or the Office of the Governor employee shall recuse himself or herself, as provided by §320.4 of this chapter (concerning Disclosure of Conflict Of Interest; Recusal), if the member or staff member, or an individual who is related to the member or staff member within the Second Degree of Affinity or Consanguinity, has a professional interest or financial interest in an entity receiving or applying to receive a grant from the Fund.

(b) An individual has a financial interest in an entity receiving or applying to receive a grant from the Fund if the individual:

(1) owns or controls, directly or indirectly, an ownership interest, including sharing in profits, proceeds, or capital gains, in an entity, or in a foundation or similar organization affiliated with an entity, receiving or applying to receive a grant from the Commission, unless the ownership interest is limited to shares owned through an investment in a publicly traded mutual fund or similar investment vehicle if the individual subject to this Chapter does not exercise any discretion or control regarding the investment of the assets of the fund or other investment vehicle; or

(2) could reasonably foresee that an action or recommendation by the Board could result in a financial benefit to the individual.

(c) An individual has a professional interest if the individual:

(1) is a member of the board of directors, other governing board, or any committee of an entity or an organization affiliated with an entity receiving or applying to receive a grant from the Fund;

(2) serves as an elected or appointed officer of an entity receiving or applying to receive a grant from the Fund or an organization affiliated with the entity;

(3) is a staff member of, consultant for, or is negotiating future employment or a consulting arrangement with an entity receiving or applying to receive a grant from the Fund or an organization affiliated with the entity; or

(4) represents in business or law, including actively seeking to represent, an entity receiving or applying to receive a grant from the Commission or an organization affiliated with the entity.

(d) Notwithstanding anything to the contrary in this Chapter, if any notice, report, or disclosure required to be delivered under this Chapter would result in the communication going solely to an individual who holds a conflict of interest related to the matter being noticed, reported, or disclosed, the reporting individual shall instead deliver the notice, report, or disclosure to the first individual from the following list who does not hold a conflict of interest:

(1) Chief Compliance Officer;

(2) Executive Director;

(3) Chair;

(4) Vice-chair; or

(5) a member of the Board, in descending order of seniority, as determined by how long the member has continuously served on the Board.

§320.4. Disclosure of Conflicts of Interest; Recusal.

(a) If a member of the Board has a conflict of interest as described by §320.3 of this chapter (relating to Conflicts of Interest) regarding an application that comes before the Commission for review or other action, the member shall:

(1) provide written notice to the Executive Director and the Chair, or the Vice-chair if the Chair holds a conflict of interest;

(2) disclose the conflict of interest in an open meeting of the Board; and

(3) recuse himself or herself from participating in the review, discussion, deliberation, and vote on the application and from accessing information regarding the matter to be decided.

(b) If the Executive Director has a conflict of interest described by §320.3 of this chapter regarding an application that comes before the Executive Director to take an action, the Executive Director shall:

(1) provide written notice to the Chair and Chief Compliance Officer of the conflict of interest; and

(2) recuse himself or herself from participating in the processing or review of the application and be prevented from accessing information regarding the matter to be decided.

(c) If the Executive Director must recuse himself or herself in a matter, the Chief Compliance Officer shall undertake the tasks and actions the Executive Director would have performed but for the conflict.

(d) If an individual other than the Executive Director is serving as staff to the Commission and has a conflict of interest described by §320.3 of this chapter regarding an application that comes before the staff member for review or other action, the staff member shall:

(1) provide written notice to the Executive Director of the conflict of interest; and

(2) recuse himself or herself from participating in the review of the application and be prevented from accessing any information regarding the matter to be decided.

(e) A member of the Board, the Executive Director, Chief Compliance Officer, or staff of the Commission with a conflict of interest may seek a waiver as provided by §320.5 of this chapter.

(f) An individual who is subject to this Chapter is considered in compliance with the conflict of interest provisions of this Chapter if the individual:

(1) reports his or her potential conflict of interest or another impropriety or self-dealing; and

(2) fully complies with the recommendations of the General Counsel and recusal requirements.

(g) If a member of the Board, the Executive Director, Chief Compliance Officer, or staff of the Commission intentionally violates this Chapter, that individual is subject to removal from further participation in the Commission's application review process.

§320.5. Exceptional Circumstances Requiring Participation.

(a) The requirements of this Chapter related to conflicts of interest may be waived under exceptional circumstances for a member of the Board, the Executive Director, Chief Compliance Officer, or staff of the Commission. The waiver may only be granted in accordance with the requirements of this section.

(b) Exceptional circumstances providing a potential basis for waiver:

(1) Expertise or unique qualifications. The individual who holds the conflict is the only individual affiliated with the Commission with the expertise and ability to appropriately evaluate an application for a grant from the Fund.

(2) Participation Significantly Outweighs Bias. The value of the participation of the individual who holds the conflict significantly outweighs the potential bias the individual may have in the review of an application.

(3) Board Discretion. The Board may determine, in an open meeting and upon a majority vote of members present, that a circumstance presented to the Board presents an exceptional circumstance that requires participation of a member or staff member. A member whose circumstances are under consideration by the Board under this provision must recuse himself or herself from participation in the discussion, consideration, and vote on the determination made in this paragraph.

(c) Procedure for seeking waiver of conflict-of-interest requirements for an exceptional circumstance:

(1) The Executive Director or a member of the Board may propose granting a waiver to a conflicted individual by submitting to the Chair a written statement about the conflict of interest, the exceptional circumstance requiring the waiver, and any proposed limitations to the waiver;

(2) the proposed waiver must be publicly reported at a meeting of the Board;

(3) a majority vote of the Board members present and voting must vote to grant a waiver; and

(4) the Commission must retain documentation of each waiver granted and retain them in accordance with the record retention policy applicable to the Commission.

§320.6. Investigation of Failures to Report Conflicts of Interest.

(a) Any individual subject to this Chapter who becomes aware of a potential unreported conflict of interest shall immediately notify the Executive Director of the potential conflict of interest. If the potential conflict of interest is held by the Executive Director, the individual may submit the notice to the Chair.

(b) An individual who is not subject to this Chapter who has a good faith belief that an individual who is subject to this Chapter has an unreported conflict of interest may submit written notice to the Executive Director of the potential conflict. If the potential conflict of interest is held by the Executive Director, the individual may submit the notice to the Chair. The written notice must provide all facts regarding the alleged conflict of interest known to the reporting individual.

(c) Upon receipt of notice of a conflict under either subsection (a) or (b) of this section, the Executive Director must notify the Chair and the General Counsel. If the Chair receives the notice, the Chair shall notify the General Counsel.

(d) After receiving a notice under this section, the General Counsel shall:

(1) investigate the matter; and

(2) provide an opinion to the Executive Director and Chair unless the alleged conflict is held by the Chair, then the opinion shall be provided to the Vice-chair instead. The opinion shall include:

(A) a statement of the facts giving rise to the alleged conflict;

(B) a determination of whether a conflict of interest, another impropriety, or self-dealing exists; and

(C) if the opinion finds that a conflict of interest or another impropriety or self dealing exists, recommendations for any appropriate course of action.

(e) After receiving the General Counsel's opinion and consulting with the member of the Board who receives notice under subsection (d) of this section, the Executive Director shall take immediate actions regarding the recusal of the individual from any discussion of or access to information regarding the matter at issue. If the alleged conflict of interest is held by the Executive Director, the Chair shall take actions to ensure the recusal of the Executive Director.

(f) The Executive Director shall determine whether a conflict of interest exists involving the individual who is the subject of the investigation. If the Executive Director is alleged to hold the conflict, the Chair shall make the determination. The determination must include actions to be taken, if any, to address the conflict of interest, including reconsideration of an application.

(1) The decision is final unless three or more members of the Board request that the issue be added to the agenda of the next meeting of the Board.

(2) If a conflict of interest is present, the individual making the determination shall report the conflict to the Board, the Chief Compliance Officer, staff of the Commission, and General Counsel.

(3) Unless specifically stated in the final determination, the validity of an action taken on an application is not affected if an individual that failed to report a conflict of interest participated in the action.

§320.7. Code of Conduct.

(a) Each member of the Board, the Executive Director, the Chief Compliance Officer, and staff of the Commission must abide by the code of conduct established in this section.

(b) All member of the Board, the Executive Director, the Chief Compliance Officer, and staff of the Commission shall avoid acts that are improper or give the appearance of impropriety in the disposition of funds and providing advice and recommendations to guide state policies.

(c) A member of the Board, the Executive Director, the Chief Compliance Officer, staff of the Commission, or the spouse of such individuals shall not:

(1) disclose confidential information, information that is excepted from public disclosure under the Texas Public Information, information contained in an application or other document in relation to which the member or staff member executed a Review and Evaluation Conflict of Interest & Non-Disclosure Certification, or information that has been ordered sealed by a court (collectively, "Protected Information"), that was acquired by reason of the member's or staff member's official position, or accept other employment, including self-employment, or engage in a business, charity, nonprofit organization, or professional activity that the member or staff member might reasonably expect would require or induce the member or staff member to disclose Protected Information that was acquired by reason of the member's or staff member's official position;

(2) accept or solicit any gift, favor, or service that could reasonably influence the member or staff member in the discharge of official duties or that the member, staff member, or spouse of the member or staff member knows or should know is being offered with the intent to influence the member's or staff member's official conduct;

(3) fail to disclose any gift or consideration if the gift or consideration is provided by a registered lobbyist;

(4) accept employment or engage in any business or professional activity that would reasonably require or induce the member or staff member to disclose confidential information acquired in the member's or staff member's official position;

(5) accept other employment or compensation that could reasonably impair the member's or staff member's independent judgment in the performance of official duties;

(6) make personal investments or have a financial interest that could reasonably create a substantial conflict between the member's or staff member's private interest and the member's or staff member's official duties;

(7) intentionally or knowingly solicit, accept, or agree to accept any benefit for exercising the member's official powers or performing the member's or staff member's official duties in favor of another;

(8) lease, directly or indirectly, any property, capital equipment, or service to any entity that receives a grant from the Fund;

(9) apply to receive a grant from the Fund;

(10) serve on the board of directors of an organization established with a grant from the Fund;

(11) serve on the board of directors of an organization that received a grant from the Fund;

(12) if a member of a professional organization, fail to comply with the standards of conduct adopted by the professional organizations of which he or she is a member;

(13) take actions that will discredit the Commission, Fund, or Board; or

(14) solicit or accept an honorarium in consideration for services as a member of the Board, a member of any subcommittee established by the Board, or a staff member.

(d) If a member of the Board, the Executive Director, Chief Compliance Officer, or staff of the Commission intentionally violates this section, that individual is subject to removal from further participation in the Commission's application review process.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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Gwen Griffen
Chair
Texas Space Commission
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TITLE 22. EXAMINING BOARDS

PART 14. TEXAS OPTOMETRY BOARD

CHAPTER 271. EXAMINATIONS

22 TAC §271.1

The Texas Optometry Board proposes the following repeal to 22 TAC Title 14 Chapter 271 Examinations.

The rules in the Chapter 271 were reviewed as a result of the Board's general rule review under Texas Government Code §2001.039. Notice of the review was published in the March 1, 2024, issue of the *Texas Register* (49 TexReg 1288). No comments were received regarding the Board's notice of review. The Board has determined that there continues to be a need for the rules in Chapter 271.

However, the Board has determined the substance of §271.1 Definitions would be better suited for Chapter 272 and is proposing to repeal the rule in its entirety.

The substance of the language will be proposed for amendment to Chapter 272 in a separate rule submission with the *Texas Register.*

Government Growth Impact Statement. For the first five-year period the repeal is in effect, the Board estimates that the repeal will have no effect on government growth. The repeal does not create or eliminate a government program; does not require the creation or elimination of employee positions; does not require the increase or decrease in future legislative appropriations to this agency; does not require an increase or decrease in fees paid to the agency; does not create a new regulation; does not expand an existing regulation; does not increase or decrease the number of individuals subject to the rule's applicability; and does not positively or adversely affect the state's economy.

Small Business, Micro-Business, and Rural Community Impact Statement. Ms. McCoy has determined for the first five-year period following the repeal, there will be no adverse effect on small businesses, micro-businesses, or rural communities and

the repeal does not positively or adversely impact the state's economy.

Regulatory Flexibility Analysis for Small and Micro-Businesses and Rural Communities. Ms. McCoy has determined that the repeal will have no adverse economic effect on small businesses, micro-businesses, or rural communities and does not positively or adversely impact the state's economy. Thus, the Board is not required to prepare a regulatory flexibility analysis pursuant to §2006.002 of the Government Code.

Takings Impact Assessment. Ms. McCoy has determined that there are no private real property interests affected by the repeal. Thus, the Board is not required to prepare a takings impact assessment pursuant to §2007.043 of the Government Code.

Local Employment Impact Statement. Ms. McCoy has determined that the repeal will have no impact on local employment or a local economy. Thus, the Board is not required to prepare a local employment impact statement pursuant to §2001.024 of the Government Code.

Public Benefit. Ms. McCoy has determined for the first five-year period the repeal is in effect there is no impact on the public.

Fiscal Note. Janice McCoy, Executive Director of the Board, has determined that for the first five-year period following the repeal, there will be no additional estimated cost, reduction in costs, or loss or increase in revenue to local governments.

Additionally, Ms. McCoy has determined that enforcing or administering the rules do not have foreseeable implications relating to the costs or revenues of state or local government.

Requirement for Rules Increasing Costs to Regulated Persons. The proposed repeal does not impose any new or additional costs to regulated persons, state agencies, special districts, or local governments; therefore, pursuant to §2001.0045 of the Government Code, no repeal or amendment of another rule is required to offset any increased costs. Additionally, no repeal or amendment of another rule is required because the proposed rules are necessary to protect the health, safety, and welfare of the residents of this state and because regulatory costs imposed by the Board on licensees is not expected to increase.

PUBLIC COMMENTS: Comments on the proposed repeal rules may be submitted electronically to: janice.mccoy@tob.texas.gov or in writing to Janice McCoy, Executive Director, Texas Optometry Board, 1801 N. Congress, Suite 9.300, Austin, Texas 78701. The deadline for furnishing comments is thirty days after publication in the *Texas Register.*

Statutory Authority. The Board proposes this rule pursuant to the authority found in §351.151 of the Occupations Code which vests the Board with the authority to adopt rules necessary to perform its duties and implement Chapter 351 of the Occupations Code.

No other sections are affected by the amendments.

§271.1. Definitions.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on May 30, 2024.

TRD-202402417

Janice McCoy
Executive Director
Texas Optometry Board
Earliest possible date of adoption: July 14, 2024
For further information, please call: (512) 305-8500

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22 TAC §§271.2, 271.6, 271.8 - 271.12

The Texas Optometry Board proposes amendments and the addition of new sections to 22 TAC Title 14 Chapter 271 Examinations. The Board is amending the following rules: §271.2 and §271.6. The Board is adding the following rules: §§271.8 - 271.12.

The rules in the Chapter 271 were reviewed as a result of the Board's general rule review under Texas Government Code §2001.039. Notice of the review was published in the March 1, 2024, issue of the *Texas Register* (49 TexReg 1288). No comments were received regarding the Board's notice of review. The Board has determined that there continues to be a need for the rules in Chapter 271.

The rules were concurrently reviewed as part of an effort by the Board's Administration and Licensing Committee to simplify the Board's application process. This review encompassed both Chapters 271 and 280. The Committee recommended that the Board combine the application for the Therapeutic license and Optometric Glaucoma Specialist designation as all graduates after 2008 qualify for the enhanced Optometric Glaucoma Specialist designation. The Board recognized that having the application in two steps was a deterrent to about 20 percent of the applicant pool who failed to complete the second application step although qualified to do so.

Additionally, the Committee recommended that the Board move all license requirements and application steps found in Chapter 280 to Chapter 271 for clarity to both staff and potential applicants.

The Board is not making changes to the following rules: §271.3 Jurisprudence Examination Administration; §271.5 Licensure without Examination; and §271.7 Criminal History Evaluation Letters.

First, the Board proposes to amend the title of Chapter 271 to "Licensing" instead of "Examinations" for clarity purposes.

The Board is amending the following rules: §271.2 Applications for Licensure as Therapeutic Optometrist and §271.6 National Board Examination to add language currently found in Chapter 280.

The Board is adding the following rules by moving language currently found in Chapter 280: §271.8 Converting Optometric License to Therapeutic Optometric License; §271.9 Licensure as Optometric Glaucoma Specialist; §271.10 Optometric Glaucoma Specialist: Required Education and Examination; §271.11 Required Education for Therapeutic Licensure; and §271.12 License Designation.

Note: current Board rule §271.1 Definitions is being repealed in a separate submission. However, the substance of the rule will be included in Chapter 272.

Overview and Explanation of the Proposed Amendments. The proposal combines the application of the Therapeutic and Optometric Glaucoma Specialist applications as all graduates after 2008 qualify for the enhanced Optometric Glaucoma Specialist

designation. This will clarify the application process for both applicants and staff. Additionally, by moving all new graduates to a single license type, the public is better protected as all licensees will have the enhanced license and be able to treat conditions to the full extent of their optometric education.

The proposal still would allow anyone who does not qualify for the Optometric Glaucoma Certification (i.e. those who graduated from optometry school prior to 2008 and who have not taken the 30-hour glaucoma course) to be licensed as a therapeutic optometrist in Texas. The agency anticipates the number of applicants who fall into this scenario to be less than 10 per year.

The difference in the cost of renewal between a therapeutic license and an optometric glaucoma specialist license is $19.28 which is collected on behalf of the Prescription Monitoring Program.

Government Growth Impact Statement. For the first five-year period the proposed rules are in effect, the Board estimates that the proposed rules will have no effect on government growth. The proposed rules do not create or eliminate a government program; do not require the creation or elimination of employee positions; do not require the increase or decrease in future legislative appropriations to this agency; do not require an increase or decrease in fees paid to the agency; do not create a new regulation; do not expand an existing regulation; do not increase or decrease the number of individuals subject to the rule's applicability; and do not positively or adversely affect the state's economy.

Small Business, Micro-Business, and Rural Community Impact Statement. Ms. McCoy has determined for the first five-year period the proposed rules are in effect, there will be no adverse effect on small businesses, micro-businesses, or rural communities and the amendments do not positively or adversely impact the state's economy.

Regulatory Flexibility Analysis for Small and Micro-Businesses and Rural Communities. Ms. McCoy has determined that the proposed rules will have no adverse economic effect on small businesses, micro-businesses, or rural communities and do not positively or adversely impact the state's economy. Thus, the Board is not required to prepare a regulatory flexibility analysis pursuant to §2006.002 of the Government Code.

Takings Impact Assessment. Ms. McCoy has determined that there are no private real property interests affected by the proposed rules. Thus, the Board is not required to prepare a takings impact assessment pursuant to §2007.043 of the Government Code.

Local Employment Impact Statement. Ms. McCoy has determined that the proposed rules will have no impact on local employment or a local economy. Thus, the Board is not required to prepare a local employment impact statement pursuant to §2001.024 of the Government Code.

Public Benefit. Ms. McCoy has determined for the first five-year period the proposed rules are in effect there will be a benefit to the general public because by moving all new graduates to a single license type, the public is better protected as all licensees will have the enhanced license and be able to treat conditions to the full extent of their optometric education.

Fiscal Note. Janice McCoy, Executive Director of the Board, has determined that for the first five-year period the proposed rules are in effect, there will be no additional estimated cost, reduction in costs, or loss or increase in revenue to local governments as a result of enforcing or administering the rules. Twenty percent of the approximately 200 applicants each year fail to submit the application for their Optometric Glaucoma Specialist certification even though they meet the qualifications. Those approximately 40 people will see an increase in their renewal fee of $19.28 (paid every two years) resulting in an increase in revenue collected of approximately $800 that will be paid to the Prescription Monitoring Program.

Additionally, Ms. McCoy has determined that enforcing or administering the rules do not have foreseeable implications relating to the costs or revenues of state or local government.

Requirement for Rules Increasing Costs to Regulated Persons. The proposed rule does not impose any new or additional costs to regulated persons, state agencies, special districts, or local governments; therefore, pursuant to §2001.0045 of the Government Code, no repeal or amendment of another rule is required to offset any increased costs. Additionally, no repeal or amendment of another rule is required because the proposed rules are necessary to protect the health, safety, and welfare of the residents of this state and because regulatory costs imposed by the Board on licensees is not expected to increase.

PUBLIC COMMENTS: Comments on the amended rules may be submitted electronically to: janice.mccoy@tob.texas.gov or in writing to Janice McCoy, Executive Director, Texas Optometry Board, 1801 N. Congress, Suite 9.300, Austin, Texas 78701. The deadline for furnishing comments is thirty days after publication in the *Texas Register.*

Statutory Authority. The Board proposes this rule pursuant to the authority found in §351.151 of the Occupations Code which vests the Board with the authority to adopt rules necessary to perform its duties and implement Chapter 351 of the Occupations Code.

The Board also proposes this rule under the authority found in Texas Optometry Act §§351.252, 351.253, 351.358, and 351.3581.

No other sections are affected by the amendments.

§271.2. Applications for Licensure as Therapeutic Optometrist.

(a) The applicant shall make application by providing [~~furnishing~~] to the Executive Director, on forms to be furnished by the Board, satisfactory evidence that the applicant has attended and graduated from a reputable school [~~university~~] or college of optometry which meets with the requirements of the Board and such other information as the Board may deem necessary for the enforcement of the Act.

(b) The applicant shall report all felony and misdemeanor criminal convictions as outlined under Texas Occupations Code Chapter 53. Failure of an applicant to report every criminal conviction is deceit, dishonesty and misrepresentation in seeking admission to practice and authorizes the Board to take disciplinary action under §351.501 of the Act. An applicant is not required to report a Class C Misdemeanor traffic violation. The applicant shall furnish any document relating to the criminal conviction as requested by the Board. The applicant shall also provide a complete criminal history by submitting fingerprints to the authority authorized by the Department of Public Safety to take the fingerprints in the form required by that authority.

(c) In such application, the applicant shall state that the applicant will abide by the laws of this state regulating the practice of optometry and that all facts, statements, and answers contained in the application are true and correct. Such application shall be signed (manually or digitally) and dated.

(d) Applicants shall submit a report of out-of-state disciplinary action prepared by an approved national databank.

(e) Any person furnishing false information in such application shall be denied the issuance of a license, or if the applicant has been licensed before it is made known to the Board of the falseness of such information, such license shall be subject to suspension, revocation, or cancellation in accordance with §351.501 of the Act.

(f) Applications must contain a certified optometry school transcript, which shall show the total number of hours of attendance, the subjects studied, the grades or marks given, and the date of graduation of the applicant. The optometry school transcript must show proof of the required education as set forth in §271.1 of this chapter (relating to Definitions). Applicants must also submit a copy of the transcript from any undergraduate school attended which shall show the total number of hours of attendance, the subjects studied, the grades or marks given, and the date of graduation of the applicant.

(g) The Board may require other documentation not specified by this section be submitted with the application. All required documents must be received within one year of application; otherwise, the applicant must reapply and pay the application fee. A person may apply for licensure prior to graduation from a reputable school [~~university~~] or college of optometry.

(h) The application must be accompanied by a fee as set forth in §273.4 of this title (relating to Fees (Not Refundable)) [~~set by the Board~~].

(i) If applicable, the applicant [~~application~~] must furnish a certificate of good standing from any jurisdiction where licensed or previously licensed. The certificate must establish that:

(1) the applicant's license has never been suspended or revoked;

(2) there are no pending disciplinary actions against the applicant; and

(3) the applicant is presently authorized to practice therapeutic optometry without restrictions.

(j) If the certificate of good standing does not establish the items in subsection (i) of this section, the applicant will be required to submit additional information for further Board review.

§271.6. National Board Examination.

(a) The Board determines that the written examination by the National Board of Examiners in Optometry (NBEO) known as Part I and Part II complies in all material respects with the examination requirements of §351.256 of the Act. The passing score on each Part of the National Board written examination is determined by the criterion-referenced standard setting approach, in which the passing score is set at the scaled score of 300. The Board will accept scores from an NBEO written examination if Part I or II was satisfactorily completed on or after January 1, 1984.

(b) The Board determines that the practical examination known as Part III by the National Board of Examiners in Optometry (NBEO) complies in all material respects with the practical examination requirements of §351.256 of the Act. The passing scores on Part III shall be determined by the NBEO. The Board will accept scores from an NBEO Part III examination if Part III was satisfactorily completed on or after June of 1994.

(c) The Board determines therapeutic optometrist examination shall be the Treatment and Management of Ocular Disease Examination (TMOD) administered by the National Board of Examiners in Optometry. A passing score from any TMOD test administered after April 1985 will be accepted. A pass/fail grade is sufficient. [~~All applicants must comply with the application process and qualification criteria of §351.254 of the Act, as well as all applicable Board rules.~~]

(d) Each applicant shall submit a true and correct copy of the applicant's score report and such other evidence of having achieved a passing grade on each part of the NBEO examination as outlined in subsections (a) and (b) of this section. No license will be issued to an applicant until evidence of passage of the NBEO examinations are [~~examination is~~] received.

§271.8. Converting Optometric License to Therapeutic Optometric License.

Optometrists licensed in Texas who graduated prior to January 1, 1991, may apply for licensure as a therapeutic optometrist. Proof of the successful completion of the minimum of 90 Board-approved classroom hours in postgraduate courses of general and ocular pharmacology and related pathology and proof of the successful passage of the TMOD must be submitted with the application.

§271.9. Licensure as Optometric Glaucoma Specialist.

(a) For licensure as an Optometric Glaucoma Specialist:

(1) Beginning January 1, 2025, an applicant under §271.2 of this chapter (relating to Applications for Licensure as Therapeutic Optometrist) who graduated after May 1, 2008 shall concurrently apply for licensure as optometric glaucoma specialist on a joint application form promulgated by the Board.

(2) An applicant under §271.2 of this chapter who graduated before May 1, 2008, may apply for a therapeutic license unless the applicant meets the requirements set out under §271.11(b) of this chapter (relating to Required Education for Therapeutic Licensure) in which case they shall apply for licensure as an optometric glaucoma specialist.

(3) A therapeutic optometrist licensed prior to January 1, 2025, may submit an application to convert the license to an optometric glaucoma specialist if the applicant meets the requirements set out under §271.10(b) of this chapter (relating to Optometric Glaucoma Specialist: Required Education and Examination).

(b) Proof of the required successfully completed education, examination, and clinical assessment as set forth in §271.10 of this chapter must accompany the application form.

(c) Proof of a two-hour continuing education course related to prescribing and monitoring controlled substances as required by Section 481.07635 of the Health and Safety Code must accompany the application form.

§271.10. Optometric Glaucoma Specialist: Required Education and Examination.

(a) Applicants who graduated after May 1, 2008, from a school or college of optometry for which the Board has issued a determination, hereby meet the education and examination requirements of §351.3581 of the Texas Optometry Act provided:

(1) the course work (as described in the Board's Resolution dated April 14, 2000) required for certification, including an instructional clinic review component, is part of the school or college of optometry's regular curriculum;

(2) the examination required for graduation from the school or college is the substantive equivalent of an examination as described in the Board's Resolution dated April 14, 2000; and

(3) the applicant received clinical training while in optometry school that satisfies the skills requirements set out in subsection (b)(3) of this section.

(b) Applicants who graduated from optometry school prior to May 1, 2008:

(1) must provide documentation showing successful completion of at least 30 verified instruction or classroom hours covering glaucoma diagnosis and treatment and pharmacology of approved oral and anti-glaucoma drugs (as described in the Board's Resolution dated April 14, 2000);

(2) must have passed, with a grade of 75 or above, the final examination covering the education course set out in subsection (b)(1) of this section; and

(3) must submit a signed and dated certification prepared by a licensed ophthalmologist or Texas licensed optometric glaucoma specialist confirming the demonstration by the applicant in an adequate and appropriate manner, as directly observed by the ophthalmologist or optometric glaucoma specialist, of the following skills: tonometry, gonioscopy, slit lamp examination, optic nerve examination/fundus, and interpretation of visual fields.

§271.11. Required Education for Therapeutic Licensure.

In order to demonstrate compliance in regard to therapeutic optometry, successful completion of at least 90 classroom hours of postgraduate course work and clinical training in general and ocular pharmacology and related pathology conducted by an accredited institution which has facilities for both didactic and clinical instruction, or via other educational programs approved by the Board, is required. Of the required 90 classroom hours, a minimum of 20 hours must be obtained in applied clinical skills. The applicant must provide documentation of successful completion of course work from the institution. Optometrists graduated after January 1, 1991, shall be considered as having met the educational requirements for a therapeutic license.

§271.12. License Designation.

(a) Designation of authority as a therapeutic optometrist will appear along with the optometrist's license number in the format of the license numbers followed by the letter "T." Such designation must appear whenever the license number is required under Board statutes or rules.

(b) Designation of authority as an optometric glaucoma specialist will appear along with the optometrist's license number in the format of the license numbers followed by the letter "T" and "G." Such designation must appear whenever the license number is required under Board statutes or rules.

(c) The license to practice must be displayed in a conspicuous place in the principal office where the optometrist practices such that the patient can view the license.

(d) In the event the original certificate is lost or destroyed, the Board may issue a duplicate certificate; the person entitled thereto must make written application to the Board for a duplicate, under affidavit setting forth that such certificate was lost or destroyed, and the circumstances under which loss or destruction occurred. Should the original subsequently be found, it must be forwarded immediately to the Board and not used by the person to whom issued originally or by any other person. A fee as set forth in §273.4 of this title (relating to Fees (Not Refundable)) must be submitted to the Board along with the affidavit for the duplicate issue.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on May 30, 2024.

TRD-202402418

Janice McCoy
Executive Director
Texas Optometry Board
Earliest possible date of adoption: July 14, 2024
For further information, please call: (512) 305-8500

CHAPTER 272. ADMINISTRATION

22 TAC §§272.1 - 272.9

The Texas Optometry Board proposes amendments and new rules to 22 TAC Title 14 Chapter 272 Administration, §§272.1 - 272.9.

The rules in the Chapter 272 were reviewed as a result of the Board's general rule review under Texas Government Code §2001.039. Notice of the review was published in the March 1, 2024, issue of the *Texas Register* (49 TexReg 1288). No comments were received regarding the Board's notice of review. The Board voted to close the rule review at its May 3, 2024, meeting.

The Board has determined that there continues to be a need for the rules in Chapter 272. The Board has also determined that changes to the following rules as currently in effect are necessary to clarify the statute: §272.1 - Open Records; §272.2 - Historically Underutilized Businesses; and §272.3 Contract and Purchasing Procedures.

In addition, the agency is proposing to move two existing rules from other chapters to Chapter 272 to include: §272.4 Public Participation in Meetings (currently in Chapter 273) and §272.5 Definitions (currently in Chapter 271).

Finally, the agency is proposing to add the following new rules: §272.6 Dual Office Holding; §272.7 Agency Staff Training and Education; §272.8 Leave Pools; and §272.9 Petition for Rulemaking.

Overview and Explanation of the Proposed Amendments. The majority of the changes made to Chapter 272 will update the agency's rules to better comply with various statutes that require the agency to have administrative rules on these issues. The proposal amends references to other administrative rules that have been updated since the Board last amended the rule. Finally, the amendment would make non-substantive capitalization changes to ensure consistency across the Board's rules.

The one substantive change is the inclusion of a definition of "synchronous" found in the new §272.5 Definitions which was not part of the original definitions moved from §271.1 - Definitions. The rule defines synchronous as "live, real-time audiovisual interaction between the practitioner and the patient in a separate location."

Government Growth Impact Statement. For the first five-year period the proposed rules are in effect, the Board estimates that the proposed rules will have no effect on government growth. The proposed rules do not create or eliminate a government program; do not require the creation or elimination of employee positions; do not require the increase or decrease in future legislative appropriations to this agency; do not require an increase or decrease in fees paid to the agency; do not create a new regulation; do not expand an existing regulation; do not increase or decrease the number of individuals subject to the rule's applicability; and do not positively or adversely affect the state's economy.

Small Business, Micro-Business, and Rural Community Impact Statement. Ms. McCoy has determined for the first five-year period the proposed rules are in effect, there will be no adverse effect on small businesses, micro-businesses, or rural communities and the amendments do not positively or adversely impact the state's economy.

Regulatory Flexibility Analysis for Small and Micro-Businesses and Rural Communities. Ms. McCoy has determined that the proposed rules will have no adverse economic effect on small businesses, micro-businesses, or rural communities and do not positively or adversely impact the state's economy. Thus, the Board is not required to prepare a regulatory flexibility analysis pursuant to §2006.002 of the Government Code.

Takings Impact Assessment. Ms. McCoy has determined that there are no private real property interests affected by the proposed rules. Thus, the Board is not required to prepare a takings impact assessment pursuant to §2007.043 of the Government Code.

Local Employment Impact Statement. Ms. McCoy has determined that the proposed rules will have no impact on local employment or a local economy. Thus, the Board is not required to prepare a local employment impact statement pursuant to §2001.024 of the Government Code.

Public Benefit. Ms. McCoy has determined for the first five-year period the proposed rules are in effect there will be a benefit to the general public because the proposed rules ensure the agency is in compliance with statute.

Fiscal Note. Janice McCoy, Executive Director of the Board, has determined that for the first five-year period the proposed rules are in effect, there will be no additional estimated cost, reduction in costs, or loss or increase in revenue to the state or local governments as a result of enforcing or administering the rules. Additionally, Ms. McCoy has determined that enforcing or administering the rules do not have foreseeable implications relating to the costs or revenues of state or local government.

Requirement for Rules Increasing Costs to Regulated Persons. The proposed rule does not impose any new or additional costs to regulated persons, state agencies, special districts, or local governments; therefore, pursuant to §2001.0045 of the Government Code, no repeal or amendment of another rule is required to offset any increased costs. Additionally, no repeal or amendment of another rule is required because the proposed rules are necessary to protect the health, safety, and welfare of the residents of this state and because regulatory costs imposed by the Board on licensees is not expected to increase.

PUBLIC COMMENTS: Comments on the amended rules may be submitted electronically to: janice.mccoy@tob.texas.gov or in writing to Janice McCoy, Executive Director, Texas Optometry Board, 1801 N. Congress, Suite 9.300, Austin, Texas 78701. The deadline for furnishing comments is thirty days after publication in the *Texas Register*.

Statutory Authority. The Board proposes this rule pursuant to the authority found in §351.151 of the Occupations Code which vests the Board with the authority to adopt rules necessary to perform its duties and implement Chapter 351 of the Occupations Code.

The Board also proposes this rule under the authority found in §574.003 Gov't Code; §656.048 Gov't Code; §661.002 Gov't Code; §661.022 Gov't Code; §2001.021 Gov't Code; §2155.076 Gov't Code; §2156.005 Gov't Code; §2161.003 Gov't Code; §2260.052 Gov't Code; §2261.202 Gov't Code; and §2261.253 Gov't Code.

No other sections are affected by the amendments.

§272.1. Open Records.

[~~(a)~~] Open records requests. The Executive Director shall be the official custodian of all Board records and the Executive Director or his or her designee shall process and respond to all requests for information in the manner prescribed by Chapter 552, Government Code. [~~The following guidelines apply to requests for records under the Open Records Act, Government Code, Chapter 552.~~

[~~(1) Requests must be in writing and reasonably identify the records requested.~~]

[~~(2) Records access will be by appointment only.~~]

[~~(3) Records access is available only during the regular business hours of the agency.~~]

[~~(4) Generally, unless confidential information is involved, review may be by physical access or by duplication at the requester's option. Any person, however, whose request would be unduly disruptive to the ongoing business of the office may be denied physical access and will only be provided the option of receiving copies.~~]

[~~(5) When the safety of any public record is at issue, physical access may be denied, and the records will be provided by duplication as previously described.~~]

[~~(6) Confidential files will not be made available for inspection or for duplication except under certain circumstances, e.g., court order.~~]

[~~(7) All open records request appointments will be referred to the executive director before complying with a request.~~]

[~~(8) The open records coordinator for the agency is the executive director.~~]

[~~(b) Charges for public records. In accordance with Chapter 428, Acts, 73rd Legislature (1993), the following specifies the charges the Texas Optometry Board will make for copies of public records. These charges are based on the full cost to the agency for providing the copies.~~]

[~~(1) Definitions. The following words and terms, when used in the section, shall have the following meanings, unless the context clearly indicates otherwise.~~]

[~~(A) Standard-size copy. A printed impression on one side of a piece of paper that measures up to 8-1/2 by 14 inches. Each side of the paper on which an impression is made is counted as a single copy. A piece of paper printed on both sides is counted as two copies.~~]

[~~(B) Copy charge. A charge for costs incurred in copying standard-size paper copies reproduced by an office machine copier or a computer printer.~~]

[~~(C) Postage and shipping charge. A charge for costs incurred in sending information to a requester, such as cost of postage, envelope, or long-distance phone call for facsimile transmission.~~]

[~~(D) Personnel charge. A charge imposed for costs incurred for personnel time expended in processing a request for public information. This charge may include the time any employee spends reading/reviewing the initial request for records, making copies of records, conducting a file search, conducting a computer search, preparing and reviewing the response to the records request (administrative oversight/review), and any other type of personnel time necessary to respond to the request.~~]

[(E) Overhead charge. A charge for direct and indirect costs incurred in addition to the personnel charge. This charge covers such costs as depreciation of capital assets, rent, maintenance and repair, and utilities.]

[(F) Microfiche and microfilm charge. A charge for costs incurred for making a copy of microfiche or microfilm.]

[(G) Remote document retrieval charge. A charge for costs incurred in obtaining information not in current use in remote storage locations.]

[(H) Computer resource charge. A charge for costs incurred in obtaining information on computers based on the amortized cost of acquisition, lease, operation, and maintenance of computer resources. This charge may also include programming time if a request requires a programmer to enter data in order to execute an existing program or create a new program so that requested information may be accessed.]

[(I) Not readily available information. Information that is not readily available includes information that requires personnel to locate and retrieve a specific file, review the file to locate the record, and replace the file after the record has been located. Information that is not readily available also includes information that requires personnel review to determine if the records contain information confidential by law. Information that is not readily available includes, but is not limited to:]

[(i) information in optometrist licensing files;]

[(ii) information in complaint files;]

[(iii) information in investigation files;]

[(iv) information in personnel files; and]

[(v) information in the agency's computerized data base system.]

[(2) Charges.]

[(A) For 1 to 50 standard-size copies of readily available information, the charge shall be $.10 per page.]

[(B) For 51 pages or more of readily available information, or any quantity of not readily available information, the charge shall be the sum of the following:]

[(i) $.10 per page;]

[(ii) personnel charge in an amount reflecting the average hourly cost for classified state employees as determined from time to time by the General Services Commission;]

[(iii) overhead charge in an amount to be determined in accordance with the guidelines of the General Services Commission;]

[(iv) microfiche and microfilm charge (if applicable) in an amount equal to the actual cost to the agency of the reproduction, or in accordance with General Services Commission Guidelines;]

[(v) remote document retrieval charge (if applicable) in an amount equal to the actual cost to the agency of the retrieval or in accordance with General Services Commission Guidelines;]

[(vi) computer resource charge (if applicable) including any programming time, in an amount equal to the cost to the agency, or in accordance with General Services Commission Guidelines; and]

[(vii) actual cost of miscellaneous supplies (if applicable) in an amount equal to the actual cost to the agency.]

[(C) If, in the opinion of the executive director, a request for information may result in substantial cost to the agency, the executive director may require the requester to make a deposit in the anticipated approximate amount of the charges, which may be applied to the costs incurred in responding to the request.]

[(D) If a particular request may involve considerable time and resources to process, the agency may advise the requesting party of what may be involved and provide an estimate of date of completion and the charges that may result.]

[(E) The agency has the discretion to furnish public records without charge or at a reduced charge if the agency determines that a waiver or reduction is in the public interest. The executive director is authorized to determine whether a public interest/benefit exists on a case-by-case basis.]

§272.2. Historically Underutilized Businesses.

The [Texas Optometry] Board adopts by reference the rules of the Comptroller of Public Accounts in 34 TAC Part 1, Chapter 20, Subchapter D, Division 1 in accordance with §2161.003 of the Government Code [promulgated by the General Services Commission regarding the Historically Underutilized Business Program which are set forth in Chapter 111, Subchapter B, of Title 1, Part 5 of the Texas Administrative Code].

§272.3. Contract and Purchasing Procedures.

(a) In accordance with [Tex. Gov't Code] §2155.076 of the Government Code, the Board adopts by reference the rules of the Comptroller of Public Accounts regarding purchasing protest procedures set forth in 34 TAC, Part 1, Chapter 20, Subchapter F, Division 3 [34 Tex. Admin. Code §20.384]. All vendor protests under this rule must be submitted to the Board's purchaser, who shall initiate a review of the protest. Any appeal to a determination of a protest by the purchaser shall be to the Executive Director [executive director], who may elect to submit the appeal to the Board for final determination. The Board shall maintain all documentation on the purchasing process that is the subject of a protest or appeal in accordance with the Board's retention schedule.

(b) In accordance with [Tex. Gov't Code] §2156.005 of the Government Code, the Board adopts by reference the rules of the Comptroller of Public Accounts regarding bid opening and tabulation set forth in 34 TAC, Part 1, Chapter 20, Subchapter C, Division 2 [34 Tex. Admin. Code §20.35].

(c) In accordance with [Tex. Gov't Code] §2260.052 of the Government Code, the Board adopts by reference the rules of the Office of the Attorney General in 1 TAC [Tex. Admin. Code] Part 3, Chapter 68 (relating to Negotiation and Mediation of Certain Contract Disputes). The rules set forth a process to permit parties to structure a negotiation or mediation in a manner that is most appropriate for a particular dispute regardless of the contract's complexity, subject matter, dollar amount, or method and time of performance.

(d) In accordance with [Tex. Gov't Code] §2261.202 of the Government Code, the Executive Director [executive director] shall be responsible for monitoring agency contracts and for monitoring agency compliance with all applicable laws governing agency contracting. The Executive Director [executive director] may delegate those duties necessary to carry out this responsibility to other agency staff who report directly to the Executive Director [executive director].

(e) Enhanced Contract and Performance Monitoring.

(1) The Board will complete a risk assessment to identify procurement contracts for goods or services from a private vendor that require enhanced contract or performance monitoring.

(2) For all contracts with a value greater than $25,000, the Executive Director will complete a risk assessment to evaluate whether enhanced contract or performance monitoring may be required. The risk assessment may consider the following factors: total cost of the contract, including contract renewals; risk of loss to the agency under the contract; risk of fraud, waste or abuse; scope of the goods or services provided; availability of agency resources; complexity of the contract; vendor past performance; and whether the vendor is a foreign or domestic person or entity.

(3) Contracts identified for enhanced contract and/or performance monitoring will be reported to the Board at the first regular Board meeting after the contract is executed. The report shall include: the basis for the determination that enhanced contract or performance monitoring is appropriate; any serious issues or risks identified with the contract, if applicable; and the plan for carrying out the enhanced contract or performance monitoring.

(4) For any contract subject to enhanced contract or performance monitoring, the Executive Director shall provide the Board with progress reports, as directed by the Board.

(5) This section does not apply to a memorandum of understanding, interagency contract, interlocal agreement, or contract for which there is not a cost.

§272.4. Public Participation in Meetings.

A scheduled time shall be established on each posted agenda to allow the opportunity for public comment on any issue under the jurisdiction of the Board. The time allowed an individual may be limited at the discretion of the chair.

§272.5. Definitions.

The following words and terms, when used in this part, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Act--The Texas Optometry Act, Chapter 351, Texas Occupations Code.

(2) APA--The Administrative Procedure Act, Chapter 2001, Government Code.

(3) Board--The Texas Optometry Board.

(4) Contested case--A proceeding, including but not restricted to licensing, in which the legal rights, duties, or privileges of a party are to be determined by the board after an opportunity for adjudicative hearing.

(5) Executive Director--Executive Director of the Texas Optometry Board.

(6) PFD--Proposal for decision.

(7) Respondent--A person against whom a formal charge has been made alleging conduct that violates the Act or rules, regulations, or orders of the Board and whose legal rights are to be determined by the board after the opportunity for an adjudicative hearing in a contested case as defined by the APA.

(8) SOAH--State Office of Administrative Hearings.

(9) Synchronous--live, real-time audiovisual interaction between the practitioner and the patient in a separate location.

§272.6. Dual Office Holding.

(a) The Executive Director and appointed members of the Board may not accept an offer to serve in another non-elective office unless they first obtain from the Board, a finding that the member has satisfied Article XVI, §40, of the Texas Constitution.

(b) The Board must make a written record of any finding under subsection (a) of this section. The finding must include any compensation that the member or Executive Director receives from holding the additional office, including salary, bonus, or per diem payment.

§272.7. Agency Staff Training and Education.

(a) In accordance with Government Code, Chapter 656, Subchapter C, agency staff may be permitted or required to attend training or education programs if those programs relate to the employee's duties or prospective duties, materially aid effective administration of the agency's functions, and serve an important public purpose.

(b) The Executive Director shall be eligible to attend training and education programs, and shall determine which other employees will be permitted or required to attend training.

(c) Employees who receive training must utilize the training opportunity to prepare for technological and legal developments facing the agency, or to increase professional capabilities or competence directly related to the work of the agency.

(d) An employee, prior to receiving training for three or more months, during which the employee does not perform the employee's regular duties, must enter into a written agreement with the Board to comply with the requirements of §656.103(a) of the Government Code. Employees who fail or refuse to enter into such an agreement shall not be permitted to attend training lasting three or more months.

(e) The Board may pay the costs and expenses related to approved training in accordance with the State Employee Training Act, the Comptroller's rules and regulations, and the Board's own policies relating to employee reimbursement.

§272.8. Leave Pools.

(a) Sick Leave Pool. The Board's sick leave pool shall be administered by the Executive Director in accordance with Chapter 661 of the Government Code, the rules and regulations of the Employees Retirement System of Texas, and the Texas Human Resources Statutes Inventory manual published by the Texas State Auditor's Office. The Executive Director shall develop and prescribe procedures for the operation of the sick leave pool, and include such procedures in the Board's personnel manual.

(b) Family Leave Pool. The Board's family leave pool shall be administered by the Executive Director in accordance with Chapter 661 of the Government Code and the Texas Human Resources Statutes Inventory manual published by the Texas State Auditor's Office. The Executive Director shall develop and prescribe procedures for the operation of the family leave pool and include such procedures in the Board's personnel manual.

§272.9. Petition for Rulemaking.

(a) Any interested person may petition for rulemaking in accordance with §2001.021 of the Government Code by submitting to the Board a written request for the adoption of a rule or rule change. The written request must contain a return mailing address for the agency's response.

(b) The written request must, at a minimum, set forth or identify the rule the petitioner wants the Board to adopt or change, reasons why the petitioner believes the requested rulemaking is necessary, and include a copy of the proposed rule or any proposed changes with deletions crossed through and additions underlined. Additionally, the written request must affirmatively show that the requestor qualifies as an interested person under this rule. Requests which do not affirmatively show that the requestor qualifies as an interested person under this rule may be denied.

(c) The written request should also address the economic cost to persons required to comply with the rule, the effects of the rule on small or micro-businesses or rural communities, and the impact the rule would have on local employment or economics, if such information can be derived from available sources without undue cost or burden.

(d) A petition for rulemaking which involves any of those matters set forth in §507.153(a) of the Occupations Code will be submitted to the Executive Director for initial review and consideration.

(e) The Board will respond to a written request for adoption of a rule from an interested person in accordance with §2001.021 of the Government Code.

(f) The term "interested person" as used in this rule, shall have the same meaning as that assigned by §2001.021(d) of the Government Code.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on May 30, 2024.

TRD-202402423
Janice McCoy
Executive Director
Texas Optometry Board
Earliest possible date of adoption: July 14, 2024
For further information, please call: (512) 305-8500

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CHAPTER 273. GENERAL RULES

22 TAC §§273.1, 273.4 - 273.10, 273.18

The Texas Optometry Board proposes amendments to 22 TAC Title 14 Chapter 273 General Rules, §§273.1, 273.4 - 273.10 and new §273.18.

The rules in the Chapter 273 were reviewed as a result of the Board's general rule review under Texas Government Code §2001.039. Notice of the review was published in the March 1, 2024, issue of the *Texas Register* (49 TexReg 1288). No comments were received regarding the Board's notice of review.

The Board has determined that there continues to be a need for the rules in Chapter 273.

The Board determined the following rules should continue as written and will not be amended: §273.2 Use of Name of Retired or Deceased Optometrist; §273.3 Contact Lenses as a Prize or Premium; §273.12 Profile Information; §273.13 Contract or Employment with Community Health Centers; §273.14 License Applications for Military Service Member, Military Veteran, and Military Spouse; §273.15 Retired License for Volunteer Charity Care; §273.16 Licensee Compliance with Board Investigations; and §273.17 Emergency Management.

The Board also determined that changes to the following rules as currently in effect are necessary to further clarify the statute: §273.1 Surrender of License; §273.4 Fee (Not Refundable); §273.5 Clinical Instruction and Practice- Limited License for Clinical Faculty; §273.6 Licenses for a Limited Period; §273.7 Inactive Licenses; §273.8 Renewal of License; §273.9 Public Interest Information; and §273.10 Licensee Compliance with Payment Obligations.

The Board is adding new rule §273.18 as Clinical Instruction for Optometry Students. The text of the new rule was previously a subsection of §273.5 Clinical Instruction and Practice- Limited License for Clinical Faculty.

The Board determined the substance of §273.11 Public Participation in Meetings should be moved to Chapter 272 - Administration. This repeal will be published as separate submission in the *Texas Register.*

Overview and Explanation of the Proposed Amendments. The majority of the changes made to Chapter 273 provide non-substantive capitalization and grammatical changes to ensure consistency across the Board's rules.

The changes to §273.4 Fees (Not Refundable) removes language that references previous steps to move from an annual to biennial license as the agency has fully transitioned to a biennial license. The proposal increases the application fee from $150 to $205 as a result of changes made to Chapter 271 that require all applicants to concurrently apply as a therapeutic optometrist and an optometric glaucoma specialist. Of the roughly 200 new licensees each year, about 80 percent pay the $205 amount each year but in two application steps. So roughly 20 percent of licensees (about 40 individuals) will see a $55 increase in the application fee paid each year.

The changes to §273.8 Renewal of License clarify that a person needs to be practicing as a therapeutic optometrist in another state in order to renew an expired license.

Government Growth Impact Statement. For the first five-year period the proposed rules are in effect, the Board estimates that the proposed rules will have no effect on government growth. The proposed rules do not create or eliminate a government program; do not require the creation or elimination of employee positions; do not require the increase or decrease in future legislative appropriations to this agency; do not create a new regulation; do not expand an existing regulation; do not increase or decrease the number of individuals subject to the rule's applicability; and do not positively or adversely affect the state's economy. The rules could increase the total application fee paid by roughly 20 percent of the applicant pool each year by a total of $55. This change would result in a total revenue increase to the state of approximately $2,200 each fiscal year.

Small Business, Micro-Business, and Rural Community Impact Statement. Ms. McCoy has determined for the first five-year period the proposed rules are in effect, there will be no adverse effect on small businesses, micro-businesses, or rural communities and the amendments do not positively or adversely impact the state's economy.

Regulatory Flexibility Analysis for Small and Micro-Businesses and Rural Communities. Ms. McCoy has determined that the proposed rules will have no adverse economic effect on small businesses, micro-businesses, or rural communities and do not positively or adversely impact the state's economy. Thus, the Board is not required to prepare a regulatory flexibility analysis pursuant to §2006.002 of the Tex. Gov't Code.

Takings Impact Assessment. Ms. McCoy has determined that there are no private real property interests affected by the proposed rules. Thus, the Board is not required to prepare a takings impact assessment pursuant to §2007.043 of the Tex. Gov't Code.

Local Employment Impact Statement. Ms. McCoy has determined that the proposed rules will have no impact on local em-

ployment or a local economy. Thus, the Board is not required to prepare a local employment impact statement pursuant to §2001.024 of the Tex. Gov't Code.

Public Benefit. Ms. McCoy has determined for the first five-year period the proposed rules are in effect there will be a benefit to the general public because the proposed rules ensure consistency across the Board's rules and provide clarity by cleaning up unnecessary language in the rules.

Fiscal Note. Janice McCoy, Executive Director of the Board, has determined that for the first five-year period the proposed rules are in effect, there will be no additional estimated cost or reduction in cost to the state or local governments as a result of enforcing or administering the rules. The rules could increase the total application fee paid by roughly 20 percent of the applicant pool each year by a total of $55. This change would result in a total revenue increase to the state of approximately $2,200 each fiscal year. Additionally, Ms. McCoy has determined that enforcing or administering the rules do not have foreseeable implications relating to the costs or revenues of state or local government.

Requirement for Rules Increasing Costs to Regulated Persons. The proposed rule could impose additional costs to a small subset of regulated persons. However, the Board proposes the rule to increase the application fee as a result of changes to Chapter 271 related to requiring all applicants to apply concurrently as a therapeutic optometrist and an optometric glaucoma specialist. This change is proposed to ensure all licensees have the most advanced license available. It reduces the burden on about 80 percent of applicants who currently have to apply in two steps with two application fees and protects the health, safety, and welfare of the residents of this state by ensuring all licensees have the same upgraded license which allows the licensee to practice at the highest scope provided by law. Therefore, pursuant to §2001.0045 of the Tex. Gov't Code, no repeal or amendment of another rule is required to offset any increased costs.

PUBLIC COMMENTS: Comments on the amended rules may be submitted electronically to: janice.mccoy@tob.texas.gov or in writing to Janice McCoy, Executive Director, Texas Optometry Board, 1801 N. Congress, Suite 9.300, Austin, Texas 78701. The deadline for furnishing comments is thirty days after publication in the *Texas Register.*

Statutory Authority. The Board proposes this rule pursuant to the authority found in §351.151 of the Tex. Occ. Code which vests the Board with the authority to adopt rules necessary to perform its duties and implement Chapter 351 of the Tex. Occ. Code.

The Board also proposes this rule under the authority found in Texas Occupations Code §§351.152 Fees and 351.302 License Renewal; and §232.0135 of the Family Code.

No other sections are affected by the amendments.

§273.1. Surrender of License.

Any person formerly licensed to practice optometry in this state, who receives notification from the Board [~~board~~] that the person's license to practice optometry has expired for failure to pay the annual renewal fee, shall within 10 days of receipt of such notification from the Board [~~board~~] either pay the applicable renewal fee or surrender the license by mailing or otherwise delivering such license to the Board [~~board~~] office. Alternatively, rather than physically surrender the license, the person may file with the Board [~~board~~] an affidavit in the form acceptable to the Executive Director [~~executive director~~] to the effect that such person is not practicing and will not practice optometry.

§273.4. Fees (Not Refundable).

(a) [~~Examination~~] Application Fee $205.00 [~~$150.00~~].

(b) License Without Examination Application Fee $305.00.

(c) Therapeutic Certification Application Fee $85.00.

(d) Optometric Glaucoma Specialist License Application Fee $55.00.

(e) Initial Therapeutic License Fee: [~~$55.00 plus $5.00 fee required by House Bill 2985, 78th Legislature. Total fee: $60.00. Beginning January 1, 2021, a fee of $265.36 plus $6.00 fee required by House Bill 2985, 78th Legislature. Total fee for biennial renewal:~~] $271.36.

(f) License Renewal.

(1) Fee for licenses renewed on or before the January 1 expiration date:

(A) Optometrist, Therapeutic Optometrist and inactive Optometric Glaucoma Specialist: $432.72 [~~$220.36 plus $1.00 fee required by House Bill 2985, 78th Legislature. Total fee: $221.36~~].

(B) Active Optometric Glaucoma Specialist: $452.00 [~~$230.00 plus $1.00 fee required by House Bill 2985, 78th Legislature. Total fee: $231.00~~].

[~~(C) Beginning January 1, 2021, the renewal fee for biennial renewal is:~~]

~~*[(i)* Optometrist, Therapeutic Optometrist and inactive Optometric Glaucoma Specialist: $430.72 plus $2.00 fee required by House Bill 2985, 78th Legislature. Total fee: $432.72.]~~

~~*[(ii)* Active Optometric Glaucoma Specialist: $450.00 plus $2.00 fee required by House Bill 2985, 78th Legislature. Total fee: $452.00]~~

~~*[(iii)* Licenses renewed for the one year for 2021: the fee will be prorated for the one-year period.]~~

(2) License fee for late renewal, one to 90 days late.

(A) Optometrist, Therapeutic Optometrist and inactive Optometric Glaucoma Specialist: $643.08 [~~$325.54 plus $1.00 fee required by House Bill 2985, 78th Legislature. Total late license fee: $326.54~~].

(B) Active Optometric Glaucoma Specialist: $672 [~~$340.00 plus $1.00 fee required by House Bill 2985, 78th Legislature. Total fee: $341.00~~].

[~~(C) Beginning January 1, 2021, the renewal fee for biennial renewal, one to 90 days late is:~~]

~~*[(i)* Optometrist, Therapeutic Optometrist and inactive Optometric Glaucoma Specialist: $641.08 plus $2.00 fee required by House Bill 2985, 78th Legislature. Total fee: $643.08.]~~

~~*[(ii)* Active Optometric Glaucoma Specialist: $670.00 plus $2.00 fee required by House Bill 2985, 78th Legislature. Total fee: $672.00.]~~

~~*[(iii)* Licenses renewed for the one year for 2021: the one to 90 days late fee will be prorated for the one-year period.]~~

(3) License fee for late renewal, 91 days to one year late.

(A) Optometrist, Therapeutic Optometrist and inactive Optometric Glaucoma Specialist: $853.44 [~~$430.72 plus $1.00 fee required by House Bill 2985, 78th Legislature. Total late license fee: $431.72~~].

(B) Optometric Glaucoma Specialist: $892.00 [$450.00 plus $1.00 fee required by House Bill 2985, 78th Legislature. Total fee: $451.00].

[(C) Beginning January 1, 2021, the renewal fee for biennial renewal 91 days to one year late is:]

[(i) Optometrist, Therapeutic Optometrist and inactive Optometric Glaucoma Specialist: $851.44 plus $2.00 fee required by House Bill 2985, 78th Legislature. Total fee: $853.44.]

[(ii) Active Optometric Glaucoma Specialist: $890.00 plus $2.00 fee required by House Bill 2985, 78th Legislature. Total fee: $892.00.]

[(iii) Licenses renewed for the one year for 2021: the 91 days to one-year late fee will be prorated for the one-year period.]

(4) Late fees (for all renewals with delayed continuing education) $420.72.

(g) Provisional License $75.00.

(h) Initial Limited Faculty License $50.00.

(i) Duplicate License, Renewal Certificate, Therapeutic Certificate or Optometric Glaucoma Specialist Certificate (lost, destroyed, or name change) $25.00.

(j) Retired License.

(1) Optometrist and Therapeutic Optometrist: $222.36 [$210.36 plus $1.00 fee required by House Bill 2985, 78th Legislature. Total fee: $211.36].

(2) Optometric Glaucoma Specialist: $232.00 [$220.00 plus $1.00 fee required by House Bill 2985, 78th Legislature. Total fee: $221.00].

[(3) Beginning January 1, 2021, the renewal fee for biennial renewal is:]

[(A) Optometrist, Therapeutic Optometrist and inactive Optometric Glaucoma Specialist: $220.36 plus $2.00 fee required by House Bill 2985, 78th Legislature. Total fee: $222.36.]

[(B) Active Optometric Glaucoma Specialist: $230.00 plus $2.00 fee required by House Bill 2985, 78th Legislature. Total fee: $232.00.]

(k) Retired License to Active License Application Fee. For individuals holding Retired License making application for active license. $30.00.

(l) Request for Criminal History Evaluation Letters $125.00.

(m) Fee for official license verification: $40.00.

(n) Fee for list of optometrists: $65.00.

§273.5. Clinical Instruction and Practice - Limited License for Clinical Faculty.

(a) Issuance of limited license. The criteria for the issuance of a limited faculty license are as follows:

(1) the applicant must be a full-time faculty member of an institution accredited by the Accreditation Council on Optometric Education (ACOE) or a state recognized accrediting entity;

(2) the applicant must be a graduate of an institution accredited by the ACOE;

(3) the applicant's practice must be limited to the premises of the institution and its affiliated clinics;

(4) the practice must be an adjunct to the institution's teaching program; and

(5) the applicant must have paid the fees required by §273.4 of this chapter [title] (relating to Fees).

(b) Duties and Responsibilities of Dean of Institution. As a condition to continued approval of the institution, the board imposes the following duties and responsibilities upon the dean of the institution relating to those faculty members performing professional optometric services in programs of the institution. The dean shall:

(1) furnish each applicant for a limited faculty license a certificate that such applicant is a bona fide member of the faculty;

(2) report immediately to the board any information received relating in any way to a member of the faculty holding only a limited license who is performing professional optometric services other than as an adjunct to such faculty member's function at the institution. Every reasonable means to prevent such unlawful practice shall be used by the dean;

(3) cooperate fully and completely with the board toward the end that the limited license provided will be used only for the purpose for which it is intended; and

(4) promptly notify the board of any changes in limited license personnel on the faculty.

(c) Application and renewal. Each member of the faculty desiring a limited license shall make written application to the Executive Director [executive director of the board] and attach to the application the original certificate of the dean herein above provided and shall enclose therewith the payment of a fee as set forth in §273.4 of this chapter [of $50] for the issuance of the limited license [and the fee imposed by Section 351.153 of the Texas Optometry Act]. The annual renewal fee for a limited license is equal to the fee charged for a regular license as specified in §273.4 of this chapter [title] (relating to Fees). Holders of limited licenses shall also be required to meet the same continuing education requirements as holders of regular licenses. Said renewal fee shall be due on January 1 and expire after December 31 of each renewal cycle [year]. Failure to pay the renewal fee on or before January 1 shall subject the license to the same requirements of renewal as a regular license, including late penalties.

(d) Validity of limited license. The limited license shall be valid as long as the holder thereof remains a faculty member of the institution and abides by all regulations of the Board [board].

(e) Limitation of limited license. It shall be a violation of this rule for the holder of a limited license who is not regularly licensed under the statutes to perform optometric services in any manner except as part of the program of the institution and as an adjunct to teaching functions in the institution.

(f) Revocation of limited license. Those persons granted a limited license shall be subject to the same disciplinary procedures as the holder of a regular license. If, after disciplinary proceedings as set out in Board [board] rules, a holder of a limited license is found to be in violation of the Texas Optometry Act or Board [board] rules, the Board [board] may revoke the limited license. In such event, the Executive Director [executive director] shall promptly notify the limited licensee and the dean of the institution.

[(g) A student currently enrolled in an approved college of optometry or school may participate in clinical instruction and practice, provided that:]

[(1) The clinical instruction and practice is conducted on the premises of an approved college of optometry or school, or the af-

filiated clinics and offices, under the instruction and supervision of a licensed optometrist, or physician employed by the college of optometry; or]

[(2) The clinical instruction and practice is conducted as an externship in the office of a licensed optometrist or physician appointed as a clinical instructor by an approved college of optometry or school. The clinical training must be under the instruction and supervision of the appointed clinical instructor.]

[(h) No provision of this rule is intended to remove an exemption provided by statute.]

§273.6. Licenses for a Limited Period.

(a) Provisional License.

(1) Requirements for Provisional License. On application for examination, a candidate may apply for a provisional license under the following circumstances:

(A) The applicant must be licensed in good standing as a therapeutic optometrist in another state, the District of Columbia, or a territory of the United States that has licensing requirements that are substantially equivalent to the requirements of the Texas Optometry Act, and must furnish proof of such licensure on board forms provided.

(B) The applicant must have passed the National Board of Examiners in Optometry (NBEO) Examination Parts I and II, after January 1, 1984, and Part III after June of 1994, as well as the Treatment and Management of Ocular Disease (TMOD) Examination after January of 1985 and must submit a true and correct copy of the applicant's score report.

(C) The applicant must have satisfied the educational requirement of §271.1 [§280.2] of this title (relating to Required Education for Therapeutic Optometrist).

(D) The applicant must not have failed an examination for a license conducted by the Board [board].

(E) The applicant's license to practice optometry must not have been revoked or suspended by any jurisdiction.

(2) Sponsorship. A candidate for provisional licensure must be sponsored by a therapeutic optometrist who is currently licensed by the Board [board] with the following conditions applicable.

(A) Prior to practice in Texas, on forms provided by the Board [board], the sponsor licensee will certify to the Board [board] the following:

(i) that such candidate will be working within the same office as the licensee, under direct supervision of the sponsor licensee; and

(ii) that such sponsor licensee is aware of the Act and rules governing provisional licensure and that the sponsorship will cease upon the invalidity of the provisional license.

(B) Sponsor licensee will be held responsible for the unauthorized practice of optometry should such provisional license expire.

(3) Hardship. An applicant for a provisional license may be excused from the requirements of sponsorship if the Board [board] determines that compliance constitutes a hardship to the applicant.

(4) Application and fee.

(A) The candidate for provisional licensure will be subject to all application requirements required by Chapter 271 of this title (relating to Licensure [Examinations]) and subject to the applicable [examination] fees established under §273.4 of this chapter [title] (relating to [Optometry] Fees (Not Refundable)). In addition, the candidate will be subject to a fee for issuance of a provisional license, as established under §273.4 of this chapter [title].

(B) No provisional license can be issued until all application forms and fees are received [in the board office] and the application is approved.

(C) A provisional license expires upon the earlier to occur of the passage of 180 days or notice by the Board [board] of the candidate's successful passage or failure of all examinations required by Chapter 271 of this title. It shall be the responsibility of the candidate and sponsor to return the provisional license to the Board [board office] upon expiration.

[(D) The candidate's failure to sit for the first scheduled board examination following application for examination invalidates the provisional license unless in the discretion of the board sufficient and reasonable evidence regarding nonappearance exists.]

(D) [(E)] Each candidate for provisional license shall receive only one nonrenewable license prior to the issuance of a therapeutic optometry license.

(5) If at any time during the provisional licensure period it is determined that the holder of such provisional license has violated the Optometry Act or Board [board] rules, such provisional license will be subject to termination.

(b) Military Limited Volunteer License.

(1) Pursuant to §351.266 of the Texas Optometry Act, the Board may issue a military limited volunteer license to practice optometry or therapeutic optometry to an applicant who:

(A) is licensed and in good standing, or was licensed and retired in good standing, as an [a] optometrist or therapeutic optometrist in another state;

(B) is or was authorized as an optometrist or therapeutic optometrist to treat personnel enlisted in a branch of the United States armed forces or veterans; and

(C) meets all other requirements prescribed by Board Rule.

(2) The Board [board] may not issue a license under this section to an applicant who:

(A) holds an optometry or therapeutic optometry license that:

(i) is currently under investigation by a state or territory of the United States, or a uniformed service of the United States;

(ii) is or was restricted, cancelled, suspended, revoked, or subject to other discipline or denial of licensure by a state or territory of the United States, or a uniformed service of the United States;

(B) holds a license issued by the Drug Enforcement Agency or a state public safety agency to prescribe, dispense, administer, supply, or sell a controlled substance that:

(i) is currently under investigation by a state or territory of the United States, or a uniformed service of the United States;

(ii) is or was restricted, cancelled, suspended, revoked, or subject to other discipline or denial by a state or territory of the United States, or a uniformed service of the United States; or

(C) is currently under investigation or has been convicted of, or placed on deferred adjudication, community supervision,

or deferred disposition for a felony or a misdemeanor involving moral turpitude.

(3) An optometrist or therapeutic optometrist who practices optometry or therapeutic optometry under a license issued under this section may:

(A) only practice at a clinic that primarily treats indigent populations; and

(B) not receive direct or indirect compensation or payment of anything of monetary value in exchange for the optometric services rendered by the optometrist or therapeutic optometrist to the indigent patients at the clinic.

(4) A military limited volunteer license holder is subject to Board [~~board~~] rules, including rules regarding disciplinary action, license registration and renewal.

(5) A military limited volunteer license shall be issued for a period of one year and may be renewed and maintained according to registration requirements as prescribed by Board Rules.

§273.7. Inactive Licenses.

(a) Placing a license on inactive status. A person who is licensed by the Board to practice optometry but who is not engaged in the practice of optometry in this state may place the license on inactive status at the time of license renewal as follows. The licensee shall:

(1) complete and submit before the expiration date a license renewal application provided by the Board;

(2) state on the renewal application that the license is to be placed on inactive status and that the licensee shall not practice optometry in Texas while the license is inactive; and

(3) pay the fee for renewal of license as specified in §273.4 of this chapter [~~title~~] (relating to Fees (Not Refundable)). Penalty fees as provided by Section 351.304 of the Act, will apply to those received after December 31 of the applicable renewal period.

(b) Reactivation of an Inactive License. A holder of a license that is on inactive status may return the license to active status by:

(1) applying for active status on a form prescribed by the Board;

(2) providing proof of completion certificates from approved continuing education programs as specified in Chapter 275 of this title (relating to Continuing Education Requirements) for the number of hours that would otherwise have been required for the renewal of the license. Approved continuing education earned within the two years prior to the licensee applying for the return to active status may be applied toward the continuing education requirement; and

(3) paying the license renewal fee specified in §273.4 of this chapter (relating to Fees (Not Refundable)).

(c) Prohibition against practicing optometry in Texas. A holder of a license that is on inactive status shall not practice optometry in this state. The practice of optometry by a holder of a license that is on inactive status constitutes the practice of optometry without a license.

§273.8. Renewal of License.

(a) Expired license.

(1) If a license is not renewed on or before the expiration date, it becomes expired. All licenses renew on a biennial basis. Initial licenses expire on the second January 1 after the date the license is first issued.

(2) If a person's license has been expired for 90 days or less, the person may renew the license by paying to the Board the amount of one and one-half times the renewal fee.

(3) If a person's license has been expired for longer than 90 days but less than one year, the person may renew the license by paying to the Board the amount of two times the renewal fee.

(4) If a person's license has been expired for one year or longer, the person may not renew the license but may obtain a new license by reapplying and passing the jurisprudence exam and complying with the requirements and procedures for obtaining an initial license. However, the Board may reinstate a license without requiring reapplication and reexamination of the jurisprudence examination an expired license of a person who was previously licensed in Texas, is currently licensed in another state, and has been in practice as a therapeutic optometrist for two years immediately preceding application for reinstatement. The person shall be required to furnish documentation of continuous practice for the two-year period and pay the renewal fee as established by subsection (a)(3) of this section. The person must furnish license verifications from each state in which the person is currently or previously licensed. A license renewal under this section is subject to the same requirements of §351.501 of the Act as a license applicant.

(5) For licenses expired for more than one year, if the person was not licensed as a therapeutic optometrist when the license expired, the person must also complete the requirements for therapeutic license as outlined in Chapter 271 of this title [~~in §§280.1 - 280.3 of this title (relating to Application for Certification Required; Education; Certified Therapeutic Optometrist Examination, respectively)~~] prior to obtaining a new license.

(6) A licensee receiving a felony or misdemeanor criminal conviction as outlined under Occupations Code Chapter 53 shall report the conviction on the next license renewal. This requirement is in addition to the 30 day reporting requirement in §277.5 of this title (relating to Convictions). This paragraph does not require the reporting of a Class C Misdemeanor traffic violation. The failure of a licensee to report a criminal conviction is deceit, dishonesty and misrepresentation in the practice of optometry and authorizes the Board to take disciplinary action under §351.501 of the Act. The licensee shall furnish any document relating to the criminal conviction as requested by the Board.

(7) Only an active licensee who has provided a complete fingerprint criminal history report to the Board is eligible to renew a license.

(b) Mandatory Continuing Education for Renewal of License.

(1) The Board may not issue a renewal license to a licensee who has not complied with the mandatory continuing education requirements unless an exemption provided by §275.1 of this title (relating to General Requirements) is applicable.

(2) If a licensee has not fulfilled the required continuing education requirements prior to the license renewal date, the license shall expire. To renew that expired license, the licensee may obtain and provide the Board with certified records that the licensee has, since the expiration of the license, completed sufficient hours of approved continuing education courses to satisfy any deficiency. Education obtained for renewal of an expired license cannot be applied toward subsequent renewal of license.

(3) The licensee cannot practice optometry until such time as education is obtained and the expired license has been renewed.

(4) The licensee must pay to the Board the license renewal fee with a late penalty fee authorized by §351.304 of the Act, plus a penalty authorized by §351.308 of the Act.

(5) The Executive Director shall determine if all requirements for renewal of license have been fulfilled, and will notify the licensee when the practice of optometry can resume.

(6) To practice optometry with an expired license shall constitute the practice of optometry without a license.

(c) Outstanding Administrative Penalty or Failure to Comply with Board Condition.

(1) The Board may refuse to renew a license to a person who has:

(A) not paid an administrative penalty owed to the Board at the time of renewal; or

(B) not complied with a term or condition of a disciplinary order or agreement issued by the Board.

(2) The Board may refuse to renew a license, until such time as:

(A) every administrative penalty payable on or before the time of renewal is paid; or

(B) all terms or conditions of a disciplinary order or agreement issued by the Board are satisfied.

§273.9. Public Interest Information.

(a) In order for the public to be informed regarding the functions of the Board [~~board~~] and the Board's [~~board's~~] procedures by which complaints are filed with and resolved by the Board [~~board~~], each licensee is required to display at every location where optometric services are provided information regarding the Board's [~~board's~~] name, address, and telephone number.

(b) The licensee may either display a placard or sign furnished by the Board [~~board~~] or provide to all patients and consumers a consumer pamphlet developed [~~furnished~~] by the Board [~~board~~] containing the name of the Board [~~board~~], mailing address, and telephone number for the purpose of directing complaints to the Board [~~board~~].

(c) The placard or sign shall be conspicuously and prominently displayed in a location where it may be seen by all patients.

(d) The consumer pamphlet, if chosen, shall be prominently displayed and available to patients at all times.

§273.10. Nonrenewal for Failure to Pay Child Support [~~Licensee Compliance with Payment Obligations~~].

[~~Child support payments; Chapter 232 of the Texas Family Code.~~]

(a) [~~(1)~~] In accordance with §232.0135 of the Family Code, an [~~An~~] application for license renewal will not be accepted if a child support agency provides the Board [~~board~~] with notice that a licensee has failed to pay child support for six months or more and requests that the Board deny the renewal of an existing license [~~board not accept the application~~].

(b) [~~(2)~~] The application will be considered once the Board [~~board~~] receives notice from the child support agency that the licensee has met one or more of the requirements set out in §232.0135(b) of the Family Code [~~is in compliance with the requirements of Chapter 232 of the Texas Family Code~~].

(c) [~~(3)~~] The Board [~~board~~] may charge the licensee a fee in an amount sufficient to recover the administrative costs incurred by the Board [~~board~~] under this chapter.

§273.18. Clinical Instruction for Optometry Student.

A student currently enrolled in an approved college of optometry or school may participate in clinical instruction and practice, provided that:

(1) The clinical instruction and practice is conducted on the premises of an approved college of optometry or school, or the affiliated clinics and offices, under the instruction and supervision of a licensed optometrist, or physician employed by the college of optometry; or

(2) The clinical instruction and practice is conducted as an externship in the office of a licensed optometrist or physician appointed as a clinical instructor by an approved college of optometry or school. The clinical training must be under the instruction and supervision of the appointed clinical instructor.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on May 30, 2024.

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Janice McCoy
Executive Director
Texas Optometry Board
Earliest possible date of adoption: July 14, 2024
For further information, please call: (512) 305-8500

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22 TAC §273.11

The Texas Optometry Board proposes the following repeal to 22 TAC Title 14 Chapter 273 General Rules, §273.11.

The rules in the Chapter 273 were reviewed as a result of the Board's general rule review under Texas Government Code §2001.039. Notice of the review was published in the March 1, 2024, issue of the *Texas Register* (49 TexReg 1288). No comments were received regarding the Board's notice of review. The Board has determined that there continues to be a need for the rules in Chapter 273.

However, the Board has determined the substance of §273.11 Public Participation in Meetings would be better suited for Chapter 272 and is proposing to repeal the rule in its entirety.

The substance of the language will be proposed for amendment to Chapter 272 in a separate rule submission with the Texas Register.

Government Growth Impact Statement. For the first five-year period the repeal is in effect, the Board estimates that the repeal will have no effect on government growth. The repeal does not create or eliminate a government program; does not require the creation or elimination of employee positions; does not require the increase or decrease in future legislative appropriations to this agency; does not require an increase or decrease in fees paid to the agency; does not create a new regulation; does not expand an existing regulation; does not increase or decrease the number of individuals subject to the rule's applicability; and does not positively or adversely affect the state's economy.

Small Business, Micro-Business, and Rural Community Impact Statement. Ms. McCoy has determined for the first five-year period following the repeal, there will be no adverse effect on small businesses, micro-businesses, or rural communities and the repeal does not positively or adversely impact the state's economy.

Regulatory Flexibility Analysis for Small and Micro-Businesses and Rural Communities. Ms. McCoy has determined that the repeal will have no adverse economic effect on small businesses, micro-businesses, or rural communities and does not positively or adversely impact the state's economy. Thus, the Board is not required to prepare a regulatory flexibility analysis pursuant to §2006.002 of the Government Code.

Takings Impact Assessment. Ms. McCoy has determined that there are no private real property interests affected by the repeal. Thus, the Board is not required to prepare a takings impact assessment pursuant to §2007.043 of the Government Code.

Local Employment Impact Statement. Ms. McCoy has determined that the repeal will have no impact on local employment or a local economy. Thus, the Board is not required to prepare a local employment impact statement pursuant to §2001.024 of the Government Code.

Public Benefit. Ms. McCoy has determined for the first five-year period the repeal is in effect there is no impact on the public.

Fiscal Note. Janice McCoy, Executive Director of the Board, has determined that for the first five-year period following the repeal, there will be no additional estimated cost, reduction in costs, or loss or increase in revenue to local governments.

Additionally, Ms. McCoy has determined that enforcing or administering the rules do not have foreseeable implications relating to the costs or revenues of state or local government.

Requirement for Rules Increasing Costs to Regulated Persons. The proposed repeal does not impose any new or additional costs to regulated persons, state agencies, special districts, or local governments; therefore, pursuant to §2001.0045 of the Government Code, no repeal or amendment of another rule is required to offset any increased costs. Additionally, no repeal or amendment of another rule is required because the proposed rules are necessary to protect the health, safety, and welfare of the residents of this state and because regulatory costs imposed by the Board on licensees is not expected to increase.

PUBLIC COMMENTS: Comments on the proposed repeal rules may be submitted electronically to: janice.mccoy@tob.texas.gov or in writing to Janice McCoy, Executive Director, Texas Optometry Board, 1801 N. Congress, Suite 9.300, Austin, Texas 78701. The deadline for furnishing comments is thirty days after publication in the *Texas Register.*

Statutory Authority. The Board proposes this rule pursuant to the authority found in §351.151 of the Occupations Code which vests the Board with the authority to adopt rules necessary to perform its duties and implement Chapter 351 of the Occupations Code.

No other sections are affected by the amendments.

§273.11. Public Participation in Meetings.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on May 30, 2024.

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Janice McCoy
Executive Director
Texas Optometry Board
Earliest possible date of adoption: July 14, 2024
For further information, please call: (512) 305-8500

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CHAPTER 280. THERAPEUTIC OPTOMETRY

22 TAC §§280.1, 280.3, 280.8

The Texas Optometry Board proposes the repeal of 22 TAC Chapter 280 Therapeutic Optometry. The Board is repealing the following rules: §280.1 Required Education; §280.3 Certified Therapeutic Optometrist Examination; and §280.8 Optometric Glaucoma Specialist: Required Education, Examination and Clinical Skills Evaluation..

The text of the rules will be added as amendments to Chapter 271 as a separate rule submission with the *Texas Register.*

Government Growth Impact Statement. For the first five-year period the repeal is in effect, the Board estimates that the repeal will have no effect on government growth. The repeal does not create or eliminate a government program; does not require the creation or elimination of employee positions; does not require the increase or decrease in future legislative appropriations to this agency; does not require an increase or decrease in fees paid to the agency; does not create a new regulation; does not expand an existing regulation; does not increase or decrease the number of individuals subject to the rule's applicability; and does not positively or adversely affect the state's economy.

Small Business, Micro-Business, and Rural Community Impact Statement. Ms. McCoy has determined for the first five-year period following the repeal, there will be no adverse effect on small businesses, micro-businesses, or rural communities and the repeal does not positively or adversely impact the state's economy.

Regulatory Flexibility Analysis for Small and Micro-Businesses and Rural Communities. Ms. McCoy has determined that the repeal will have no adverse economic effect on small businesses, micro-businesses, or rural communities and does not positively or adversely impact the state's economy. Thus, the Board is not required to prepare a regulatory flexibility analysis pursuant to §2006.002 of the Government Code.

Takings Impact Assessment. Ms. McCoy has determined that there are no private real property interests affected by the repeal. Thus, the Board is not required to prepare a takings impact assessment pursuant to §2007.043 of the Government Code.

Local Employment Impact Statement. Ms. McCoy has determined that the repeal will have no impact on local employment or a local economy. Thus, the Board is not required to prepare a local employment impact statement pursuant to §2001.024 of the Government Code.

Public Benefit. Ms. McCoy has determined for the first five-year period the repeal is in effect there is no impact on the public.

Fiscal Note. Janice McCoy, Executive Director of the Board, has determined that for the first five-year period following the repeal, there will be no additional estimated cost, reduction in costs, or loss or increase in revenue to local governments.

Additionally, Ms. McCoy has determined that enforcing or administering the rules do not have foreseeable implications relating to the costs or revenues of state or local government.

Requirement for Rules Increasing Costs to Regulated Persons. The proposed repeal does not impose any new or additional costs to regulated persons, state agencies, special districts, or local governments; therefore, pursuant to §2001.0045 of the

Government Code, no repeal or amendment of another rule is required to offset any increased costs. Additionally, no repeal or amendment of another rule is required because the proposed rules are necessary to protect the health, safety, and welfare of the residents of this state and because regulatory costs imposed by the Board on licensees is not expected to increase.

PUBLIC COMMENTS: Comments on the proposed repeal rules may be submitted electronically to: janice.mccoy@tob.texas.gov or in writing to Janice McCoy, Executive Director, Texas Optometry Board, 1801 N. Congress, Suite 9.300, Austin, Texas 78701. The deadline for furnishing comments is thirty days after publication in the *Texas Register.*

Statutory Authority. The Board proposes this repeal pursuant to the authority found in §351.151 of the Occupations Code which vests the Board with the authority to adopt rules necessary to perform its duties and implement Chapter 351 of the Occupations Code.

No other sections are affected by the repeal.

§280.1. Required Education.

§280.3. Certified Therapeutic Optometrist Examination.

§280.8. Optometric Glaucoma Specialist: Required Education, Examination and Clinical Skills Evaluation.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on May 30, 2024.

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Janice McCoy
Executive Director
Texas Optometry Board
Earliest possible date of adoption: July 14, 2024
For further information, please call: (512) 305-8500

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22 TAC §§280.1, 280.5, 280.9

The Texas Optometry Board proposes amendments to 22 TAC Title 14 Chapter 280 Therapeutic Optometry. The Board is amending the following rules: §280.1 Application for Therapeutic Certification; §280.9 Application for Licensure as Optometric Glaucoma Specialist; and §280.5(f) Prescription and Diagnostic Drugs for Therapeutic Optometry.

The rules in the Chapter 280 were reviewed as part of an effort by the Board's Administration and Licensing Committee to simplify the Board's application process. The Committee recommended that the Board combine the application of the Therapeutic and Optometric Glaucoma Specialist applications as all graduates after 2008 qualify for the enhanced Optometric Glaucoma Specialist designation. The Board recognized that having the application in two steps was a deterrent to about 20 percent of the applicant pool who failed to complete the second application step.

Additionally, the Board was concurrently reviewing Chapter 271 - Examinations under its quadrennial rules review process. The Committee recommended that the Board move all license requirements and applications steps to Chapter 271 for clarity to both staff and potential applicants.

As such the Board proposes to move all education and examination requirements found in Chapter 280 to Chapter 271 - which also is being published in the *Texas Register* for public comment.

The Board is not making changes to the following rules: §280.6 Procedures Authorized for Therapeutic Optometrists and §280.10 Optometric Glaucoma Specialist: Administration and Prescribing of Oral Medications and Anti-Glaucoma Drugs

The following rules are being amended to remove the licensing requirements: §280.1 Application for Therapeutic Certification and §280.9 Application for Licensure as Optometric Glaucoma Specialist. The language remaining in these sections outlines the current authority provided to each license type.

The Board is making changes to §280.5(f) Prescription and Diagnostic Drugs for Therapeutic Optometry unrelated to the licensing process.

Finally, the following rules are being repealed from Chapter 280 and being readopted in Chapter 271: §280.2 Required Education; §280.3 Certified Therapeutic Optometrist Examination; and §280.8 Optometric Glaucoma Specialist: Required Education, Examination and Clinical Skills Evaluation. The repeal can be found in a separate rule proposal in the *Texas Register.*

Overview and Explanation of the Proposed Amendments. The proposal combines the application of the Therapeutic and Optometric Glaucoma Specialist applications as all graduates after 2008 qualify for the enhanced Optometric Glaucoma Specialist designation. This will clarify the application process for both applicants and staff. Additionally, by moving all new graduates to a single license type, the public is better protected as all licensees will have the enhanced license and be able to treat conditions to the full extent of their optometric education.

The one substantive change that is not related to the licensing process is the clarification found in §280.5(f) as the Board realized the language adopted in 2023 was not clear in that therapeutic optometrists only have prescriptive authority for over the counter oral medications. The language is proposed to read: "A therapeutic optometrist may administer and prescribe all: (1) ophthalmic devices; (2) over-the-counter medications including oral and other treatments; and (3) appropriate prescription topical pharmaceutical agents used for diagnosing and treating visual defects, abnormal conditions, and diseases of the human eye and adnexa."

Government Growth Impact Statement. For the first five-year period the proposed rules are in effect, the Board estimates that the proposed rules will have no effect on government growth. The proposed rules do not create or eliminate a government program; do not require the creation or elimination of employee positions; do not require the increase or decrease in future legislative appropriations to this agency; do not require an increase or decrease in fees paid to the agency; do not create a new regulation; do not expand an existing regulation; do not increase or decrease the number of individuals subject to the rule's applicability; and do not positively or adversely affect the state's economy.

Small Business, Micro-Business, and Rural Community Impact Statement. Ms. McCoy has determined for the first five-year period the proposed rules are in effect, there will be no adverse effect on small businesses, micro-businesses, or rural communities and the amendments do not positively or adversely impact the state's economy.

Regulatory Flexibility Analysis for Small and Micro-Businesses and Rural Communities. Ms. McCoy has determined that the proposed rules will have no adverse economic effect on small businesses, micro-businesses, or rural communities and do not positively or adversely impact the state's economy. Thus, the Board is not required to prepare a regulatory flexibility analysis pursuant to §2006.002 of the Government Code.

Takings Impact Assessment. Ms. McCoy has determined that there are no private real property interests affected by the proposed rules. Thus, the Board is not required to prepare a takings impact assessment pursuant to §2007.043 of the Government Code.

Local Employment Impact Statement. Ms. McCoy has determined that the proposed rules will have no impact on local employment or a local economy. Thus, the Board is not required to prepare a local employment impact statement pursuant to §2001.024 of the Government Code.

Public Benefit. Ms. McCoy has determined for the first five-year period the proposed rules are in effect there will be a benefit to the general public because by moving all new graduates to a single license type, the public is better protected as all licensees will have the enhanced license and be able to treat conditions to the full extent of their optometric education.

Fiscal Note. Janice McCoy, Executive Director of the Board, has determined that for the first five-year period the proposed rules are in effect, there will be no additional estimated cost, reduction in costs, or loss or increase in revenue to the state or local governments as a result of enforcing or administering the rules. Additionally, Ms. McCoy has determined that enforcing or administering the rules do not have foreseeable implications relating to the costs or revenues of state or local government.

Requirement for Rules Increasing Costs to Regulated Persons. The proposed rule does not impose any new or additional costs to regulated persons, state agencies, special districts, or local governments; therefore, pursuant to §2001.0045 of the Government Code, no repeal or amendment of another rule is required to offset any increased costs. Additionally, no repeal or amendment of another rule is required because the proposed rules are necessary to protect the health, safety, and welfare of the residents of this state and because regulatory costs imposed by the Board on licensees is not expected to increase.

PUBLIC COMMENTS: Comments on the amended rules may be submitted electronically to: janice.mccoy@tob.texas.gov or in writing to Janice McCoy, Executive Director, Texas Optometry Board, 1801 N. Congress, Suite 9.300, Austin, Texas 78701. The deadline for furnishing comments is thirty days after publication in the *Texas Register.*

Statutory Authority. The Board proposes this rule pursuant to the authority found in §351.151 of the Occupations Code which vests the Board with the authority to adopt rules necessary to perform its duties and implement Chapter 351 of the Occupations Code.

The Board also proposes this rule under the authority found in Texas Optometry Act §§351.252, 351.253, 351.358, and 351.3581.

No other sections are affected by the amendments.

§280.1. [~~Application for~~] Therapeutic License [~~Certification~~].

(a) Therapeutic optometrists are licensed [~~To be certified~~] to administer and prescribe ophthalmic devices, over-the-counter medications, and topical ocular pharmaceutical agents, other than antiglaucoma agents, for the purpose of diagnosing and treating visual defects, abnormal conditions and diseases of the human eye and adnexa, and to be able to remove superficial foreign matter and eyelashes from the external eye or adnexa [~~, a licensed optometrist must submit a completed application on forms provided by the Texas Optometry Board (Board). After September 1, 1992, all applicants for initial licensure in Texas must be licensed as a therapeutic optometrist in order to practice optometry in Texas~~].

(b) A licensed optometrist who is not certified as a therapeutic optometrist may only use topical ocular pharmaceutical agents for the purpose of ascertaining and measuring the powers of vision of the human eye, examining and diagnosing visual defects, abnormal conditions, and diseases of the human eye and adnexa, and fitting lenses or prisms to correct or remedy any defect or abnormal condition of vision.

~~[(c) An application for certification must be completed by the applicant, signed, and forwarded to the Board along with an application fee. Proof of the required education as set forth in §280.2 of this title (relating to Required Education) must accompany the application form.]~~

~~[(d) Successful examination results of the Treatment and Management of Ocular Disease (TMOD) Examination must be submitted prior to the issuance of the certificate to practice as a therapeutic optometrist.]~~

~~[(e) Designation of authority as a certified therapeutic optometrist will appear along with the optometrist's license number in the format of the license numbers followed by the letter "T." Such designation must appear whenever the license number is required under Board statutes or Board rules.]~~

~~[(f) In the event the original certification is lost or destroyed, the Board may issue a duplicate certificate; the person entitled thereto must make written application to the Board for a duplicate, under affidavit setting forth that such certificate was lost or destroyed, and the circumstances under which loss or destruction occurred. Should the original subsequently be found, it must be forwarded immediately to the Board and not used by the person to whom issued originally or by any other person. A fee must be submitted to the Board along with the affidavit for the duplicate issue.]~~

~~[(g) Successful completion of a Board approved examination testing knowledge of general and ocular pharmacology and related pathology with particular emphasis on the topical application of pharmaceutical agents shall be required, as defined in §280.3 of this title (relating to Certified Therapeutic Optometrist Examination).]~~

§280.5. Prescription and Diagnostic Drugs for Therapeutic Optometry.

(a) A therapeutic optometrist may administer and prescribe any drug authorized by Section 351.358 of the [~~Texas Optometry~~] Act.

(b) To prohibit substitution of a generically equivalent drug product on a written prescription drug order, a therapeutic optometrist must write across the face of the written prescription, in the therapeutic optometrist's own handwriting, "brand necessary" or "brand medically necessary." If the therapeutic optometrist does not clearly indicate "brand necessary" or "brand medically necessary," the pharmacist may substitute a generically equivalent drug product in compliance with the Texas Pharmacy Act, (Tex. Occ. Code Sections 562.008 and 562.009), and §309.3 of this title (relating to Substitution Requirements).

(c) All prescriptions shall contain the following information:

(1) the date of issuance;

(2) the name and address of the patient for whom the drug is prescribed;

(3) the name, strength, and quantity of the drug, medicine, or device prescribed;

(4) the direction for use of the drug, medicine, or device prescribed;

(5) the name and address of the therapeutic optometrist;

(6) the manually written signature of the prescribing therapeutic optometrist; or an electronic signature provided that the prescription is electronically signed by the practitioner using a system which electronically replicates the practitioner's manual signature on the written prescription, and provided:

(A) that security features of the system require the practitioner to authorize each use; and

(B) the prescription is printed on paper that is designed to prevent unauthorized copying of a completed prescription and to prevent the erasure or modification of information written on the prescription by the prescribing practitioner; and

(7) the license number of the prescribing therapeutic optometrist including the therapeutic designation.

(d) The prescribing therapeutic optometrist issuing verbal or electronic prescription drug orders to a pharmacist shall furnish the same information required for a written prescription, except for the written signature. If the therapeutic optometrist does not clearly indicate "brand necessary" or "brand medically necessary" when communicating the prescription to the pharmacist, the pharmacist may substitute a generically equivalent drug product in compliance with the Texas Pharmacy Act and §309.3 of this title (related to Substitution Requirements).

(e) A therapeutic optometrist may charge a reasonable fee for drugs administered within the optometric office, but a therapeutic optometrist shall not charge for any drugs supplied to the patient as take-home medication. Any drug supplied by a therapeutic optometrist other than an over-the counter drug shall be labeled in compliance with the following information in compliance with the Texas Dangerous Drug Act (Health and Safety Code, Chapter 483), and it shall contain the following:

(1) the name, address, and telephone number of the therapeutic optometrist;

(2) the date of dispensing;

(3) the name of the patient;

(4) the name and strength of the drug; and

(5) the directions for use.

(f) A therapeutic optometrist may administer and prescribe all:

(1) ophthalmic devices;

(2) over-the-counter medications including oral and other treatments; and

(3) appropriate prescription topical [~~or oral~~] pharmaceutical agents used for diagnosing and treating visual defects, abnormal conditions, and diseases of the human eye and adnexa.

(g) The authority of an optometric glaucoma specialist to prescribe antiglaucoma drugs is defined by Section 351.3581 of the [~~Texas Optometry~~] Act.

(h) A therapeutic optometrist may possess and administer cocaine eye drops for diagnostic purpose. The cocaine eye drops must be no greater than 10 percent solution in prepackaged liquid form.

(1) A therapeutic optometrist must observe all requirements of the Texas Controlled Substances Act, the Health and Safety Code, Chapter 481, and all requirements of the Texas Department of Public Safety (DPS) Drug Rules in making application and maintaining renewal of a United States Drug Enforcement Administration (DEA) registration number for possession of the cocaine eye drops, a Schedule II controlled substance.

(2) The therapeutic optometrist must use the required DEA form for the purchase of the cocaine eye drops and shall maintain a complete and accurate record of purchases (to include samples received from pharmaceutical manufacturer representatives) and administration of controlled substances. The maximum amount to be purchased and maintained in an office of practice shall be no more than two vials, one opened and one in inventory.

(3) The recordkeeping listed in this section shall be subject to inspection at all times by the Texas Department of Public Safety, the U.S. Drug Enforcement Administration, and the Texas Optometry Board. Any officer or employee of the governmental agencies shall have the right to inspect and copy records, reports, and other documents and inspect security controls, inventory, and premises where such cocaine eye drops are possessed or administered.

(4) Minimum security controls shall be established to include but not limited to:

(A) establishing adequate security to prevent unauthorized access and diversion of the controlled substance; [~~,~~]

(B) during the course of business activities, not allowing any individual access to the storage area for controlled substances except those authorized by the therapeutic optometrist; [~~,~~]

(C) storing the controlled substance in a securely locked, substantially constructed cabinet or security cabinet which shall meet the requirements under the DPS Drug Rules; or [~~,~~]

(D) not employ in any manner an individual that would have access to controlled substances who has had a federal or state application for controlled substances denied or revoked, or have been convicted of a felony offense under any state or federal law relating to controlled substances or been convicted of any other felony, or have been a licensee of a health regulatory agency whose license has been revoked, canceled, or suspended.

(5) Failure of the therapeutic optometrist to maintain strict security and proper accountability of controlled substances shall be deemed to be a violation of the [~~Texas Optometry~~] Act, §351.501 and §351.551.

§280.9. [~~Application for Licensure as~~] Optometric Glaucoma Specialist.

[~~(a)~~] [~~A licensed therapeutic optometrist must submit a completed application on forms provided by the Texas Optometry Board (Board) to be eligible for licensure as an optometric glaucoma specialist.~~] An optometric glaucoma specialist may:

(1) administer and prescribe appropriate medications by topical or oral means for the purpose of diagnosing and treating visual defects, abnormal conditions and diseases of the human vision system, including the eye and adnexa, as set forth in §280.10 of this chapter (relating to Optometric Glaucoma Specialist: Administration and Prescribing of Oral Medications and Anti-Glaucoma Drugs); and

(2) treat glaucoma, as set forth in §351.3581 of the [~~Texas Optometry~~] Act and §280.10 of this chapter, including the administration and prescribing of appropriate medications by topical, oral, or parenteral means.

[(b) A completed application for license as an optometric glaucoma specialist consists of a signed application form entirely filled out by the applicant and forwarded to the Board along with an application fee. Proof of the required successfully completed education, examination and clinical assessment as set forth in §280.8 of this chapter (relating to Required Education) must accompany the application form. The Board may license the applicant as an optometric glaucoma specialist provided the applicant submits a completed application as defined in this rule, and provided that the applicant is currently licensed and authorized to practice therapeutic optometry in this state.]

[(c) The license to practice as an optometric glaucoma specialist must be displayed along with all licenses in a conspicuous place in the principal office where the optometrist practices.]

[(d) Designation of authority as an optometric glaucoma specialist will appear along with the optometrist's license number in the format of the license numbers followed by the letter "T" and "G." Such designation must appear whenever the license number is required under Board statutes or Board rules.]

[(e) In the event the original certification is lost or destroyed, the Board may issue a duplicate certificate; the person entitled thereto must make written application to the Board for a duplicate, under affidavit setting forth that such certificate was lost or destroyed, and the circumstances under which loss or destruction occurred. Should the original subsequently be found, it must be forwarded immediately to the Board and not used by the person to whom issued originally or by any other person. A fee must be submitted to the Board along with the affidavit for the duplicate issue.]

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on May 30, 2024.

TRD-202402422
Janice McCoy
Executive Director
Texas Optometry Board
Earliest possible date of adoption: July 14, 2024
For further information, please call: (512) 305-8500

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PART 15. TEXAS STATE BOARD OF PHARMACY

CHAPTER 281. ADMINISTRATIVE PRACTICE AND PROCEDURES

SUBCHAPTER C. DISCIPLINARY GUIDELINES

22 TAC §281.69

The Texas State Board of Pharmacy proposes amendments to §281.69, concerning Automatic Denial or Revocation. The amendments, if adopted, correct subparagraph lettering and grammatical errors.

Daniel Carroll, Pharm.D., Executive Director/Secretary, has determined that, for the first five-year period the rules are in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule. Dr. Carroll has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the amendments will be clear and grammatically correct regulations. There is no anticipated adverse economic impact on large, small or micro-businesses (pharmacies), rural communities, or local or state employment. Therefore, an economic impact statement and regulatory flexibility analysis are not required.

For each year of the first five years the proposed amendments will be in effect, Dr. Carroll has determined the following:

(1) The proposed amendments do not create or eliminate a government program;

(2) Implementation of the proposed amendments does not require the creation of new employee positions or the elimination of existing employee positions;

(3) Implementation of the proposed amendments does not require an increase or decrease in the future legislative appropriations to the agency;

(4) The proposed amendments do not require an increase or decrease in fees paid to the agency;

(5) The proposed amendments do not create a new regulation;

(6) The proposed amendments do not limit or expand an existing regulation;

(7) The proposed amendments do not increase or decrease the number of individuals subject to the rule's applicability; and

(8) The proposed amendments do not positively or adversely affect this state's economy.

Written comments on the amendments may be submitted to Eamon D. Briggs, Deputy General Counsel, Texas State Board of Pharmacy, 1801 Congress Avenue, Suite 13.100, Austin, Texas, 78701-1319, FAX (512) 305-8061. Comments must be received by 5:00 p.m., July 30, 2024.

The amendments are proposed under §§551.002 and 554.051 of the Texas Pharmacy Act (Chapters 551 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

§281.69. Automatic Denial or Revocation.

(a) Notwithstanding subsection (c) of this section, as required in Texas Occupations Code, §§108.052 and 108.053, the board shall deny an application for licensure as a pharmacist [by] or immediately upon receiving notification as specified in §108.053(b) revoke the pharmacist license of a person who:

(1) is required to register as a sex offender under Chapter 62, Code of Criminal Procedure;

(2) has been previously convicted of or placed on deferred adjudication community supervision for the commission of a felony offense involving the use or threat of force; or

(3) has been previously convicted of or placed on deferred adjudication community supervision for the commission of an offense:

(A) under Penal Code, §§22.011, 22.02, 22.021, or 22.04, or an offense under the laws of another state or federal law that is equivalent to an offense under one of those sections;

(B) committed:

(i) when the applicant held a license as a health care professional in this state or another state; and

(ii) in the course of providing services within the scope of the applicant's license; and

(C) [~~(4)~~] in which the victim of the offense was a patient of the applicant.

(b) As specified in Texas Occupations Code, §108.054, a person whose license application is denied under this subsection:

(1) based on a conviction or placement on deferred adjudication community supervision for an offense described by subsections (a)(2) or (3) of this section may reapply for a license if the conviction or deferred adjudication is reversed, set aside, or vacated on appeal; or

(2) based on a requirement to register as a sex offender under Chapter 62, Code of Criminal Procedure, may reapply for a license after the expiration of the period for which the person is required to register.

(c) As specified in Texas Occupations Code, §108.055, a person whose license is revoked under this subsection:

(1) based on a conviction or placement on deferred adjudication community supervision for an offense described by subsections (a)(2) or (3) of this section may apply for reinstatement of the license if the conviction or deferred adjudication is reversed, set aside, or vacated on appeal; or

(2) based on a requirement to register as a sex offender under Chapter 62, Code of Criminal Procedure, may apply for reinstatement of the license after the expiration of the period for which the person is required to register.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on May 24, 2024.

TRD-202402353
Daniel Carroll, Pharm.D.
Executive Director
Texas State Board of Pharmacy
Earliest possible date of adoption: July 14, 2024
For further information, please call: (512) 305-8084

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TITLE 25. HEALTH SERVICES

PART 1. DEPARTMENT OF STATE HEALTH SERVICES

CHAPTER 133. HOSPITAL LICENSING
SUBCHAPTER C. OPERATIONAL REQUIREMENTS

25 TAC §133.41, §133.49

The Executive Commissioner of the Texas Health and Human Services Commission (HHSC) proposes amendments to §133.41, concerning Hospital Functions and Services, and §133.49, concerning Reporting Requirements.

BACKGROUND AND PURPOSE

The purpose of the proposal is to implement House Bill (H.B.) 3162, 88th Legislature, Regular Session, 2023. H.B. 3162 amended Texas Health and Safety Code (HSC) Chapter 166 Subchapters B and E and HSC Chapter 313.

HSC §166.046, as amended by H.B. 3162, in part requires a health care facility's ethics or medical committee to review a physician's refusal to honor an advance directive or health care or treatment decision made by or on behalf of a patient determined to be incompetent or otherwise mentally or physically incapable of communication. Amended HSC §166.046 also requires the facility to provide a written notice to the person responsible for the patient's health care decisions that the facility's ethics or medical committee will meet at least seven days later to review the physician's refusal to honor the patient's advanced directive or health care treatment decision.

HSC §166.054, as added by H.B. 3162, requires a health care facility to report certain information to HHSC within 180 days after the health care facility provides the written notice required under HSC §166.046. New HSC §166.054 also requires HHSC to adopt rules for reporting, protecting, and aggregating this information.

SECTION-BY-SECTION SUMMARY

The proposed amendment to §133.41(f)(6)(G) and §133.41(k)(3)(G) updates existing references to HSC Chapter 166 to ensure consistency with amended HSC Chapter 166. The proposed amendment to §133.41 also corrects outdated information, replaces the "Department of State Health Services" or "department" with the "Texas Health and Human Services Commission (HHSC)" or "HHSC" in certain places, and makes minor, non-substantive changes to formatting and grammar for clarity and consistency with HHSC rulemaking guidelines.

The proposed amendment to §133.49 ensures consistency with amended HSC §166.054. New subchapter (d) requires a facility to complete and submit the Ethics or Medical Committee Reporting Form to HHSC after the facility provides the written notice required under HSC §166.046(b)(1) and describes the information collected in the form. New subsection (e) describes the process of publishing the aggregate report. New subsection (f) provides how the information in the forms may not be used. The proposed amendment also corrects outdated information and makes minor, non-substantive changes to formatting and grammar for clarity and consistency with HHSC rulemaking guidelines.

FISCAL NOTE

Trey Wood, HHSC Chief Financial Officer, has determined that for each year of the first five years that the rules will be in effect, enforcing or administering the rules does not have foreseeable implications relating to costs or revenues of state or local governments.

GOVERNMENT GROWTH IMPACT STATEMENT

HHSC has determined that during the first five years that the rules will be in effect:

(1) the proposed rules will not create or eliminate a government program;

(2) implementation of the proposed rules will not affect the number of HHSC employee positions;

(3) implementation of the proposed rules will result in no assumed change in future legislative appropriations;

(4) the proposed rules will not affect fees paid to HHSC;

(5) the proposed rules will not create a new regulation;

(6) the proposed rules will expand existing regulations;

(7) the proposed rules will not change the number of individuals subject to the rules; and

(8) the proposed rules will not affect the state's economy.

SMALL BUSINESS, MICRO-BUSINESS, AND RURAL COMMUNITY IMPACT ANALYSIS

Trey Wood has also determined that there will be no adverse economic effect on small businesses, micro-businesses, or rural communities because the proposed rules do not impose a cost or require small businesses, micro-businesses, or rural communities to alter their current business practices.

LOCAL EMPLOYMENT IMPACT

The proposed rules will not affect a local economy.

COSTS TO REGULATED PERSONS

Texas Government Code §2001.0045 does not apply to these rules because the rules do not impose a cost on regulated persons and are necessary to implement legislation that does not specifically state that §2001.0045 applies to the rules.

PUBLIC BENEFIT AND COSTS

Stephen Pahl, Deputy Executive Commissioner for Regulatory Services, has determined that for each year of the first five years the rules are in effect, the public will benefit from increased consistency between the hospital rules and new statutory requirements for advanced directives.

Trey Wood has also determined that for the first five years the rules are in effect, there are no anticipated economic costs to persons who are required to comply with the proposed rules because the rules do not require persons subject to the rules to alter their current business practices; these entities are required to comply with the law as added by H.B. 3162 and the proposed amendments only ensure consistency with current statutory requirements, codify the name of the reporting form in rule, and make other minor, non-substantive changes.

TAKINGS IMPACT ASSESSMENT

HHSC has determined that the proposal does not restrict or limit an owner's right to the owner's property that would otherwise exist in the absence of government action and, therefore, does not constitute a taking under Texas Government Code §2007.043.

PUBLIC COMMENT

Written comments on the proposal may be submitted to Rules Coordination Office, P.O. Box 13247, Mail Code 4102, Austin, Texas 78711-3247, or street address 701 W. 51st Street, Austin, Texas 78751; or emailed to HCR_PRU@hhs.texas.gov.

To be considered, comments must be submitted no later than 31 days after the date of this issue of the *Texas Register.* Comments must be (1) postmarked or shipped before the last day of the comment period; (2) hand-delivered before 5:00 p.m. on the last working day of the comment period; or (3) emailed before midnight on the last day of the comment period. If the last day to submit comments falls on a holiday, comments must be postmarked, shipped, or emailed before midnight on the following business day to be accepted. When emailing comments, please indicate "Comments on Proposed Rule 24R003" in the subject line.

STATUTORY AUTHORITY

The amendments are authorized by Texas Government Code §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of services by the health and human services agencies; HSC §241.026, which requires HHSC to develop, establish, and enforce standards for the construction, maintenance, and operation of licensed hospitals; and HSC §166.054, which requires HHSC to adopt rules to establish a standard form for the requirements for reporting meetings of an ethics or medical committee meeting to review a physician's refusal to honor an advance directive of or health care or treatment decision made by or on behalf of a patient who is determined to be incompetent or is otherwise mentally or physically incapable of communication and to protect and aggregate any information HHSC receives under this section.

The amendments implement Texas Government Code §531.0055 and HSC §166.046, §166.0465, §166.052, HSC §166.054, §166.203, §166.204, §166.205, and §166.206.

§133.41. Hospital Functions and Services.

(a) Anesthesia services. If the hospital furnishes anesthesia services, these services shall be provided in a well-organized manner under the direction of a qualified physician in accordance with the Texas Occupations Code Subtitle B [~~Medical Practice Act~~] and the Texas Occupations Code Chapter 301 [~~Nursing Practice Act~~]. The hospital is responsible for and shall document all anesthesia services administered in the hospital.

(1) Organization and staffing. The organization of anesthesia services shall be appropriate to the scope of the services offered. Only personnel who have been approved by the facility to provide anesthesia services shall administer anesthesia. All approvals or delegations of anesthesia services as authorized by law shall be documented and include the training, experience, and qualifications of the person who provided the service.

(2) Delivery of services. Anesthesia services shall be consistent with needs and resources. Policies on anesthesia procedure shall include the delineation of pre-anesthesia and post-anesthesia responsibilities. The policies shall ensure that the following are provided for each patient.

(A) A pre-anesthesia evaluation by an individual qualified to administer anesthesia under paragraph (1) of this subsection shall be performed within 48 hours before [~~prior to~~] surgery.

(B) An intraoperative anesthesia record shall be provided. The record shall include any complications or problems occurring during the anesthesia including time, description of symptoms, review of affected systems, and treatments rendered. The record shall correlate with the controlled substance administration record.

(C) A post-anesthesia follow-up report shall be written by the person administering the anesthesia before transferring the patient from the post-anesthesia care unit and shall include evaluation for recovery from anesthesia, level of activity, respiration, blood pressure, level of consciousness, and patient's oxygen saturation level.

(i) With respect to inpatients, a post-anesthesia evaluation for proper anesthesia recovery shall be performed after transfer from the post-anesthesia care unit and within 48 hours after surgery by the person administering the anesthesia, registered nurse (RN), or physician in accordance with policies and procedures approved by the

medical staff and using criteria written in the medical staff bylaws for postoperative monitoring of anesthesia.

(ii) With respect to outpatients, immediately before [~~prior to~~] discharge, a post-anesthesia evaluation for proper anesthesia recovery shall be performed by the person administering the anesthesia, RN, or physician in accordance with policies and procedures approved by the medical staff and using criteria written in the medical staff bylaws for postoperative monitoring of anesthesia.

(b) Chemical dependency services.

(1) Chemical dependency unit. A hospital may not admit patients to a chemical dependency services unit unless the unit is approved by the Texas Health and Human Services Commission (HHSC) [~~Department of State Health Services (department)~~] as meeting the requirements of §133.163(q) of this title (relating to Spatial Requirements for New Construction).

(2) Admission criteria. A hospital providing chemical dependency services shall have written admission criteria that are applied uniformly to all patients who are admitted to the chemical dependency unit.

(A) The hospital's admission criteria shall include procedures to prevent the admission of minors for a condition which is not generally recognized as responsive to treatment in an inpatient setting for chemical dependency services.

(i) The following conditions are not generally recognized as responsive to treatment in a treatment facility for chemical dependency unless the minor to be admitted is qualified because of other disabilities, such as:

(I) cognitive disabilities due to intellectual disability;

(II) learning disabilities; or

(III) psychiatric disorders.

(ii) A minor may be qualified for admission based on other disabilities which would be responsive to chemical dependency services.

(iii) A minor patient shall be separated from adult patients.

(B) The hospital shall have a preadmission examination procedure under which each patient's condition and medical history are reviewed by a member of the medical staff to determine whether the patient is likely to benefit significantly from an intensive inpatient program or assessment.

(C) A voluntarily admitted patient shall sign an admission consent form before [~~prior to~~] admission to a chemical dependency unit which includes verification that the patient has been informed of the services to be provided and the estimated charges.

(3) Compliance. A hospital providing chemical dependency services in an identifiable unit within the hospital shall comply with Chapter 448, Subchapter B of this title (relating to Standard of Care Applicable to All Providers).

(c) Comprehensive medical rehabilitation services.

(1) Rehabilitation units. A hospital may not admit patients to a comprehensive medical rehabilitation services unit unless the unit is approved by HHSC [~~the department~~] as meeting the requirements of §133.163(z) of this title.

(2) Equipment and space. The hospital shall have the necessary equipment and sufficient space to implement the treatment plan described in paragraph (7)(C) of this subsection and allow for adequate care. Necessary equipment is all equipment necessary to comply with all parts of the written treatment plan. The equipment shall be on-site or available through an arrangement with another provider. Sufficient space is the physical area of a hospital which in the aggregate, constitutes the total amount of the space necessary to comply with the written treatment plan.

(3) Emergency requirements. Emergency personnel, equipment, supplies and medications for hospitals providing comprehensive medical rehabilitation services shall be as follows.

(A) A hospital that provides comprehensive medical rehabilitation services shall have emergency equipment, supplies, medications, and designated personnel assigned for providing emergency care to patients and visitors.

(B) The emergency equipment, supplies, and medications shall be properly maintained and immediately accessible to all areas of the hospital. The emergency equipment shall be periodically tested according to the policy adopted, implemented, and enforced by the hospital.

(C) At a minimum, the emergency equipment and supplies shall include those specified in subsection (e)(4) of this section.

(D) The personnel providing emergency care in accordance with this subsection shall be staffed for 24-hour coverage and accessible to all patients receiving comprehensive medical rehabilitation services. At least one person who is qualified by training to perform advanced cardiac life support and administer emergency drugs shall be on duty each shift.

(E) All direct patient care licensed personnel shall maintain current certification in cardiopulmonary resuscitation (CPR).

(4) Medications. A rehabilitation hospital's governing body shall adopt, implement, and enforce policies and procedures that require all medications to be administered by licensed nurses, physicians, or other licensed professionals authorized by law to administer medications.

(5) Organization and Staffing.

(A) A hospital providing comprehensive medical rehabilitation services shall be organized and staffed to ensure the health and safety of the patients.

(i) All provided services shall be consistent with accepted professional standards and practice.

(ii) The organization of the services shall be appropriate to the scope of the services offered.

(iii) The hospital shall adopt, implement, and enforce written patient care policies that govern the services it furnishes.

(B) The provision of comprehensive medical rehabilitation services in a hospital shall be under the medical supervision of a physician who is on duty and available, or who is on-call 24 hours each day.

(C) A hospital providing comprehensive medical rehabilitation services shall have a medical director or clinical director who supervises and administers the provision of comprehensive medical rehabilitation services.

(i) The medical director or clinical director shall be a physician who is board certified or eligible for board certification in physical medicine and rehabilitation, orthopedics, neurology, neurosurgery, internal medicine, or rheumatology as appropriate for the rehabilitation program.

(ii) The medical director or clinical director shall be qualified by training or at least two years training and experience to serve as medical director or clinical director. A person is qualified under this subsection if the person has training and experience in the treatment of rehabilitation patients in a rehabilitation setting.

(6) Admission criteria. A hospital providing comprehensive medical rehabilitation services shall have written admission criteria that are applied uniformly to all patients who are admitted to the comprehensive medical rehabilitation unit.

(A) The hospital's admission criteria shall include procedures to prevent the admission of a minor for a condition which is not generally recognized as responsive to treatment in an inpatient setting for comprehensive medical rehabilitation services.

(i) The following conditions are not generally recognized as responsive to treatment in an inpatient setting for comprehensive medical rehabilitation services unless the minor to be admitted is qualified because of other disabilities, such as:

(I) cognitive disabilities due to intellectual disability;

(II) learning disabilities; or

(III) psychiatric disorders.

(ii) A minor may be qualified for admission based on other disabilities which would be responsive to comprehensive medical rehabilitation services.

(B) The hospital shall have a preadmission examination procedure under which each patient's condition and medical history are reviewed by a member of the medical staff to determine whether the patient is likely to benefit significantly from an intensive inpatient program or assessment.

(7) Care and services.

(A) A hospital providing comprehensive medical rehabilitation services shall use a coordinated interdisciplinary team which is directed by a physician and which works in collaboration to develop and implement the patient's treatment plan.

(i) The interdisciplinary team for comprehensive medical rehabilitation services shall have available to it, at the hospital at which the services are provided or by contract, members of the following professions as necessary to meet the treatment needs of the patient:

(I) physical therapy;

(II) occupational therapy;

(III) speech-language pathology;

(IV) therapeutic recreation;

(V) social services and case management;

(VI) dietetics;

(VII) psychology;

(VIII) respiratory therapy;

(IX) rehabilitative nursing;

(X) certified orthotics;

(XI) certified prosthetics;

(XII) pharmaceutical care; and

(XIII) in the case of a minor patient, persons who have specialized education and training in emotional, mental health, or chemical dependency problems, as well as the treatment of minors.

(ii) The coordinated interdisciplinary team approach used in the rehabilitation of each patient shall be documented by periodic entries made in the patient's medical record to denote:

(I) the patient's status in relationship to goal attainment; and

(II) that team conferences are held at least every two weeks to determine the appropriateness of treatment.

(B) An initial assessment and preliminary treatment plan shall be performed or established by the physician within 24 hours of admission.

(C) The physician in coordination with the interdisciplinary team shall establish a written treatment plan for the patient within seven working days of the date of admission.

(i) Comprehensive medical rehabilitation services shall be provided in accordance with the written treatment plan.

(ii) The treatment provided under the written treatment plan shall be provided by staff who are qualified to provide services under state law. The hospital shall establish written qualifications for services provided by each discipline for which there is no applicable state statute for professional licensure or certification.

(iii) Services provided under the written treatment plan shall be given in accordance with the orders of physicians, dentists, podiatrists, or practitioners who are authorized by the governing body, hospital administration, and medical staff to order the services, and the orders shall be incorporated in the patient's record.

(iv) The written treatment plan shall delineate anticipated goals and specify the type, amount, frequency, and anticipated duration of service to be provided.

(v) Within 10 working days after the date of admission, the written treatment plan shall be provided. It shall be in the person's primary language, if practicable. What is or would have been practicable shall be determined by the facts and circumstances of each case. The written treatment plan shall be provided to:

(I) the patient;

(II) a person designated by the patient; and

(III) upon request, a family member, guardian, or individual who has demonstrated on a routine basis responsibility and participation in the patient's care or treatment, but only with the patient's consent unless such consent is not required by law.

(vi) The written treatment plan shall be reviewed by the interdisciplinary team at least every two weeks.

(vii) The written treatment plan shall be revised by the interdisciplinary team if a comprehensive reassessment of the patient's status or the results of a patient case review conference indicates the need for revision.

(viii) The revision shall be incorporated into the patient's record within seven working days after the revision.

(ix) The revised treatment plan shall be reduced to writing in the person's primary language, if practicable, and provided to:

(I) the patient;

(II) a person designated by the patient; and

(III) upon request, a family member, guardian, or individual who has demonstrated on a routine basis responsibility and participation in the patient's care or treatment, but only with the patient's consent unless such consent is not required by law.

(8) Discharge and continuing care plan. The patient's interdisciplinary team shall prepare a written continuing care plan that addresses the patient's needs for care after discharge.

(A) The continuing care plan for the patient shall include recommendations for treatment and care and information about the availability of resources for treatment or care.

(B) If the patient's interdisciplinary team deems it impracticable to provide a written continuing care plan before [~~prior to~~] discharge, the patient's interdisciplinary team shall provide the written continuing care plan to the patient within two working days after the date of discharge.

(C) Before [~~Prior to~~] discharge or within two working days after the date of discharge, the written continuing care plan shall be provided in the person's primary language, if practicable, to:

(i) the patient;

(ii) a person designated by the patient; and

(iii) upon request, to a family member, guardian, or individual who has demonstrated on a routine basis responsibility and participation in the patient's care or treatment, but only with the patient's consent unless such consent is not required by law.

(d) Dietary services. The hospital shall have organized dietary services that are directed and staffed by adequate qualified personnel. However, a hospital that has a contract with an outside food management company or an arrangement with another hospital may meet this requirement if the company or other hospital has a dietitian who serves the hospital on a full-time, part-time, or consultant basis, and if the company or other hospital maintains at least the minimum requirements specified in this section, and provides for the frequent and systematic liaison with the hospital medical staff for recommendations of dietetic policies affecting patient treatment. The hospital shall ensure that there are sufficient personnel to respond to the dietary needs of the patient population being served.

(1) Organization.

(A) The hospital shall have a full-time employee who is qualified by experience or training to serve as director of the food and dietetic service, and be responsible for the daily management of the dietary services.

(B) There shall be a qualified dietitian who works full-time, part-time, or on a consultant basis. If by consultation, such services shall occur at least once per month for not less than eight hours. The dietitian shall:

(i) be currently licensed under the laws of this state to use the titles of licensed dietitian or provisional licensed dietitian, or be a registered dietitian;

(ii) maintain standards for professional practice;

(iii) supervise the nutritional aspects of patient care;

(iv) make an assessment of the nutritional status and adequacy of nutritional regimen, as appropriate;

(v) provide diet counseling and teaching, as appropriate;

(vi) document nutritional status and pertinent information in patient medical records, as appropriate;

(vii) approve menus; and

(viii) approve menu substitutions.

(C) There shall be administrative and technical personnel competent in their respective duties. The administrative and technical personnel shall:

(i) participate in established departmental or hospital training pertinent to assigned duties;

(ii) conform to food handling techniques in accordance with paragraph (2)(E)(viii) of this subsection;

(iii) adhere to clearly defined work schedules and assignment sheets; and

(iv) comply with position descriptions which are job specific.

(2) Director. The director shall:

(A) comply with a position description which is job specific;

(B) clearly delineate responsibility and authority;

(C) participate in conferences with administration and department heads;

(D) establish, implement, and enforce policies and procedures for the overall operational components of the department to include[~~, but not be limited to~~]:

(i) quality assessment and performance improvement program;

(ii) frequency of meals served;

(iii) nonroutine occurrences; and

(iv) identification of patient trays; and

(E) maintain authority and responsibility for the following[~~, but not be limited to~~]:

(i) orientation and training;

(ii) performance evaluations;

(iii) work assignments;

(iv) supervision of work and food handling techniques;

(v) procurement of food, paper, chemical, and other supplies, to include implementation of first-in first-out rotation system for all food items;

(vi) ensuring there is a four-day food supply on hand at all times;

(vii) menu planning; and

(viii) ensuring compliance with Chapter 228 of this title (relating to Retail Food Establishments).

(3) Diets. Menus shall meet the needs of the patients.

(A) Therapeutic diets shall be prescribed by the physicians [~~physician(s)~~] responsible for the care of the patients. The dietary department of the hospital shall:

(i) establish procedures for the processing of therapeutic diets to include[~~, but not be limited to~~]:

(I) accurate patient identification;

(II) transcription from nursing to dietary services;

(III) diet planning by a dietitian;

(IV) regular review and updating of diet when necessary; and

(V) written and verbal instruction to patient and family. It shall be in the patient's primary language, if practicable, before [~~prior to~~] discharge. What is or would be [~~have been~~] practicable shall be determined by the facts and circumstances of each case;

(ii) ensure that therapeutic diets are planned in writing by a qualified dietitian;

(iii) ensure that menu substitutions are approved by a qualified dietitian;

(iv) document pertinent information about the patient's response to a therapeutic diet in the medical record; and

(v) evaluate therapeutic diets for nutritional adequacy.

(B) Nutritional needs shall be met in accordance with recognized dietary practices and in accordance with orders of the physicians [~~physician(s)~~] or appropriately credentialed practitioners [~~practitioner(s)~~] responsible for the care of the patients. The following requirements shall be met.

(i) Menus shall provide a sufficient variety of foods served in adequate amounts at each meal according to the guidance provided in the Recommended Dietary Allowances (RDA), as published by the Food and Nutrition Board, Commission on Life Sciences, National Research Council, Tenth edition, 1989[~~, which may be obtained by writing the National Academies Press, 500 Fifth Street, NW Lockbox 285, Washington, D.C. 20055, telephone (888) 624-8373~~].

(ii) A maximum of 15 hours shall not be exceeded between the last meal of the day (i.e., supper) and the breakfast meal, unless a substantial snack is provided. The hospital shall adopt, implement, and enforce a policy on the definition of "substantial" to meet each patient's varied nutritional needs.

(C) A current therapeutic diet manual approved by the dietitian and medical staff shall be readily available to all medical, nursing, and food service personnel. The therapeutic manual shall:

(i) be revised as needed, not to exceed 5 years;

(ii) be appropriate for the diets routinely ordered in the hospital;

(iii) have standards in compliance with the RDA;

(iv) contain specific diets which are not in compliance with RDA; and

(v) be used as a guide for ordering and serving diets.

(e) Emergency services. All licensed hospital locations, including multiple-location sites, shall have an emergency suite that complies with §133.161(a)(1)(A) of this chapter [~~title~~] (relating to Requirements for Buildings in Which Existing Licensed Hospitals Are [~~are~~] Located) or §133.163(f) of this title, and the following.

(1) Organization. The organization of the emergency services shall be appropriate to the scope of the services offered.

(A) The services shall be organized under the direction of a qualified member of the medical staff who is the medical director or clinical director.

(B) The services shall be integrated with other departments of the hospital.

(C) The policies and procedures governing medical care provided in the emergency suite shall be established by and shall be a continuing responsibility of the medical staff.

(D) Medical records indicating patient identification, complaint, physician, nurse, time admitted to the emergency suite, treatment, time discharged, and disposition shall be maintained for all emergency patients.

(E) Each freestanding emergency medical care facility shall advertise as an emergency room. The facility shall display notice that it functions as an emergency room.

(i) The notice shall explain that patients who receive medical services will be billed according to comparable rates for hospital emergency room services in the same region.

(ii) The notice shall be prominently and conspicuously posted for display in a public area of the facility that is readily available to each patient, managing conservator, or guardian. The postings shall be easily readable and consumer-friendly. The notice shall be in English and in a second language appropriate to the demographic makeup of the community served.

(2) Personnel.

(A) There shall be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the hospital.

(B) Except for comprehensive medical rehabilitation hospitals and pediatric and adolescent hospitals that generally provide care that is not administered for or in expectation of compensation:

(i) there shall be on duty and available at all times at least one person qualified as determined by the medical staff to initiate immediate appropriate lifesaving measures; and

(ii) in general hospitals where the emergency treatment area is not contiguous with other areas of the hospital that maintain 24-hour [~~24 hour~~] staffing by qualified staff (including [~~but not limited to~~] separation by one or more floors in multiple-occupancy buildings), qualified personnel must be physically present in the emergency treatment area at all times.

(C) Except for comprehensive medical rehabilitation hospitals and pediatric and adolescent hospitals that generally provide care that is not administered for or in expectation of compensation, the hospital shall provide that one or more physicians shall be available at all times for emergencies, as follows.

(i) General hospitals, except for hospitals designated as critical access hospitals (CAHs) by the Centers for Medicare & Medicaid Services (CMS), located in counties with a population of 100,000 or more shall have a physician qualified to provide emergency medical care on duty in the emergency treatment area at all times.

(ii) Special hospitals, hospitals designated as CAHs by the CMS, and general hospitals located in counties with a population of less than 100,000 shall have a physician on-call and able to respond in person, or by radio or telephone within 30 minutes.

(D) Schedules, names, and telephone numbers of all physicians and others on emergency call duty, including alternates, shall be maintained. Schedules shall be retained for no less than one year.

(3) Supplies and equipment. Adequate age-appropriate [~~age appropriate~~] supplies and equipment shall be available and in

readiness for use. Equipment and supplies shall be available for the administration of intravenous medications as well as facilities for the control of bleeding and emergency splinting of fractures. Provision shall be made for the storage of blood and blood products as needed. The emergency equipment shall be periodically tested according to the policy adopted, implemented, and enforced by the hospital.

(4) Required emergency equipment. At a minimum, the age-appropriate [~~age appropriate~~] emergency equipment and supplies shall include the following:

(A) emergency call system;

(B) oxygen;

(C) mechanical ventilatory assistance equipment, including airways, manual breathing bag, and mask;

(D) cardiac defibrillator;

(E) cardiac monitoring equipment;

(F) laryngoscopes and endotracheal tubes;

(G) suction equipment;

(H) emergency drugs and supplies specified by the medical staff;

(I) stabilization devices for cervical injuries;

(J) blood pressure monitoring equipment; and

(K) pulse oximeter or similar medical device to measure blood oxygenation.

(5) Participation in local emergency medical service (EMS) system.

(A) General hospitals shall participate in the local EMS system, based on the hospital's capabilities and capacity, and the locale's existing EMS plan and protocols.

(B) The provisions of subparagraph (A) of this paragraph do not apply to a comprehensive medical rehabilitation hospital or a pediatric and adolescent hospital that generally provides care that is not administered for or in expectation of compensation.

(6) Emergency services for sexual assault survivors. This section does not affect the duty of a health care facility to comply with the requirements of the federal Emergency Medical Treatment and Active Labor Act of 1986 (42 U.S.C. §1395dd) that are applicable to the facility. The hospital shall develop, implement, and enforce policies and procedures to ensure that after a sexual assault survivor presents to the hospital following a sexual assault, the hospital shall provide the care specified under Texas [~~the~~] Health and Safety Code (HSC)[~~,~~] Chapter 323.

(f) Governing body.

(1) Legal responsibility. There shall be a governing body responsible for the organization, management, control, and operation of the hospital, including appointment of the medical staff. For hospitals owned and operated by an individual or by partners, the individual or partners shall be considered the governing body.

(2) Organization. The governing body shall be formally organized in accordance with a written constitution and bylaws which clearly set forth the organizational structure and responsibilities.

(3) Meeting records. Records of governing body meetings shall be maintained.

(4) Responsibilities relating to the medical staff.

(A) The governing body shall ensure that the medical staff has current bylaws, rules, and regulations which are implemented and enforced.

(B) The governing body shall approve medical staff bylaws and other medical staff rules and regulations.

(C) In hospitals that provide obstetrical services, the governing body shall ensure that the hospital collaborates with physicians providing services at the hospital to develop quality initiatives, through the adoption, implementation, and enforcement of appropriate hospital policies and procedures, to reduce the number of elective or nonmedically indicated induced deliveries or cesarean sections performed at the hospital on a woman before the 39th week of gestation.

(D) In hospitals that provide obstetrical services, the governing body shall ensure that the hospital implements a newborn audiological screening program, consistent with the requirements of HSC [~~Health and Safety Code,~~] Chapter 47 [~~(Hearing Loss in Newborns)~~], and performs, either directly or through a referral to another program, audiological screenings for the identification of hearing loss on each newborn or infant born at the facility before the newborn or infant is discharged. These audiological screenings are required to be performed on all newborns or infants before discharge from the facility unless:

(i) a parent or legal guardian of the newborn or infant declines the screening;

(ii) the newborn or infant requires emergency transfer to a tertiary care facility before [~~prior to~~] the completion of the screening;

(iii) the screening previously has been completed; or

(iv) the newborn was discharged from the facility not more than 10 hours after birth and a referral for the newborn was made to another program.

(E) In hospitals that provide obstetrical services, the governing body shall adopt, implement, and enforce policies and procedures related to the testing of any newborn for critical congenital heart disease (CCHD) that may present themselves at birth. The facility shall implement testing programs for all infants born at the facility for CCHD. In the event that a newborn is presented at the emergency room following delivery at a birthing center or a home birth that may or may not have been assisted by a midwife, the facility shall ascertain if any testing for CCHD had occurred and, if not, shall provide the testing necessary to make such determination. The rules concerning the CCHD procedures and requirements are described in Chapter 37, [~~Maternal and Infant Health Services,~~] Subchapter E[~~, Newborn Screening for Critical Congenital Heart Disease, §§37.75 - 37.79~~] of this title (relating to Newborn Screening for Critical Congenital Heart Disease).

(F) The governing body shall determine, in accordance with state law and with the advice of the medical staff, which categories of practitioners are eligible candidates for appointment to the medical staff.

(i) In considering applications for medical staff membership and privileges or the renewal, modification, or revocation of medical staff membership and privileges, the governing body must ensure that each physician, podiatrist, and dentist is afforded procedural due process.

(I) If a hospital's credentials committee has failed to take action on a completed application as required by subclause (VIII) of this clause, or a physician, podiatrist, or dentist is subject to a professional review action that may adversely affect his medical

staff membership or privileges, and the physician, podiatrist, or dentist believes that mediation of the dispute is desirable, the physician, podiatrist, or dentist may require the hospital to participate in mediation as provided in Texas Civil Practice and Remedies Code (CPRC)[,] Chapter 154. The mediation shall be conducted by a person meeting the qualifications required by CPRC §154.052 and within a reasonable period of time.

(II) Subclause (I) of this clause does not authorize a cause of action by a physician, podiatrist, or dentist against the hospital other than an action to require a hospital to participate in mediation.

(III) An applicant for medical staff membership or privileges may not be denied membership or privileges on any ground that is otherwise prohibited by law.

(IV) A hospital's bylaw requirements for staff privileges may require a physician, podiatrist, or dentist to document the person's current clinical competency and professional training and experience in the medical procedures for which privileges are requested.

(V) In granting or refusing medical staff membership or privileges, a hospital may not differentiate on the basis of the academic medical degree held by a physician.

(VI) Graduate medical education may be used as a standard or qualification for medical staff membership or privileges for a physician, if [~~provided~~] that equal recognition is given to training programs accredited by the Accreditation Council for Graduate Medical Education and by the American Osteopathic Association.

(VII) Board certification may be used as a standard or qualification for medical staff membership or privileges for a physician, provided that equal recognition is given to certification programs approved by the American Board of Medical Specialties and the Bureau of Osteopathic Specialists.

(VIII) A hospital's credentials committee shall act expeditiously and without unnecessary delay when a licensed physician, podiatrist, or dentist submits a completed application for medical staff membership or privileges. The hospital's credentials committee shall take action on the completed application not later than the 90th day after the date on which the application is received. The governing body of the hospital shall take final action on the application for medical staff membership or privileges not later than the 60th day after the date on which the recommendation of the credentials committee is received. The hospital must notify the applicant in writing of the hospital's final action, including a reason for denial or restriction of privileges, not later than the 20th day after the date on which final action is taken.

(ii) The governing body is authorized to adopt, implement and enforce policies concerning the granting of clinical privileges to advanced practice registered nurses (APRNs) and physician assistants, including policies relating to the application process, reasonable qualifications for privileges, and the process for renewal, modification, or revocation of privileges.

(I) If the governing body of a hospital has adopted, implemented and enforced a policy of granting clinical privileges to APRNs or physician assistants, an individual APRN or physician assistant who qualifies for privileges under that policy shall be entitled to certain procedural rights to provide fairness of process, as determined by the governing body of the hospital, when an application for privileges is submitted to the hospital. At a minimum, any policy adopted shall specify a reasonable period for the processing and consideration of the application and shall provide for written notification to the applicant of any final action on the application by the hospital, including any reason for denial or restriction of the privileges requested.

(II) If an APRN or physician assistant has been granted clinical privileges by a hospital, the hospital may not modify or revoke those privileges without providing certain procedural rights to provide fairness of process, as determined by the governing body of the hospital, to the APRN or physician assistant. At a minimum, the hospital shall provide the APRN or physician assistant written reasons for the modification or revocation of privileges and a mechanism for appeal to the appropriate committee or body within the hospital, as determined by the governing body of the hospital.

(III) If a hospital extends clinical privileges to an APRN or physician assistant conditioned on the APRN or physician assistant having a sponsoring or collaborating relationship with a physician and that relationship ceases to exist, the APRN or physician assistant and the physician shall provide written notification to the hospital that the relationship no longer exists. Once the hospital receives such notice from an APRN or physician assistant and the physician, the hospital shall be deemed to have met its obligations under this section by notifying the APRN or physician assistant in writing that the APRN's or physician assistant's clinical privileges no longer exist at that hospital.

(IV) Nothing in this clause shall be construed as modifying Texas [~~Subtitle B, Title 3,~~] Occupations Code[,] Chapter 204 or 301, or any other law relating to the scope of practice of physicians, APRNs, or physician assistants.

(V) This clause does not apply to an employer-employee relationship between an APRN or physician assistant and a hospital.

(G) The governing body shall ensure that the hospital complies with the requirements concerning physician communication and contracts as set out in HSC [~~Health and Safety Code,~~] §241.1015 [~~(Physician Communication and Contracts)~~].

(H) The governing body shall ensure the hospital complies with the requirements for reporting to the Texas Medical Board the results and circumstances of any professional review action in accordance with Texas [~~the Medical Practice Act,~~] Occupations Code[,] §160.002 and §160.003.

(I) The governing body shall be responsible for and ensure that any policies and procedures adopted by the governing body to implement the requirements of this chapter shall be implemented and enforced.

(5) Hospital administration. The governing body shall appoint a chief executive officer or administrator who is responsible for managing the hospital.

(6) Patient care. In accordance with hospital policy adopted, implemented, and enforced, the governing body shall ensure that:

(A) every patient is under the care of:

(i) a physician; this[~~. This~~] provision is not to be construed to limit the authority of a physician to delegate tasks to other qualified health care personnel to the extent recognized under state law or the state's regulatory mechanism;

(ii) a dentist who is legally authorized to practice dentistry by the state and who is acting within the scope of his or her license; or

(iii) a podiatrist, but only with respect to functions which he or she is legally authorized by the state to perform.

(B) patients are admitted to the hospital only by members of the medical staff who have been granted admitting privileges;

(C) a physician is on duty or on-call at all times;

(D) specific colored condition alert wrist bands that have been standardized for all hospitals licensed under HSC [~~Health and Safety Code,~~] Chapter 241, are used as follows:

(i) red wrist bands for allergies;

(ii) yellow wrist bands for fall risks; and

(iii) purple wrist bands for do not resuscitate status;

(E) the governing body shall consider the addition of the following optional condition alert wrist bands and document[~~. This consideration must be documented~~] in the minutes of the meeting of the governing body in which the discussion was held:

(i) green wrist bands for latex allergy; and

(ii) pink wrist bands for restricted extremity; [~~and~~]

(F) the governing body shall adopt, implement, and enforce a policy and procedure regarding the removal of personal wrist bands and bracelets as well as a patient's right to refuse to wear condition alert wrist bands; and

(G) the governing body shall adopt, implement, and enforce policies and procedures regarding do-not-resuscitate (DNR) [~~DNR~~] orders issued in the hospital by the attending physician that comply with HSC [~~Health and Safety Code,~~] Chapter 166, Subchapter E [~~(relating to Health Care Facility Do-Not-Resuscitate Orders)~~], including policies and procedures regarding the rights of a patient and person authorized to make treatment decisions regarding the patient's DNR status; notice and medical record requirements for DNR orders and revocations; and actions the attending physician and hospital must take pursuant to HSC [~~Health and Safety Code~~] §166.206 when the [~~attending~~] physician or hospital and the patient or person authorized to make treatment decisions regarding the patient's DNR status are in disagreement about the execution of, or compliance with, a DNR order. The policies and procedures shall include the following [~~that~~]:

(i) Except in circumstances described by HSC [~~Health and Safety Code~~] §166.203(a)(2) and (3), a DNR order issued for a patient is valid only if a physician providing direct care to the patient [~~the patient's attending physician~~] issues the order, the order is dated, and the order is issued in compliance with:

(I) the written and dated directions of a patient who was competent at the time the patient wrote the directions;

(II) the oral directions of a competent patient delivered to or observed by two competent adult witnesses, at least one of whom must be a person not listed under HSC [~~Health and Safety Code~~] §166.003(2)(E) or (F);

(III) the directions in an advance directive enforceable under HSC [~~Health and Safety Code~~] §166.005 or executed in accordance with HSC [~~Health and Safety Code~~] §§166.032, 166.034, [~~or~~] 166.035, 166.082, 166.084, or 166.085;

(IV) the directions of a patient's:

(-a-) legal guardian;

(-b-) [~~or~~] agent under a medical power of attorney acting in accordance with HSC [~~Health and Safety Code,~~] Chapter 166, Subchapter D [~~(relating to Medical Power of Attorney)~~]; or

(-c-) proxy as designated and authorized by a directive executed in accordance with HSC Chapter 166, Subchapter B to make a treatment decision for the patient if the patient becomes incompetent or otherwise mentally or physically incapable of communication; or

(V) a treatment decision made in accordance with HSC [~~Health Safety Code~~] §166.039.

(ii) A DNR order that is not issued in accordance with HSC [~~Health and Safety Code~~] §166.203(a)(1) is valid only if:

(I) the patient's attending physician issues the order, the order is dated,[~~;~~] and[~~:~~]

(-a-) [~~(I)~~] the order is not contrary to the directions of a patient who was competent at the time the patient conveyed the directions;

(-b-) [~~(II)~~] in the reasonable medical judgment of the patient's attending physician, the patient's death is imminent, within minutes to hours, regardless of the provision of cardiopulmonary resuscitation; and

(-c-) [~~(III)~~] in the reasonable medical judgment of the patient's attending physician, the DNR order is medically appropriate; or[~~.~~]

(II) the patient's attending physician issues the order for a patient who is incompetent or otherwise mentally or physically incapable of communication and the order is in compliance with a decision:

(-a-) agreed upon by the attending physician and the person responsible for the patient's health care decisions; and

(-b-) concurred in by another physician who is not involved in the direct treatment of the patient or who is a representative of an ethics or medical committee of the health care facility in which the person is a patient.

(iii) A DNR order takes effect at the time the order is issued, as provided by HSC [~~Health and Safety Code~~] §166.203(b), provided the order is placed in the patient's medical record as soon as practicable, and may be issued and entered in a format acceptable under the policies of the hospital.

(iv) Unless notice is provided in accordance with HSC §166.204(a), before [~~Before~~] placing in a patient's medical record a DNR order described by HSC [~~Health and Safety Code~~] §166.203(a)(2), a [~~the~~] physician, physician assistant, nurse, or other person acting on behalf of the hospital shall:

(I) notify the patient of the order's issuance; or

(II) if the patient is incompetent, make a reasonably diligent effort to contact or cause to be contacted and notify of the order's issuance:

(-a-) the patient's known agent under a medical power of attorney or legal guardian; or[~~;~~]

(-b-) for a patient who does not have a known agent under a medical power of attorney or legal guardian, a person described by HSC [~~Health and Safety Code~~] §166.039(b)(1), (2), or (3).

(v) In accordance with HSC §166.205(a), a [~~A~~] physician providing direct care to a patient for whom a DNR order is issued shall revoke the patient's DNR order if [~~the patient, or the patient's agent under a medical power of attorney or the patient's legal guardian if the patient is incompetent~~]:

(I) an advance directive that serves as the basis of the DNR order is properly revoked in accordance with HSC Chapter 166; [~~effectively revokes an advance directive, in accordance with~~

~~Health and Safety Code §166.042, for which a DNR order is issued under Health and Safety Code §166.203(a); or~~]

(II) the patient expresses to any person providing direct care to the patient a revocation of consent to or intent to revoke a DNR order issued under HSC [~~Health and Safety Code~~] §166.203(a); or[~~.~~]

(III) the DNR order was issued under HSC §166.203(a)(1)(D) or (E) or §166.203(a)(3) and the person responsible for the patient's health care decisions expresses to any person providing direct care to the patient a revocation of consent to or intent to revoke the DNR order.

(vi) A person providing direct care to a patient under the supervision of a physician shall notify the physician of a request to revoke a DNR order or the revocation of an advance directive under HSC [~~Health and Safety Code~~] §166.205(a).

(vii) A patient's attending physician may at any time revoke a DNR order executed under: [~~Health and Safety Code §166.203(a)(2).~~]

(I) HSC §166.203(a)(1)(A), (B), or (C), provided that:

(-a-) the order is for a patient who is incompetent or otherwise mentally or physically incapable of communication; and

(-b-) the decision to revoke the order is:

(-1-) agreed on by the attending physician and the person responsible for the patient's health care decisions; and

(-2-) concurred in by another physician who is not involved in the direct treatment of the patient or who is a representative of an ethics or medical committee of the health care facility in which the person is a patient;

(II) HSC §166.203(a)(1)(E), provided that the order's issuance was based on a treatment decision made in accordance with HSC §166.039(e);

(III) HSC §166.203(a)(2); or

(IV) HSC §166.203(a)(3).

(viii) A patient's attending physician shall revoke a DNR order issued for the patient under HSC §166.203(a)(2) if, in the attending physician's reasonable medical judgment, the condition described by HSC §166.203(a)(2)(B)(i) is no longer satisfied.

(ix) For a patient who was incompetent at the time notice otherwise would have been provided to the patient under HSC §166.203(c)(1) and if a physician providing direct care to the patient later determines that, based on the physician's reasonable medical judgment, the patient has become competent, a physician, physician assistant, or nurse providing direct care to the patient shall disclose the order to the patient, provided that the physician, physician assistant, or nurse has actual knowledge:

(I) of the order; and

(II) that a physician providing direct care to the patient has determined that the patient has become competent.

(x) [~~(viii)~~] On admission to the hospital, the hospital shall provide to the patient or person authorized to make treatment decisions regarding the patient's DNR status notice of the policies and procedures adopted under this subparagraph.

(7) Services. The governing body shall be responsible for all services furnished in the hospital, whether furnished directly or under contract. The governing body shall ensure that services are provided in a safe and effective manner that permits the hospital to comply with applicable rules and standards. At hospitals that have a mental health service unit, the governing body shall adopt, implement, and enforce procedures for the completion of criminal background checks on all prospective employees that would be considered for assignment to that unit, except for persons currently licensed by this state as health professionals.

(8) Nurse Staffing. The governing body shall adopt, implement, and enforce a written nurse staffing policy to ensure that an adequate number and skill mix of nurses are available to meet the level of patient care needed. The governing body policy shall require that hospital administration adopt, implement, and enforce a nurse staffing plan and policies that:

(A) require significant consideration be given to the nurse staffing plan recommended by the hospital's nurse staffing committee and the committee's evaluation of any existing plan;

(B) are based on the needs of each patient care unit and shift and on evidence relating to patient care needs;

(C) ensure that all nursing assignments consider client safety, and are commensurate with the nurse's educational preparation, experience, knowledge, and physical and emotional ability;

(D) require use of the official nurse services staffing plan as a component in setting the nurse staffing budget;

(E) encourage nurses to provide input to the nurse staffing committee relating to nurse staffing concerns;

(F) protect from retaliation nurses who provide input to the nurse staffing committee; and

(G) comply with subsection (o) of this section.

(9) Photo identification badge. The governing body shall adopt a policy requiring employees, physicians, contracted employees, and individuals in training who provide direct patient care at the hospital to wear a photo identification badge during all patient encounters, unless precluded by adopted isolation or sterilization protocols. The badge must be of sufficient size and worn in a manner to be visible and must clearly state:

(A) at minimum the individual's first or last name;

(B) the department of the hospital with which the individual is associated;

(C) the type of license held by the individual, if applicable under Texas [~~Title 3,~~] Occupations Code Title 3; and

(D) the provider's status as a student, intern, trainee, or resident, if applicable.

(g) Infection control. The hospital shall provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There shall be an active program for the prevention, control, and surveillance of infections and communicable diseases.

(1) Organization and policies. A person shall be designated as infection control professional. The hospital shall ensure that policies governing prevention, control and surveillance of infections and communicable diseases are developed, implemented and enforced.

(A) There shall be a system for identifying, reporting, investigating, and controlling health care associated infections and communicable diseases between patients and personnel.

(B) The infection control professional shall maintain a log of all reportable diseases and health care associated infections designated as epidemiologically significant according to the hospital's infection control policies.

(C) A written policy shall be adopted, implemented, and enforced for reporting all reportable diseases to the local health authority and the Texas [~~Infectious Disease Surveillance and Epidemiology Branch,~~] Department of State Health Services (DSHS)[~~, Mail Code 2822, P.O. Box 149347, Austin, Texas 78714-9347,~~] in accordance with Chapter 97 of this title (relating to Communicable Diseases)[~~,~~] and HSC §98.103 and §98.1045 [~~Health and Safety Code, §§98.103, 98.104, and 98.1045 (relating to Reportable Infections, Alternative for Reportable Surgical Site Infections, and Reporting of Preventable Adverse Events)~~].

(D) The infection control program shall include active participation by the pharmacist.

(2) Responsibilities of the chief executive officer (CEO), medical staff, and chief nursing officer (CNO). The CEO, the medical staff, and the CNO shall be responsible for the following.

(A) The hospital-wide quality assessment and performance improvement program and training programs shall address problems identified by the infection control professional.

(B) Successful corrective action plans in affected problem areas shall be implemented.

(3) Universal precautions. The hospital shall adopt, implement, and enforce a written policy to monitor compliance of the hospital and its personnel and medical staff with universal precautions in accordance with HSC Chapter 85[~~, Acquired Immune Deficiency Syndrome and Human Immunodeficiency Virus Infection~~].

(h) Laboratory services. The hospital shall maintain directly[~~,~~] or have available adequate laboratory services to meet the needs of its patients.

(1) Hospital laboratory services. A hospital that provides laboratory services shall comply with the Clinical Laboratory Improvement Amendments of 1988 (CLIA 1988), in accordance with the requirements specified in 42 Code of Federal Regulations (CFR)[~~,~~] §§493.1 - 493.1780. CLIA 1988 applies to all hospitals with laboratories that examine human specimens for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

(2) Contracted laboratory services. The hospital shall ensure that all laboratory services provided to its patients through a contractual agreement are performed in a facility certified in the appropriate specialties and subspecialties of service in accordance with the requirements specified in 42 CFR Part 493 to comply with CLIA 1988.

(3) Adequacy of laboratory services. The hospital shall ensure the following.

(A) Emergency laboratory services shall be available 24 hours a day.

(B) A written description of services provided shall be available to the medical staff.

(C) The laboratory shall make provision for proper receipt and reporting of tissue specimens.

(D) The medical staff and a pathologist shall determine which tissue specimens require a macroscopic (gross) examination and which require both macroscopic and microscopic examination.

(E) When blood and blood components are stored, there shall be written procedures readily available containing directions on how to maintain them within permissible temperatures and including instructions to be followed in the event of a power failure or other disruption of refrigeration. A label or tray with the recipient's first and last names and identification number, donor unit number and interpretation of compatibility, if performed, shall be attached securely to the blood container.

(F) The hospital shall establish a mechanism for ensuring that the patient's physician or other licensed health care professional is made aware of critical value lab results, as established by the medical staff, before or after the patient is discharged.

(4) Chemical hygiene. A hospital that provides laboratory services shall adopt, implement, and enforce written policies and procedures to manage, minimize, or eliminate the risks to laboratory personnel of exposure to potentially hazardous chemicals in the laboratory which may occur during the normal course of job performance.

(i) Linen and laundry services. The hospital shall provide sufficient clean linen to ensure the comfort of the patient.

(1) For purposes of this subsection, contaminated linen is linen which has been soiled with blood or other potentially infectious materials or may contain sharps. Other potentially infectious materials means:

(A) [~~the following~~] human body fluids such as[~~:~~] semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids;

(B) any unfixed tissue or organ (other than intact skin) from a human (living or dead); and

(C) Human Immunodeficiency Virus (HIV)-containing cell or tissue cultures, organ cultures, and HIV or Hepatitis B Virus (HBV)-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

(2) The hospital, whether it operates its own laundry or uses commercial service, shall ensure the following.

(A) Employees of a hospital involved in transporting, processing, or otherwise handling clean or soiled linen shall be given initial and follow-up in-service training to ensure a safe product for patients and to safeguard employees in their work.

(B) Clean linen shall be handled, transported, and stored by methods that will ensure its cleanliness.

(C) All contaminated linen shall be placed and transported in bags or containers labeled or color-coded.

(D) Employees who have contact with contaminated linen shall wear gloves and other appropriate personal protective equipment.

(E) Contaminated linen shall be handled as little as possible and with a minimum of agitation. Contaminated linen shall not be sorted or rinsed in patient care areas.

(F) All contaminated linen shall be bagged or put into carts at the location where it was used.

(i) Bags containing contaminated linen shall be closed before [~~prior to~~] transport to the laundry.

(ii) Whenever contaminated linen is wet and presents a reasonable likelihood of soak-through of or leakage from the bag or container, the linen shall be deposited and transported in bags that prevent leakage of fluids to the exterior.

(iii) All linen placed in chutes shall be bagged.

(iv) If chutes are not used to convey linen to a central receiving or sorting room, then adequate space shall be allocated on the various nursing units for holding the bagged contaminated linen.

(G) Linen shall be processed as follows.[:]

(i) If hot water is used, linen shall be washed with detergent in water with a temperature of at least 71 degrees Centigrade (160 degrees Fahrenheit) for 25 minutes. Hot water requirements specified in Table 5 of §133.169(e) of this chapter [~~title~~] (relating to Tables) shall be met.

(ii) If low-temperature (less than or equal to 70 degrees Centigrade) (158 degrees Fahrenheit) laundry cycles are used, chemicals suitable for low-temperature washing at proper use concentration shall be used.

(iii) Commercial dry cleaning of fabrics soiled with blood also renders these items free of the risk of pathogen transmission.

(H) Flammable liquids shall not be used to process laundry[~~,~~] but may be used for equipment maintenance.

(j) Medical record services. The hospital shall have a medical record service that has administrative responsibility for medical records. A medical record shall be maintained for every individual who presents to the hospital for evaluation or treatment.

(1) The organization of the medical record service shall be appropriate to the scope and complexity of the services performed. The hospital shall employ or contract with adequate personnel to ensure prompt completion, filing, and retrieval of records.

(2) The hospital shall have a system of coding and indexing medical records. The system shall allow for timely retrieval by diagnosis and procedure, [~~in order~~] to support medical care evaluation studies.

(3) The hospital shall adopt, implement, and enforce a policy to ensure that the hospital complies with HSC[~~,~~] Chapter 241, Subchapters [~~Subchapter~~] G and [~~(Disclosure of Health Care Information) and Subchapter~~] E, §241.103~~,~~ [~~(Preservation of Records)~~] and §241.1031 [~~(relating to Preservation of Record from Forensic Medical Examination)~~].

(4) The medical record shall contain information to justify admission and continued hospitalization, support the diagnosis, reflect significant changes in the patient's condition, and describe the patient's progress and response to medications and services. Medical records shall be accurately written, promptly completed, properly filed and retained, and accessible.

(5) If an attending physician issues a DNR order for a patient under HSC [~~Health and Safety Code,~~] Chapter 166, Subchapter E [~~(relating to Health Care Facility Do-Not-Resuscitate Orders)~~], that order shall be entered into the patient medical record as soon as practicable. In the event a physician revokes a DNR order under HSC [~~Health and Safety Code,~~] Chapter 166, Subchapter E, that revocation shall be entered into the patient medical record as soon as practicable. To the extent this paragraph conflicts with requirements elsewhere in this subsection, this paragraph prevails.

(6) Medical record entries must be legible, complete, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided, consistent with hospital policies and procedures.

(7) All orders (except verbal orders) must be dated, timed, and authenticated the next time the prescriber or another practitioner who is responsible for the care of the patient and has been credentialed by the medical staff and granted privileges which are consistent with the written orders provides care to the patient, assesses the patient, or documents information in the patient's medical record.

(8) All verbal orders must be dated, timed, and authenticated within 96 hours by the prescriber or another practitioner who is responsible for the care of the patient and has been credentialed by the medical staff and granted privileges which are consistent with the written orders.

(A) Use of signature stamps by physicians and other licensed practitioners credentialed by the medical staff may be allowed in hospitals when the signature stamp is authorized by the individual whose signature the stamp represents. The administrative offices of the hospital shall have on file a signed statement to the effect that he or she is the only one who has the stamp and uses it. The use of a signature stamp by any other person is prohibited.

(B) A list of computer codes and written signatures shall be readily available and shall be maintained under adequate safeguards.

(C) Signatures by facsimile shall be acceptable. If received on a thermal machine, the facsimile document shall be copied onto regular paper.

(9) Medical records (reports and printouts) shall be retained by the hospital in their original or legally reproduced form for a period of at least ten years. A legally reproduced form is a medical record retained in hard copy, microform (microfilm or microfiche), or other electronic medium. Films, scans, and other image records shall be retained for a period of at least five years. For retention purposes, medical records that shall be preserved for ten years include:

(A) identification data;

(B) the medical history of the patient;

(C) evidence of a physical examination, including a health history, performed no more than 30 days before [~~prior to~~] admission or within 24 hours after admission, which[~~. The medical history and physical examination~~] shall be placed in the patient's medical record within 24 hours after admission;

(D) an updated medical record entry documenting an examination, completed and documented in the patient's medical record within 24 hours after admission, for any changes in the patient's condition when the medical history and physical examination are completed within 30 days before admission[~~. This updated examination shall be completed and documented in the patient's medical record within 24 hours after admission~~];

(E) admitting diagnosis;

(F) diagnostic and therapeutic orders;

(G) properly executed informed consent forms for procedures and treatments specified by the medical staff, or by federal or state laws if applicable, to require written patient consent;

(H) clinical observations, including the results of therapy and treatment, all orders, nursing notes, medication records, vital signs, and other information necessary to monitor the patient's condition;

(I) reports of procedures, tests, and their results, including laboratory, pathology, and radiology reports;

(J) results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient;

(K) discharge summary with outcome of hospitalization, disposition of care, and provisions for follow-up care; and

(L) final diagnosis with completion of medical records within 30 calendar days following discharge.

(10) A hospital may not destroy a medical record from the forensic medical examination of a sexual assault victim until the 20th anniversary of the date the record was created, in accordance with HSC[~~,~~] Chapter 241, Subchapter E, §241.1031.

(11) If a patient was less than 18 years of age at the time the patient [~~he~~] was last treated, the hospital may authorize the disposal of those medical records relating to the patient on or after the date of the patient's [~~his~~] 20th birthday or on or after the 10th anniversary of the date on which the patient [~~he~~] was last treated, whichever date is later.

(12) The hospital shall not destroy medical records that relate to any matter that is involved in litigation if the hospital knows the litigation has not been finally resolved.

(13) The hospital shall provide written notice to a patient, or a patient's legally authorized representative, that the hospital may authorize the disposal of medical records relating to the patient on or after the periods specified in this section. The notice shall be provided to the patient or the patient's legally authorized representative not later than the date on which the patient who is or will be the subject of a medical record is treated, except in an emergency treatment situation. In an emergency treatment situation, the notice shall be provided to the patient or the patient's legally authorized representative as soon as is reasonably practicable following the emergency treatment situation.

(14) If a licensed hospital should close, the hospital shall notify HHSC [~~the department~~] at the time of closure the disposition of the medical records, including the location of where the medical records will be stored and the identity and telephone number of the custodian of the records.

(k) Medical staff.

(1) The medical staff shall be composed of physicians and may also be composed of podiatrists, dentists and other practitioners appointed by the governing body.

(A) The medical staff shall periodically conduct appraisals of its members according to medical staff bylaws.

(B) The medical staff shall examine credentials of candidates for medical staff membership and make recommendations to the governing body on the appointment of the candidate.

(2) The medical staff shall be well-organized and accountable to the governing body for the quality of the medical care provided to patients.

(A) The medical staff shall be organized in a manner approved by the governing body.

(B) If the medical staff has an executive committee, a majority of the members of the committee shall be doctors of medicine or osteopathy.

(C) Records of medical staff meetings shall be maintained.

(D) The responsibility for organization and conduct of the medical staff shall be assigned only to an individual physician.

(E) Each medical staff member shall sign a statement signifying they will abide by medical staff and hospital policies.

(3) The medical staff shall adopt, implement, and enforce bylaws, rules, and regulations to carry out its responsibilities. The bylaws shall:

(A) be approved by the governing body;

(B) include a statement of the duties and privileges of each category of medical staff (for example [~~e.g.~~], active, courtesy, consultant);

(C) describe the organization of the medical staff;

(D) describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body;

(E) include criteria for determining the privileges to be granted and a procedure for applying the criteria to individuals requesting privileges;

(F) include a requirement that a physical examination and medical history be done no more than 30 days before or 24 hours after an admission for each patient by a physician or other qualified practitioner who has been granted these privileges by the medical staff:[~~.~~]

(i) the [~~The~~] medical history and physical examination shall be placed in the patient's medical record within 24 hours after admission;[~~.~~]

(ii) when [~~When~~] the medical history and physical examination are completed within the 30 days before admission, an updated examination for any changes in the patient's condition must be completed and documented in the patient's medical record within 24 hours after admission; and

(G) include procedures regarding DNR orders issued in the hospital by an attending physician that comply with HSC [~~Health and Safety Code,~~] Chapter 166, Subchapter E [~~(relating to Health Care Facility Do-Not-Resuscitate Orders)~~], including policies and procedures regarding the rights of a patient and person authorized to make treatment decisions regarding the patient's DNR status; notice and medical record requirements for DNR orders and revocations; and actions the attending physician and hospital must take pursuant to HSC [~~Health and Safety Code~~] §166.206 when the [~~attending~~] physician or hospital and the patient or person authorized to make treatment decisions regarding the patient's DNR status are in disagreement about the execution of, or compliance with, a DNR order. [~~The procedures shall include that:~~]

(i) Except in circumstances described by HSC [~~Health and Safety Code~~] §166.203(a)(2) and (3), the procedures shall include that a DNR order issued for a patient is valid only if a physician providing direct care to the patient [~~the patient's attending physician~~] issues the order, the order is dated, and the order is issued in compliance with:

(I) the written and dated directions of a patient who was competent at the time the patient wrote the directions;

(II) the oral directions of a competent patient delivered to or observed by two competent adult witnesses, at least one of whom must be a person not listed under HSC [~~Health and Safety Code~~] §166.003(2)(E) or (F);

(III) the directions in an advance directive enforceable under HSC [~~Health and Safety Code~~] §166.005 or executed

in accordance with HSC [~~Health and Safety Code~~] §§166.032, 166.034, [~~or~~] 166.035, 166.082, 166.084, or 166.085;

(IV) the directions of a patient's:

(-a-) legal guardian;

(-b-) [~~or~~] agent under a medical power of attorney acting in accordance with HSC [~~Health and Safety Code,~~] Chapter 166, Subchapter D [~~(relating to Medical Power of Attorney)~~]; or

(-c-) proxy as designated and authorized by a directive executed in accordance with HSC Chapter 166, Subchapter B to make a treatment decision for the patient if the patient becomes incompetent or otherwise mentally or physically incapable of communication; or

(V) a treatment decision made in accordance with HSC [~~Health Safety Code~~] §166.039.

(ii) The procedures shall include that a [~~A~~] DNR order that is not issued in accordance with HSC [~~Health and Safety Code~~] §166.203(a)(1) is valid only if:

(I) the patient's attending physician issues the order, the order is dated;[~~,~~] and[~~:~~]

(-a-) [~~(I)~~] the order is not contrary to the directions of a patient who was competent at the time the patient conveyed the directions;

(-b-) [~~(II)~~] in the reasonable medical judgment of the patient's attending physician, the patient's death is imminent, within minutes to hours, regardless of the provision of cardiopulmonary resuscitation; and

(-c-) [~~(III)~~] in the reasonable medical judgment of the patient's attending physician, the DNR order is medically appropriate; or[~~.~~]

(II) the patient's attending physician issues the order for a patient who is incompetent or otherwise mentally or physically incapable of communication, and the order is in compliance with a decision:

(-a-) agreed upon by the attending physician and the person responsible for the patient's health care decisions; and

(-b-) concurred in by another physician, who is not involved in the direct treatment of the patient or who is a representative of an ethics or medical committee of the health care facility in which the person is a patient.

(iii) The procedures shall include that a [~~A~~] DNR order takes effect at the time the order is issued, as provided by HSC [~~Health and Safety Code~~] §166.203(b), provided the order is placed in the patient's medical record as soon as practicable, and may be issued and entered in a format acceptable under the policies of the hospital.

(iv) The procedures shall include that unless notice is provided in accordance with HSC §166.204(a), before [~~Before~~] placing in a patient's medical record a DNR order described by HSC [~~Health and Safety Code~~] §166.203(a)(2), a [~~the~~] physician, physician assistant, nurse, or other person acting on behalf of the hospital shall:

(I) notify the patient of the order's issuance; or

(II) if the patient is incompetent, make a reasonably diligent effort to contact or cause to be contacted and inform of the order's issuance:

(-a-) the patient's known agent under a medical power of attorney or legal guardian; or[~~,~~]

(-b-) for a patient who does not have a known agent under a medical power of attorney or legal guardian, a person described by HSC [~~Health and Safety Code~~] §166.039(b)(1), (2), or (3).

(v) The procedures shall include that in accordance with HSC §166.205(a), a [~~A~~] physician providing direct care to a patient for whom a DNR order is issued shall revoke the patient's DNR order if [~~the patient or the patient's agent under a medical power of attorney or the patient's legal guardian if the patient is incompetent~~]:

(I) an advance directive that serves as the basis of the DNR order is properly revoked in accordance with HSC Chapter 166 [~~effectively revokes an advance directive, in accordance with Health and Safety Code §166.042, for which a DNR order is issued under Health and Safety Code §166.203(a)~~]; [~~or~~]

(II) the patient expresses to any person providing direct care to the patient a revocation of consent to or intent to revoke a DNR order issued under HSC [~~Health and Safety Code~~] §166.203(a); or[~~.~~]

(III) the DNR order was issued under HSC §166.203(a)(1)(D) or (E) or §166.203(a)(3), and the person responsible for the patient's health care decisions expresses to any person providing direct care to the patient a revocation of consent to or intent to revoke the DNR order.

(vi) The procedures shall include that a [~~A~~] person providing direct care to a patient under the supervision of a physician shall notify the physician of the request to revoke a DNR order or the revocation of an advance directive under HSC [~~Health and Safety Code~~] §166.205(a).

(vii) The procedures shall include that a [~~A~~] patient's attending physician may at any time revoke a DNR order executed under: [~~Health and Safety Code §166.203(a)(2).~~]

(I) HSC §166.203(a)(1)(A), (B), or (C), provided that:

(-a-) the order is for a patient who is incompetent or otherwise mentally or physically incapable of communication; and

(-b-) the decision to revoke the order is:

(-1-) agreed on by the attending physician and the person responsible for the patient's health care decisions; and

(-2-) concurred in by another physician who is not involved in the direct treatment of the patient or who is a representative of an ethics or medical committee of the health care facility in which the person is a patient;

(II) HSC §166.203(a)(1)(E), provided that the order's issuance was based on a treatment decision made in accordance with HSC §166.039(e);

(III) HSC §166.203(a)(2); or

(IV) HSC §166.203(a)(3).

(viii) The procedures shall include that a patient's attending physician shall revoke a DNR order issued for the patient under HSC §166.203(a)(2) if, in the attending physician's reasonable medical judgment, the condition described by HSC §166.203(a)(2)(B)(i) is no longer satisfied.

(ix) The procedures shall include that for a patient who was incompetent at the time notice otherwise would have been provided to the patient under HSC §166.203(c)(1) and if a physician providing direct care to the patient later determines that, based on the physician's reasonable medical judgment, the patient has become competent, a physician, physician assistant, or nurse providing direct care to the patient shall disclose the order to the patient, provided that the physician, physician assistant, or nurse has actual knowledge:

(I) of the order; and

(II) that a physician providing direct care to the patient has determined that the patient has become competent.

(l) Mental health services.

(1) Mental health services unit. A hospital may not admit patients to a mental health services unit unless the unit is approved by HHSC [~~the department~~] as meeting the requirements of §133.163(q) of this title.

(2) Admission criteria. A hospital providing mental health services shall have written admission criteria that are applied uniformly to all patients who are admitted to the service.

(A) The hospital's admission criteria shall include procedures to prevent the admission of minors for a condition which is not generally recognized as responsive to treatment in an inpatient setting for mental health services.

(i) The following conditions are not generally recognized as responsive to treatment in a hospital unless the minor to be admitted is qualified because of other disabilities, such as:

(I) cognitive disabilities due to intellectual disability; or

(II) learning disabilities.

(ii) A minor may be qualified for admission based on other disabilities which would be responsive to mental health services.

(B) The medical record shall contain evidence that admission consent was given by the patient, the patient's legal guardian, or the managing conservator, if applicable.

(C) The hospital shall have a preadmission examination procedure under which each patient's condition and medical history are reviewed by a member of the medical staff to determine whether the patient is likely to benefit significantly from an intensive inpatient program or assessment.

(D) A voluntarily admitted patient shall sign an admission consent form before [~~prior to~~] admission to a mental health unit which includes verification that the patient has been informed of the services to be provided and the estimated charges.

(3) Compliance. A hospital providing mental health services shall comply with the following rules [~~administered by the department. The rules are~~]:

(A) 26 TAC Chapter 568 [~~Chapter 411, Subchapter J of this title~~] (relating to Standards of Care and Treatment in Psychiatric Hospitals);

(B) Chapter 404, Subchapter E of this title (relating to Rights of Persons Receiving Mental Health Services);

(C) Chapter 405, Subchapter E of this title (relating to Electroconvulsive Therapy (ECT));

(D) Chapter 414, Subchapter I of this title (relating to Consent to Treatment with Psychoactive Medication--Mental Health Services); and

(E) Chapter 415, Subchapter F of this title (relating to Interventions in Mental Health Programs).

(m) Mobile, transportable, and relocatable units. The hospital shall adopt, implement, and enforce procedures which address the potential emergency needs for those inpatients who are taken to mobile units on the hospital's premises for diagnostic procedures or treatment.

(n) Nuclear medicine services. If the hospital provides nuclear medicine services, these services shall meet the needs of the patients in accordance with acceptable standards of practice and be licensed in accordance with §289.256 of this title (relating to Medical and Veterinary Use of Radioactive Material).

(1) Policies and procedures. Policies and procedures shall be adopted, implemented, and enforced which will describe the services nuclear medicine provides in the hospital and how employee and patient safety will be maintained.

(2) Organization and staffing. The organization of the nuclear medicine services shall be appropriate to the scope and complexity of the services offered.

(A) There shall be a medical director or clinical director who is a physician qualified in nuclear medicine.

(B) The qualifications, training, functions, and responsibilities of nuclear medicine personnel shall be specified by the medical director or clinical director and approved by the medical staff.

(3) Delivery of services. Radioactive materials shall be prepared, labeled, used, transported, stored, and disposed of in accordance with acceptable standards of practice and in accordance with §289.256 of this title.

(A) In-house preparation of radiopharmaceuticals shall be by, or under, the direct supervision of an appropriately trained licensed pharmacist or physician.

(B) There shall be proper storage and disposal of radioactive materials.

(C) If clinical laboratory tests are performed by the nuclear medicine services staff, the nuclear medicine staff shall comply with CLIA 1988 in accordance with the requirements specified in 42 CFR Part 493.

(D) Nuclear medicine workers shall be provided personnel monitoring dosimeters to measure their radiation exposure. Exposure reports and documentation shall be available for review.

(4) Equipment and supplies. Equipment and supplies shall be appropriate for the types of nuclear medicine services offered and shall be maintained for safe and efficient performance. The equipment shall be inspected, tested, and calibrated at least annually by qualified personnel.

(5) Records. The hospital shall maintain signed and dated reports of nuclear medicine interpretations, consultations, and procedures.

(A) The physician approved by the medical staff to interpret diagnostic procedures shall sign and date the interpretations of these tests.

(B) The hospital shall maintain records of the receipt and disposition of radiopharmaceuticals until disposal is authorized by DSHS' [~~the department's Radiation Safety Licensing Branch~~] in accordance with §289.256 of this title.

(C) Nuclear medicine services shall be ordered only by an individual whose scope of state licensure and whose defined staff privileges allow such referrals.

(o) Nursing services. The hospital shall have an organized nursing service that provides 24-hour nursing services as needed.

(1) Organization. The hospital shall have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care.

(A) Nursing services shall be under the administrative authority of a chief nursing officer (CNO) who shall be an RN and comply with one of the following:

(i) possess a master's degree in nursing;

(ii) possess a master's degree in health care administration or business administration;

(iii) possess a master's degree in a health-related field obtained through a curriculum that included courses in administration and management; or

(iv) be progressing under a written plan to obtain the nursing administration qualifications associated with a master's degree in nursing, which[. ~~The plan~~] shall:

(I) describe efforts to obtain the knowledge associated with graduate education and to increase administrative and management skills and experience;

(II) include courses related to leadership, administration, management, performance improvement and theoretical approaches to delivering nursing care; and

(III) provide a time-line for accomplishing skills.

(B) The CNO in hospitals with 100 or fewer licensed beds and located in counties with a population of less than 50,000, or in hospitals that have been certified by the Centers for Medicare and Medicaid Services as critical access hospitals in accordance with the [~~Code of Federal Regulations, Title~~] 42 CFR[, ~~Volume 3,~~] Part 485, Subpart F, §485.606(b), shall be exempted from the requirements in subparagraph (A)(i) - (iv) of this paragraph.

(C) The CNO shall be responsible for the operation of the services, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital.

(D) The CNO shall report directly to the individual who has authority to represent the hospital and who is responsible for the operation of the hospital according to the policies and procedures of the hospital's governing board.

(E) The CNO shall participate with leadership from the governing body, medical staff, and clinical areas, in planning, promoting and conducting performance improvement activities.

(2) Staffing and delivery of care.

(A) The nursing services shall adopt, implement and enforce a procedure to verify that hospital nursing personnel for whom licensure is required have valid and current licensure.

(B) There shall be adequate numbers of RNs, licensed vocational nurses (LVNs), and other personnel to provide nursing care to all patients as needed.

(C) There shall be supervisory and staff personnel for each department or nursing unit to provide, when needed, the immediate availability of an RN to provide care for any patient.

(D) An RN shall be on duty in each building of a licensed hospital that contains at least one nursing unit where patients are present. The RN shall supervise and evaluate the nursing care for each patient and assign the nursing care to other nursing personnel in accordance with the patient's needs and the specialized qualifications and competence of the nursing staff available.

(E) The nursing staff shall develop and keep current a nursing plan of care for each patient which addresses the patient's needs.

(F) The hospital shall establish a nurse staffing committee as a standing committee of the hospital. The committee shall be established in accordance with HSC [~~Health and Safety Code (HSC),~~] §§161.031 - 161.033, to be responsible for soliciting and receiving input from nurses on the development, ongoing monitoring, and evaluation of the staffing plan. As provided by HSC, §161.032, the hospital's records and review relating to evaluation of these outcomes and indicators are confidential and not subject to disclosure under Texas Government Code[,] Chapter 552 and not subject to disclosure, discovery, subpoena or other means of legal compulsion for their release. As used in this subsection, "committee" or "staffing committee" means a nurse staffing committee established under this subparagraph.

(i) The committee shall be composed of:

(I) at least 60 percent [~~60%~~] registered nurses who are involved in direct patient care at least 50 percent [~~50%~~] of their work time and selected by their peers who provide direct care during at least 50 percent [~~50%~~] of their work time;

(II) at least one representative from either infection control, quality assessment and performance improvement or risk management;

(III) members who are representative of the types of nursing services provided at the hospital; and

(IV) the chief nursing officer of the hospital who is a voting member.

(ii) Participation on the committee by a hospital employee as a committee member shall be part of the employee's work time and the hospital shall compensate that member for that time accordingly. The hospital shall relieve the committee member of other work duties during committee meetings.

(iii) The committee shall meet at least quarterly.

(iv) The responsibilities of the committee shall be to:

(I) develop and recommend to the hospital's governing body a nurse staffing plan that meets the requirements of subparagraph (G) of this paragraph;

(II) review, assess and respond to staffing concerns expressed to the committee;

(III) identify the nurse-sensitive outcome measures the committee will use to evaluate the effectiveness of the official nurse services staffing plan;

(IV) evaluate, at least semiannually, the effectiveness of the official nurse services staffing plan and variations between the plan and the actual staffing; and

(V) submit to the hospital's governing body, at least semiannually, a report on nurse staffing and patient care outcomes, including the committee's evaluation of the effectiveness of the official nurse services staffing plan and aggregate variations between the staffing plan and actual staffing.

(G) The hospital shall adopt, implement, and enforce a written official nurse services staffing plan. As used in this subsection, "patient care unit" means a unit or area of a hospital in which registered nurses provide patient care.

(i) The official nurse services staffing plan and policies shall:

(I) require significant consideration to be given to the nurse staffing plan recommended by the hospital's nurse staffing committee and the committee's evaluation of any existing plan;

(II) be based on the needs of each patient care unit and shift and on evidence relating to patient care needs;

(III) require use of the official nurse services staffing plan as a component in setting the nurse staffing budget;

(IV) encourage nurses to provide input to the nurse staffing committee relating to nurse staffing concerns;

(V) protect from retaliation nurses who provide input to the nurse staffing committee; and

(VI) comply with subsection (o) of this section.

(ii) The plan shall:

(I) set minimum staffing levels for patient care units that are:

(-a-) based on multiple nurse and patient considerations including:

(-1-) patient characteristics and number of patients for whom care is being provided, including number of admissions, discharges and transfers on a unit;

(-2-) intensity of patient care being provided and variability of patient care across a nursing unit;

(-3-) scope of services provided;

(-4-) context within which care is provided, including architecture and geography of the environment, and the availability of technology; and

(-5-) nursing staff characteristics, including staff consistency and tenure, preparation and experience, and the number and competencies of clinical and non-clinical support staff the nurse must collaborate with or supervise.

(-b-) determined by the nursing assessment and in accordance with evidence-based safe nursing standards; and

(-c-) recalculated at least annually, or as necessary;

(II) include a method for adjusting the staffing plan shift to shift for each patient care unit based on factors, such as, the intensity of patient care to provide staffing flexibility to meet patient needs;

(III) include a contingency plan when patient care needs unexpectedly exceed direct patient care staff resources;

(IV) include how on-call time will be used;

(V) reflect current standards established by private accreditation organizations, governmental entities, national nursing professional associations, and other health professional organizations and should be developed based upon a review of the codes of ethics developed by the nursing profession through national nursing organizations;

(VI) include a mechanism for evaluating the effectiveness of the official nurse services staffing plan based on patient needs, nursing sensitive quality indicators, nurse satisfaction measures collected by the hospital and evidence based nurse staffing standards. At least one from each of the following three types of outcomes shall be correlated to the adequacy of staffing:

(-a-) nurse-sensitive patient outcomes selected by the nurse staffing committee, such as, patient falls, adverse drug events, injuries to patients, skin breakdown, pneumonia, infection rates, upper gastrointestinal bleeding, shock, cardiac arrest, length of stay, or patient readmissions;

(-b-) operational outcomes, such as, work-related injury or illness, vacancy and turnover rates, nursing care hours per patient day, on-call use, or overtime rates; and

(-c-) substantiated patient complaints related to staffing levels;

(VII) incorporate a process that facilitates the timely and effective identification of concerns about the adequacy of the staffing plan by the nurse staffing committee established pursuant to subparagraph (F) of this paragraph. This process shall include:

(-a-) a prohibition on retaliation for reporting concerns;

(-b-) a requirement that nurses report concerns timely through appropriate channels within the hospital;

(-c-) orientation of nurses on how to report concerns and to whom;

(-d-) encouraging nurses to provide input to the committee relating to nurse staffing concerns;

(-e-) review, assessment, and response by the committee to staffing concerns expressed to the committee;

(-f-) a process for providing feedback during the committee meeting on how concerns are addressed by the committee established under subparagraph (F) of this paragraph; and

(-g-) use of the nurse safe harbor peer review process pursuant to Texas Occupations Code[,] §303.005;

(VIII) include policies and procedures that require:

(-a-) orientation of nurses and other personnel who provide nursing care to all patient care units to which they are assigned on either a temporary or permanent basis;

(-b-) that the orientation of nurses and other personnel and the competency to perform nursing services is documented in accordance with hospital policy;

(-c-) that nursing assignments be congruent with documented competency; and

(IX) be used by the hospital as a component in setting the nurse staffing budget and guiding the hospital in assigning nurses hospital wide.

(iii) The hospital shall make readily available to nurses on each patient care unit at the beginning of each shift the official nurse services staffing plan levels and current staffing levels for that unit and that shift.

(iv) There shall be a semiannual evaluation by the staffing committee of the effectiveness of the official nurse services staffing plan and variations between the staffing plan and actual staffing. The evaluation shall consider the outcomes and nursing-sensitive indicators as set out in clause (ii)(VI) of this subparagraph, patient needs, nurse satisfaction measures collected by the hospital, and evidence based nurse staffing standards. This evaluation shall be documented in the minutes of the committee established under subparagraph (F) of this paragraph and presented to the hospital's governing body. Hospitals may determine whether this evaluation is done on a unit or facility level basis. To assist the committee with the semiannual evaluation, the hospital shall report to the committee the variations between the staffing plan and actual staffing. This report of variations shall be confidential and not subject to disclosure under Texas Government Code[,] Chapter 552 and not subject to disclosure, discovery, subpoena, or other means of legal compulsion for their release.

(v) The staffing plan shall be retained for a period of two years.

(H) Nonemployee licensed nurses who are working in the hospital shall adhere to the policies and procedures of the hospital. The CNO shall provide for the adequate orientation, supervision, and evaluation of the clinical activities of nonemployee nursing personnel which occur within the responsibility of the nursing services.

(I) The hospital shall annually report to DSHS [~~the department~~] on:

(i) whether the hospital's governing body has adopted a nurse staffing policy;

(ii) whether the hospital has established a nurse staffing committee that meets the membership requirements of subparagraph (F) of this paragraph;

(iii) whether the nurse staffing committee has evaluated the hospital's official nurse services staffing plan and has reported the results of the evaluation to the hospital's governing body; and

(iv) the nurse-sensitive outcome measures the committee adopted for use in evaluating the hospital's official nurse services staffing plan.

(3) Mandatory overtime. The hospital shall adopt, implement, and enforce policies on use of mandatory overtime.

(A) As used in this subsection:

(i) "on-call time" means time spent by a nurse who is not working but who is compensated for availability; and

(ii) "mandatory overtime" means a requirement that a nurse work hours or days that are in addition to the hours or days scheduled, regardless of the length of a scheduled shift or the number of scheduled shifts each week. Mandatory overtime does not include prescheduled on-call time or time immediately before or after a scheduled shift necessary to document or communicate patient status to ensure patient safety.

(B) A hospital may not require a nurse to work mandatory overtime, and a nurse may refuse to work mandatory overtime.

(C) This section does not prohibit a nurse from volunteering to work overtime.

(D) A hospital may not use on-call time as a substitute for mandatory overtime.

(E) The prohibitions on mandatory overtime do not apply if:

(i) a health care disaster, such as a natural or other type of disaster that increases the need for health care personnel, unexpectedly affects the county in which the nurse is employed or affects a contiguous county;

(ii) a federal, state, or county declaration of emergency is in effect in the county in which the nurse is employed or is in effect in a contiguous county;

(iii) there is an emergency or unforeseen event of a kind that:

(I) does not regularly occur;

(II) increases the need for health care personnel at the hospital to provide safe patient care; and

(III) could not prudently be anticipated by the hospital; or

(iv) the nurse is actively engaged in an ongoing medical or surgical procedure and the continued presence of the nurse through the completion of the procedure is necessary to ensure the health and safety of the patient. The nurse staffing committee shall ensure that scheduling a nurse for a procedure that could be anticipated to require the nurse to stay beyond the end of his or her scheduled shift does not constitute mandatory overtime.

(F) If a hospital determines that an exception exists under subparagraph (E) of this paragraph, the hospital shall, to the extent possible, make and document a good faith effort to meet the staffing need through voluntary overtime, including calling per diems and agency nurses, assigning floats, or requesting an additional day of work from off-duty employees.

(G) A hospital may not suspend, terminate, or otherwise discipline or discriminate against a nurse who refuses to work mandatory overtime.

(4) Drugs and biologicals. Drugs and biologicals shall be prepared and administered in accordance with federal and state laws, the orders of the individuals granted privileges by the medical staff, and accepted standards of practice.

(A) All drugs and biologicals shall be administered by, or under supervision of, nursing or other personnel in accordance with federal and state laws and regulations, including applicable licensing rules, and in accordance with the approved medical staff policies and procedures.

(B) All orders for drugs and biologicals shall be in writing, dated, timed, and signed by the individual responsible for the care of the patient as specified under subsection (f)(6)(A) of this section. When telephone or verbal orders must be used, they shall be:

(i) accepted only by personnel who are authorized to do so by the medical staff policies and procedures, consistent with federal and state laws;

(ii) dated, timed, and authenticated within 96 hours by the prescriber or another practitioner who is responsible for the care of the patient and has been credentialed by the medical staff and granted privileges which are consistent with the written orders; and

(iii) used infrequently.

(C) There shall be a hospital procedure for immediately reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs to the attending physician and, if appropriate, to the hospital-wide quality assessment and performance improvement program.

(5) Blood transfusions.

(A) Transfusions shall be prescribed in accordance with hospital policy and administered in accordance with a written protocol for the administration of blood and blood components and the use of infusion devices and ancillary equipment.

(B) Personnel administering blood transfusions and intravenous medications shall have special training for this duty according to written, adopted, implemented, and enforced hospital policy.

(C) Blood and blood components shall be transfused through a sterile, pyrogen-free transfusion set that has a filter designed to retain particles potentially harmful to the recipient.

(D) The patient must be observed during the transfusion and for an appropriate time thereafter for suspected adverse reactions.

(E) Pretransfusion and posttransfusion vital signs shall be recorded.

(F) When warming of blood is indicated, this shall be accomplished during its passage through the transfusion set. The warming system shall be equipped with a visible thermometer and may have an audible warning system. Blood shall not be warmed above 42 degrees Celsius.

(G) Drugs or medications, including those intended for intravenous use, shall not be added to blood or blood components. A 0.9 percent [~~0.9%~~] sodium chloride injection, United States Pharmacopeia, may be added to blood or blood components. Other solutions intended for intravenous use may be used in an administration set or added to blood or blood components under either of the following conditions:

(i) they have been approved for this use by the Federal Drug Administration; or

(ii) there is documentation available to show that addition to the component involved is safe and efficacious.

(H) There shall be a system for detection, reporting and evaluation of suspected complications of transfusion. Any adverse event experienced by a patient in association with a transfusion is to be regarded as a suspected transfusion complication. In the event of a suspected transfusion complication, the personnel attending the patient shall notify immediately a responsible physician and the transfusion service and document the complication in the patient's medical record. All suspected transfusion complications shall be evaluated promptly according to an established procedure.

(I) Following the transfusion, the blood transfusion record or a copy shall be made a part of the patient's medical record.

(6) Reporting and peer review of a vocational or registered nurse. A hospital shall adopt, implement, and enforce a policy to ensure that the hospital complies with the Texas Occupations Code §§301.401 - 301.403, 301.405, and Chapter 303 [~~(relating to Grounds for Reporting Nurse, Duty of Nurse to Report, Duty of Peer Review Committee to Report, Duty of Person Employing Nurse to Report, and Nursing Peer Review respectively)~~], and with the rules adopted by the Texas Board of Nursing [~~Board of Nurse Examiners~~] in 22 TAC §217.16 (relating to Minor Incidents), §217.19 (relating to Incident-Based Nursing Peer Review and Whistleblower Protections), and §217.20 (relating to Safe Harbor Nursing Peer Review [~~for Nurses~~] and Whistleblower Protections).

(7) Policies and procedures related to workplace safety.

(A) The hospital shall adopt, implement, and enforce policies and procedures related to the work environment for nurses which:

(i) improve workplace safety and reduce the risk of injury, occupational illness, and violence; and

(ii) increase the use of ergonomic principles and ergonomically designed devices to reduce injury and fatigue.

(B) The policies and procedures adopted under subparagraph (A) of this paragraph, at a minimum, must include:

(i) evaluating new products and technology that incorporate ergonomic principles;

(ii) educating nurses in the application of ergonomic practices;

(iii) conducting workplace audits to identify areas of risk of injury, occupational illness, or violence and recommending ways to reduce those risks;

(iv) controlling access to those areas identified as having a high risk of violence; and

(v) promptly reporting crimes committed against nurses to appropriate law enforcement agencies.

(8) Safe patient handling and movement practices.

(A) The hospital shall adopt, implement, and enforce policies and procedures to identify, assess, and develop strategies to control risk of injury to patients and nurses associated with the lifting, transferring, repositioning, or movement of a patient.

(B) The policies and procedures shall establish a process that, at a minimum, includes the following:

(i) analysis of the risk of injury to both patients and nurses posed by the patient handling needs of the patient populations served by the hospital and the physical environment in which patient handling and movement occurs;

(ii) education of nurses in the identification, assessment, and control of risks of injury to patients and nurses during patient handling;

(iii) evaluation of alternative ways to reduce risks associated with patient handling, including evaluation of equipment and the environment;

(iv) restriction, to the extent feasible with existing equipment and aids, of manual patient handling or movement of all or most of a patient's weight to emergency, life-threatening, or otherwise exceptional circumstances;

(v) collaboration with and annual report to the nurse staffing committee;

(vi) procedures for nurses to refuse to perform or be involved in patient handling or movement that the nurse believes in good faith will expose a patient or a nurse to an unacceptable risk of injury;

(vii) submission of an annual report to the governing body on activities related to the identification, assessment, and development of strategies to control risk of injury to patients and nurses associated with the lifting, transferring, repositioning, or movement of a patient; and

(viii) development of architectural plans for constructing or remodeling a hospital or a unit of a hospital in which patient handling and movement occurs, with consideration of the feasibility of incorporating patient handling equipment or the physical space and construction design needed to incorporate that equipment at a later date.

(p) Outpatient services. If the hospital provides outpatient services, the services shall meet the needs of the patients in accordance with acceptable standards of practice.

(1) Organization. Outpatient services shall be appropriately organized and integrated with inpatient services.

(2) Personnel.

(A) The hospital shall assign an individual to be responsible for outpatient services.

(B) The hospital shall have appropriate physicians on staff and other professional and nonprofessional personnel available.

(q) Pharmacy services. The hospital shall provide pharmaceutical services that meet the needs of the patients.

(1) Compliance. The hospital shall provide a pharmacy which is licensed, as required, by the Texas State Board of Pharmacy. Pharmacy services shall comply with all applicable statutes and rules.

(2) Organization. The hospital shall have a pharmacy directed by a licensed pharmacist.

(3) Medical staff. The medical staff shall be responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical services.

(4) Pharmacy management and administration. The pharmacy or drug storage area shall be administered in accordance with accepted professional principles.

(A) Standards of practice as defined by state law shall be followed regarding the provision of pharmacy services.

(B) The pharmaceutical services shall have an adequate number of personnel to ensure quality pharmaceutical services including emergency services.

(i) The staff shall be sufficient in number and training to respond to the pharmaceutical needs of the patient population being served. There shall be an arrangement for emergency services.

(ii) Employees shall provide pharmaceutical services within the scope of their license and education.

(C) Drugs and biologicals shall be properly stored to ensure ventilation, light, security, and temperature controls.

(D) Records shall have sufficient detail to follow the flow of drugs from entry through dispensation.

(E) There shall be adequate controls over all drugs and medications including the floor stock. Drug storage areas shall be approved by the pharmacist, and floor stock lists shall be established.

(F) Inspections of drug storage areas shall be conducted throughout the hospital under pharmacist supervision.

(G) There shall be a drug recall procedure.

(H) A full-time, part-time, or consulting pharmacist shall be responsible for developing, supervising, and coordinating all the activities of the pharmacy services.

(i) Direction of pharmaceutical services may not require on-premises supervision but may be accomplished through regularly scheduled visits in accordance with state law.

(ii) A job description or other written agreement shall clearly define the responsibilities of the pharmacist.

(I) Current and accurate records shall be kept of the receipt and disposition of all scheduled drugs.

(i) There shall be a record system in place that provides the information on controlled substances in a readily retrievable manner which is separate from the patient record.

(ii) Records shall trace the movement of scheduled drugs throughout the services, documenting utilization or wastage.

(iii) The pharmacist shall be responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and reconciled with written orders.

(5) Delivery of services. To [~~In order to~~] provide patient safety, drugs and biologicals shall be controlled and distributed in accordance with applicable standards of practice, consistent with federal and state laws.

(A) All compounding, packaging, and dispensing of drugs and biologicals shall be under the supervision of a pharmacist and performed consistent with federal and state laws.

(B) All drugs and biologicals shall be kept in a secure area, and locked when appropriate.

(i) A policy shall be adopted, implemented, and enforced to ensure the safeguarding, transferring, and availability of keys to the locked storage area.

(ii) Drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 shall be kept locked within a secure area.

(C) Outdated, mislabeled, or otherwise unusable drugs and biologicals shall not be available for patient use.

(D) When a pharmacist is not available, drugs and biologicals shall be removed from the pharmacy or storage area only by personnel designated in the policies of the medical staff and pharmaceutical service, in accordance with federal and state laws.

(i) There shall be a current list of individuals identified by name and qualifications who are designated to remove drugs from the pharmacy.

(ii) Only amounts sufficient for immediate therapeutic needs shall be removed.

(E) Drugs and biologicals not specifically prescribed as to time or number of doses shall automatically be stopped after a reasonable time that is predetermined by the medical staff.

(i) Stop order policies and procedures shall be consistent with those of the nursing staff and the medical staff rules and regulations.

(ii) A protocol shall be established by the medical staff for the implementation of the stop order policy, in order that drugs shall be reviewed and renewed, or automatically stopped.

(iii) A system shall be in place to determine compliance with the stop order policy.

(F) Drug administration errors, adverse drug reactions, and incompatibilities shall be immediately reported to the attending physician and, if appropriate, to the hospital-wide quality assessment and performance improvement program. There shall be a mechanism in place for capturing, reviewing, and tracking medication errors and adverse drug reactions.

(G) Abuses and losses of controlled substances shall be reported, in accordance with applicable federal and state laws, to the individual responsible for the pharmaceutical services, and to the chief executive officer, as appropriate.

(H) Information relating to drug interactions and information on drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration shall be immediately available to the professional staff.

(i) A pharmacist shall be readily accessible by telephone or other means to discuss drug therapy, interactions, side effects, dosage, assist in drug selection, and assist in the identification of drug induced problems.

(ii) There shall be staff development programs on drug therapy available to facility staff to cover such topics as new drugs added to the formulary, how to resolve drug therapy problems, and other general information as the need arises.

(I) A formulary system shall be established by the medical staff to ensure quality pharmaceuticals at reasonable costs.

(r) Quality assessment and performance improvement. The governing body shall ensure that there is an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement (QAPI) program to evaluate the provision of patient care.

(1) Program scope. The hospital-wide QAPI program shall reflect the complexity of the hospital's organization and services and have a written plan of implementation. The program must include an ongoing program that shows measurable improvements in the indicators for which there is evidence that they will improve health outcomes[,] and identify and reduce medical errors.

(A) All hospital departments and services, including services furnished under contract or arrangement shall be evaluated.

(B) Health care associated infections shall be evaluated.

(C) Medication therapy shall be evaluated.

(D) All medical and surgical services performed in the hospital shall be evaluated as they relate to appropriateness of diagnosis and treatment.

(E) The program must measure, analyze, and track quality indicators, including adverse patients' events, and other aspects of performance that assess processes of care, hospital services and operations.

(F) Data collected must be used to monitor the effectiveness and safety of service and quality of care, and to identify opportunities for changes that will lead to improvement.

(G) Priorities must be established for performance improvement activities that focus on high-risk, high-volume, or problem-prone areas, taking into consideration the incidence, prevalence, and severity of problems in those areas, and how health outcomes and quality of care may be affected.

(H) Performance improvement activities which affect patient safety, including analysis of medical errors and adverse patient events, must be established, and preventive actions implemented.

(I) Success of actions implemented as a result of performance improvement activities must be measured, and ongoing performance must be tracked to ensure improvements are sustained.

(2) Responsibility and accountability. The hospital's governing body, medical staff and administrative staff are responsible and accountable for ensuring that:

(A) an ongoing program for quality improvement is defined, implemented and maintained, and that program requirements are met;

(B) an ongoing program for patient safety, including reduction of medical errors, is defined, implemented and maintained;

(C) the hospital-wide QAPI efforts address priorities for improved quality of care and patient safety, and that all improvement actions are evaluated; and

(D) adequate resources are allocated for measuring, assessing, improving, and sustaining the hospital's resources, and for reducing risk to patients.

(3) Medically-related patient care services. The hospital shall have an ongoing plan, consistent with available community and hospital resources, to provide or make available social work, psychological, and educational services to meet the medically-related needs of its patients. The hospital also shall have an effective, ongoing discharge planning program that facilitates the provision of follow-up care.

(A) Discharge planning shall be completed before [prior to] discharge.

(B) Patients, along with necessary medical information, shall be transferred or referred to appropriate facilities, agencies, or outpatient services, as needed for follow-up or ancillary care.

(C) Screening and evaluation before patient discharge from hospital. In accordance with 42 CFR [Code of Federal Regulations (CFR),] Part 483, Subpart C [(relating to Requirements for Long Term Care Facilities)] and the HHSC rules [of the Department of Aging and Disability Services (DADS)] set forth in 26 [40] TAC Chapter 303 [17] (relating to Preadmission Screening and Resident Review (PASRR)), all patients who are being considered for discharge from the hospital to a nursing facility shall be screened, and if appropriate, evaluated, before [prior to] discharge by the hospital and admission to the nursing facility to determine whether the patient may have a mental illness, intellectual disability or developmental disability.

(i) If the screening indicates that the patient has a mental illness, intellectual disability or developmental disability, the hospital shall contact and arrange for the local mental health authority designated pursuant to HSC [Health and Safety Code,] §533.035, to conduct before [prior to] hospital discharge an evaluation of the patient in accordance with the applicable provisions of the PASRR rules.

(ii) The purpose of PASRR is:

(I) [(i)] to ensure that placement of the patient in a nursing facility is necessary;

(II) [(ii)] to identify alternate placement options when applicable; and

(III) [(iii)] to identify specialized services that may benefit the person with a diagnosis of mental illness, intellectual disability, or developmental disability.

(4) Implementation. The hospital must take actions aimed at performance improvement and, after implementing those actions, the hospital must measure its success, and track performance to ensure that improvements are sustained.

(s) Radiology services. The hospital shall maintain, or have available, diagnostic radiologic services according to needs of the patients. All radiology equipment, including X-ray equipment, mammography equipment and laser equipment, shall be licensed and registered as required under Chapter 289 of this title (relating to Radiation Control). If therapeutic services are also provided, the services, as well as the diagnostic services, shall meet professionally approved standards for safety and personnel qualifications as required in §289.227 of this title (relating to Use of Radiation Machines in the Healing Arts); §289.229 of this title (relating to Radiation Safety Requirements for Accelerators, Therapeutic Radiation Machines, Simulators, and Electronic Brachytherapy Devices); §289.230 of this title (relating to Certification of Mammography Systems and Mammography Machines Used for Interventional Breast Radiography); and §289.231 of this title (relating to General Provisions and Standards for Protection Against Machine-Produced Radiation) [§§289.227, 289.229, 289.230 and 289.231 of this title (relating to Registration Regulations)]. In a special hospital, portable X-ray equipment may be acceptable as a minimum requirement.

(1) Policies and procedures. Policies and procedures shall be adopted, implemented, and enforced which will describe the radiology services provided in the hospital and how employee and patient safety will be maintained.

(2) Safety for patients and personnel. The radiology services, particularly ionizing radiology procedures, shall minimize hazards to patients and personnel.

(A) Proper safety precautions shall be maintained against radiation hazards. This includes adequate radiation shielding, safety procedures and equipment maintenance and testing.

(B) Inspection of equipment shall be made by or under the supervision of a licensed medical physicist in accordance with §289.227(o) of this title [~~(relating to Use of Radiation Machines in the Healing Arts)~~]. Defective equipment shall be promptly repaired or replaced.

(C) Radiation workers shall be provided personnel monitoring dosimeters to measure the amount of radiation exposure they receive. Exposure reports and documentation shall be available for review.

(D) Radiology services shall be provided only on the order of individuals granted privileges by the medical staff.

(3) Personnel.

(A) A qualified full-time, part-time, or consulting radiologist shall supervise the ionizing radiology services and shall interpret only those radiology tests that are determined by the medical staff to require a radiologist's specialized knowledge. For purposes of this section a radiologist is a physician who is qualified by education and experience in radiology in accordance with medical staff bylaws.

(B) Only personnel designated as qualified by the medical staff shall use the radiology equipment and administer procedures.

(4) Records. Records of radiology services shall be maintained. The radiologist or other individuals who have been granted privileges to perform radiology services shall sign reports of his or her interpretations.

(t) Renal dialysis services.

(1) Hospitals may provide inpatient dialysis services without an additional license under HSC Chapter 251. Hospitals providing outpatient dialysis services shall be licensed under HSC Chapter 251.

(2) Hospitals may provide outpatient dialysis services when the governor or the president of the United States declares a disaster in this state or another state. The hospital may provide outpatient dialysis only during the term of the disaster declaration.

(3) Equipment.

(A) Maintenance and repair. All equipment used by a facility, including backup equipment, shall be operated within manufacturer's specifications, and maintained free of defects which could be a potential hazard to patients, staff, or visitors. Maintenance and repair of all equipment shall be performed by qualified staff or contract personnel.

(i) Staff shall be able to identify malfunctioning equipment and report such equipment to the appropriate staff for immediate repair.

(ii) Medical equipment that malfunctions must be clearly labeled and immediately removed from service until the malfunction is identified and corrected.

(iii) Written evidence of all maintenance and repairs shall be maintained.

(iv) After repairs or alterations are made to any equipment or system, the equipment or system shall be thoroughly tested for proper operation before returning to service. This testing must be documented.

(v) A facility shall comply with the federal Food, Drug, and Cosmetic Act, 21 United States Code (USC)[~~,~~] §360i(b), concerning reporting when a medical device as defined in 21 USC §321(h) has or may have caused or contributed to the injury or death of a patient of the facility.

(B) Preventive maintenance. A facility shall develop, implement, and enforce a written preventive maintenance program to ensure patient care related equipment used in a facility receives electrical safety inspections, if appropriate, and maintenance at least annually or more frequently as recommended by the manufacturer. The preventive maintenance may be provided by facility staff or by contract.

(C) Backup machine. At least one complete dialysis machine shall be available on site as backup for every ten dialysis machines in use. At least one of these backup machines must be completely operational during hours of treatment. Machines not in use during a patient shift may be counted as backup except at the time of an initial or an expansion survey.

(D) Pediatric patients. If pediatric patients are treated, a facility shall use equipment and supplies, to include blood pressure cuffs, dialyzers, and blood tubing, appropriate for this special population.

(E) Emergency equipment and supplies. A facility shall have emergency equipment and supplies immediately accessible in the treatment area.

(i) At a minimum, the emergency equipment and supplies shall include the following:

(I) oxygen;

(II) mechanical ventilatory assistance equipment, to include airways, manual breathing bag, and mask;

(III) suction equipment;

(IV) supplies specified by the medical director;

(V) electrocardiograph; and

(VI) automated external defibrillator or defibrillator.

(ii) If pediatric patients are treated, the facility shall have the appropriate type and size emergency equipment and supplies listed in clause (i) of this subparagraph for this special population.

(iii) A facility shall establish, implement, and enforce a policy for the periodic testing and maintenance of the emergency equipment. Staff shall properly maintain and test the emergency equipment and supplies and document the testing and maintenance.

(F) Transducer protector. A transducer protector shall be replaced when wetted during a dialysis treatment and shall be used for one treatment only.

(4) Water treatment and dialysate concentrates.

(A) Compliance required. A facility shall meet the requirements of this section. A facility may follow more stringent requirements than the minimum standards required by this section.

(i) The facility administrator and medical director shall each demonstrate responsibility for the water treatment and dialysate supply systems to protect hemodialysis patients from adverse effects arising from known chemical and microbial contaminates that may be found in improperly prepared dialysate, to ensure that the

dialysate is correctly formulated and meets the requirements of all applicable quality standards.

(ii) The facility administrator and medical director must assure that policies and procedures related to water treatment and dialysate are understandable and accessible to the operator [~~operator(s)~~] and that the training program includes quality testing, risks and hazards of improperly prepared concentrate and bacterial issues.

(iii) The facility administrator and medical director must be informed before [~~prior to~~] any alteration of, or any device being added to, the water system.

(B) Water treatment. These requirements apply to water intended for use in the delivery of hemodialysis, including the preparation of concentrates from powder at a dialysis facility and dialysate.

(i) The design for the water treatment system in a facility shall be based on considerations of the source water for the facility and designed by a water quality professional with education, training, or experience in dialysis system design.

(ii) When a public water system supply is not used by a facility, the source water shall be tested by the facility at monthly intervals in the same manner as a public water system as described in 30 TAC §290.104 (relating to Summary of Maximum Contaminant Levels, Maximum Residual Disinfectant Levels, Treatment Techniques, and Action Levels), and 30 TAC §290.109 (relating to Microbial Contaminants) as adopted by the Texas Commission on Environmental Quality (TCEQ).

(iii) The physical space in which the water treatment system is located must be adequate to allow for maintenance, testing, and repair of equipment. If mixing of dialysate is performed in the same area, the physical space must also be adequate to house and allow for the maintenance, testing, and repair of the mixing equipment and for performing the mixing procedure.

(iv) The water treatment system components shall be arranged and maintained so that bacterial and chemical contaminant levels in the product water do not exceed the standards for hemodialysis water quality described in §4.2.1 (concerning Water Bacteriology) and §4.2.2 (concerning Maximum Level of Chemical Contaminants) of the American National Standard, Water Treatment Equipment for Hemodialysis Applications, August 2001 Edition, published by the Association for the Advancement of Medical Instrumentation (AAMI). [~~All documents published by the AAMI as referenced in this section may be obtained by writing the following address: 1110 North Glebe Road, Suite 220, Arlington, Virginia 22201.~~]

(v) Written policies and procedures for the operation of the water treatment system must be developed and implemented. Parameters for the operation of each component of the water treatment system must be developed in writing and known to the operator. Each major water system component shall be labeled in a manner that identifies the device; describes its function, how performance is verified and actions to take in the event performance is not within an acceptable range.

(vi) The materials of any components of water treatment systems (including piping, storage, filters, and distribution systems) that contact the purified water shall not interact chemically or physically so as to affect the purity or quality of the product water adversely. Such components shall be fabricated from unreactive materials (e.g., plastics) or appropriate stainless steel. The use of materials that are known to cause toxicity in hemodialysis, such as copper, brass, galvanized material, or aluminum, is prohibited.

(vii) Chemicals infused into the water such as iodine, acid, flocculants, and complexing agents shall be shown to be nondialyzable or shall be adequately removed from product water. Monitors or specific test procedures to verify removal of additives shall be provided and documented.

(viii) Each water treatment system shall include reverse osmosis membranes or deionization tanks and a minimum of two carbon tanks in series. If the source water is from a private supply which does not use chlorine/chloramine, the water treatment system shall include reverse osmosis membranes or deionization tanks and a minimum of one carbon tank.

(I) Reverse osmosis membranes. Reverse osmosis membranes, if used, shall meet the standards in §4.3.7 (concerning Reverse Osmosis) of the American National Standard, Water Treatment Equipment for Hemodialysis Applications, August 2001 Edition, published by the AAMI.

(II) Deionization systems.

(-a-) Deionization systems, if used, shall be monitored continuously to produce water of one megohm-centimeter (cm) or greater specific resistivity (or conductivity of one microsiemen/cm or less) at 25 degrees Celsius. An audible and visual alarm shall be activated when the product water resistivity falls below this level and the product water stream shall be prevented from reaching any point of use.

(-b-) Patients shall not be dialyzed on deionized water with a resistivity less than 1.0 megohm-cm measured at the output of the deionizer.

(-c-) A minimum of two deionization (DI) tanks in series shall be used with resistivity monitors including audible and visual alarms placed pre and post the final DI tank in the system. The alarms must be audible in the patient care area.

(-d-) Feed water for deionization systems shall be pretreated with activated carbon adsorption, or a comparable alternative, to prevent nitrosamine formation.

(-e-) If a deionization system is the last process in a water treatment system, it shall be followed by an ultrafilter or other bacteria and endotoxin reducing device.

(III) Carbon tanks.

(-a-) The carbon tanks must contain acid washed carbon, 30-mesh or smaller with a minimum iodine number of 900.

(-b-) A minimum of two carbon adsorption beds shall be installed in a series configuration.

(-c-) The total empty bed contact time (EBCT) shall be at least ten minutes, with the final tank providing at least five minutes EBCT. Carbon adsorption systems used to prepare water for portable dialysis systems are exempt from the requirement for the second carbon and a ten-minute [~~ten minute~~] EBCT if removal of chloramines to below 0.1 milligram (mg)/1 is verified before each treatment.

(-d-) A means shall be provided to sample the product water immediately prior to the final bed(s). Water from this port(s) must be tested for chlorine/chloramine levels immediately prior to each patient shift.

(-e-) All samples for chlorine or chloramine [~~chlorine/chloramine~~] testing must be drawn when the water treatment system has been operating for at least 15 minutes.

(-f-) Tests for total chlorine, which include both free and combined forms of chlorine, may be used as a single analysis with the maximum allowable concentration of 0.1 mg/liter (L). Test results of greater than 0.5 parts per million (ppm) for chlorine or 0.1 ppm for chloramine from the port between the initial tank(s)

and final tank(s) shall require testing to be performed at the final exit and replacement of the initial tank(s).

(-g-) In a system without a holding tank, if test results at the exit of the final tank(s) are greater than the parameters for chlorine or chloramine described in this subclause, dialysis treatment shall be immediately terminated to protect patients from exposure to chlorine or chloramine [~~chlorine/chloramine~~] and the medical director shall be notified. In systems with holding tanks, if the holding tank tests <1 mg/L for total chlorine, the reverse osmosis (RO) may be turned off and the product water in the holding tank may be used to finish treatments in process. The medical director shall be notified.

(-h-) If means other than granulated carbon are used to remove chlorine/chloramine, the facility's governing body must approve such use in writing after review of the safety of the intended method for use in hemodialysis applications. If such methods include the use of additives, there must be evidence the product water does not contain unsafe levels of these additives.

(ix) Water softeners, if used, shall be tested at the end of the treatment day to verify their capacity to treat a sufficient volume of water to supply the facility for the entire treatment day and shall be fitted with a mechanism to prevent water containing the high concentrations of sodium chloride used during regeneration from entering the product water line during regeneration.

(x) If used, the face [~~face(s)~~] of a timer [~~timer(s)~~] used to control any component of the water treatment or dialysate delivery system shall be visible to the operator at all times. Written evidence that timers are checked for operation and accuracy each day of operation must be maintained.

(xi) Filter housings, if used during disinfectant procedures, shall include a means to clear the lower portion of the housing of the disinfecting agents. Filter housings shall be opaque.

(xii) Ultrafilters, or other bacterial reducing filters, if used, shall be fitted with pressure gauges on the inlet and outlet water lines to monitor the pressure drop across the membrane. Ultrafilters shall be included in routine disinfection procedures.

(xiii) If used, storage tanks shall have a conical or bowl-shaped [~~bowl shaped~~] base and shall drain from the lowest point of the base. Storage tanks shall have a tight-fitting lid and be vented through a hydrophobic 0.2 micron air filter. Means shall be provided to effectively disinfect any storage tank installed in a water distribution system.

(xiv) Ultraviolet (UV) lights, if used, shall be monitored at the frequency recommended by the manufacturer. A log sheet shall be used to record monitoring.

(xv) Water treatment system piping shall be labeled to indicate the contents of the pipe and direction of flow.

(xvi) The water treatment system must be continuously monitored during patient treatment and be guarded by audible and visual alarms which can be seen and heard in the dialysis treatment area should water quality drop below specific parameters. Quality monitor sensing cells shall be located as the last component of the water treatment system and at the beginning of the distribution system. No water treatment components that could affect the quality of the product water as measured by this device shall be located after the sensing cell.

(xvii) When deionization tanks do not follow a reverse osmosis system, parameters for the rejection rate of the membranes must assure that the lowest rate accepted would provide product water in compliance with §4.2.2 (concerning Maximum Level of Chemical Contaminants) of the American National Standard, Water Treatment Equipment for Hemodialysis Applications, August 2001 Edition published by the AAMI.

(xviii) A facility shall maintain written logs of the operation of the water treatment system for each treatment day. The log-book [~~log book~~] shall include each component's operating parameter and the action taken when a component is not within the facility's set parameters.

(xix) Microbiological testing of product water shall be conducted.

(I) Frequency. Microbiological testing shall be conducted monthly and following any repair or change to the water treatment system. For a newly installed water distribution system, or when a change has been made to an existing system, weekly testing shall be conducted for one month to verify that bacteria and endotoxin levels are consistently within the allowed limits.

(II) Sample sites. At a minimum, sample sites chosen for the testing shall include the beginning of the distribution piping, at any site of dialysate mixing, and the end of the distribution piping.

(III) Technique. Samples shall be collected [~~immediately~~] before sanitizing or disinfecting [~~sanitization/disinfection of~~] the water treatment system and dialysis machines. Water testing results shall be routinely trended and reviewed by the medical director [~~in order~~] to determine if results seem questionable or if there is an opportunity for improvement. The medical director shall determine if there is a need for retesting. Repeated results of "no growth" shall be validated via an outside laboratory. A calibrated loop may not be used in microbiological testing of water samples. Colonies shall be counted using a magnifying device.

(IV) Expected results. Product water used to prepare dialysate, concentrates from powder, or to reprocess dialyzers for multiple use, shall contain a total viable microbial count less than 200 colony forming units (CFU)/millimeter (ml) and an endotoxin concentration less than 2 endotoxin units (EU)/ml. The action level for the total viable microbial count in the product water shall be 50 CFU/ml and the action level for the endotoxin concentration shall be 1 EU/ml.

(V) Required action for unacceptable results. If the action levels described at subclause (IV) of this clause are observed in the product water, corrective measures shall be taken promptly to reduce the levels into an acceptable range.

(VI) Records. All bacteria and endotoxin results shall be recorded on a log sheet [~~in order~~] to identify trends that may indicate the need for corrective action.

(xx) If ozone generators are used to disinfect any portion of the water or dialysate delivery system, testing based on the manufacturer's direction shall be used to measure the ozone concentration each time disinfection is performed, to include testing for safe levels of residual ozone at the end of the disinfection cycle. Testing for ozone in the ambient air shall be conducted on a periodic basis as recommended by the manufacturer. Records of all testing must be maintained in a log.

(xxi) If used, hot water disinfection systems shall be monitored for temperature and time of exposure to hot water as specified by the manufacturer. Temperature of the water shall be recorded at a point furthest from the water heater, where the lowest water temperature is likely to occur. The water temperature shall be measured each time a disinfection cycle is performed. A record that verifies successful completion of the heat disinfection shall be maintained.

(xxii) After chemical disinfection, means shall be provided to restore the equipment and the system in which it is installed to a safe condition relative to residual disinfectant before [~~prior to~~] the product water being used for dialysis applications.

(xxiii) Samples of product water must be submitted for chemical analysis every six months and must demonstrate that the quality of the product water used to prepare dialysate or concentrates from powder, meets §4.2.2 (concerning Maximum Level of Chemical Contaminants) of the American National Standard, Water Treatment Equipment for Hemodialysis Applications, August 2001 Edition, published by the AAMI.

(I) Samples for chemical analysis shall be collected at the end of the water treatment components and at the most distal point in each water distribution loop, if applicable. All other outlets from the distribution loops shall be inspected to ensure that the outlets are fabricated from compatible materials. Appropriate containers and pH adjustments shall be used to ensure accurate determinations. New facilities or facilities that add or change the configuration of the water distribution system must draw samples at the most distal point for each water distribution loop, if applicable, on a one-time [~~one time~~] basis.

(II) Additional chemical analysis shall be submitted if substantial changes are made to the water treatment system or if the percent rejection of a reverse osmosis system decreased 5.0 percent [~~5.0%~~] or more from the percent rejection measured at the time the water sample for the preceding chemical analysis was taken.

(xxiv) Facility records must include all test results and evidence that the medical director has reviewed the results of the water quality testing and directed corrective action when indicated.

(xxv) Only persons qualified by the education or experience may operate, repair, or replace components of the water treatment system.

(C) Dialysate.

(i) Quality control procedures shall be established to ensure ongoing conformance to policies and procedures regarding dialysate quality.

(ii) Each facility shall set all hemodialysis machines to use only one family of concentrates. When new machines are put into service or the concentrate family or concentrate manufacturer is changed, samples shall be sent to a laboratory for verification.

(iii) Before [~~prior to~~] each patient treatment, staff shall verify the dialysate conductivity and pH of each machine with an independent device.

(iv) Bacteriological testing shall be conducted.

(I) Frequency. Responsible facility staff shall develop a schedule to ensure each hemodialysis machine is tested quarterly for bacterial growth and the presence of endotoxins. Hemodialysis machines of home patients shall be cultured monthly until results not exceeding 200 CFU/ml are obtained for three consecutive months, then quarterly samples shall be cultured.

(II) Acceptable limits. Dialysate shall contain less than 200 CFU/ml and an endotoxin concentration of less than 2 EU/ml. The action level for total viable microbial count shall be 50 CFU/ml and the action level for endotoxin concentration shall be 1 EU/ml.

(III) Action to be taken. Disinfection and retesting shall be done when bacterial or endotoxin counts exceed the action levels. Additional samples shall be collected when there is a clinical indication of a pyrogenic reaction and/or septicemia.

(v) Only a licensed nurse may use an additive to increase concentrations of specific electrolytes in the acid concentrate. Mixing procedures shall be followed as specified by the additive manufacturer. When additives are prescribed for a specific patient, the container holding the prescribed acid concentrate shall be labeled with the name of the patient, the final concentration of the added electrolyte, the date the prescribed concentrate was made, and the name of the person who mixed the additive.

(vi) All components used in concentrate preparation systems (including mixing and storage tanks, pumps, valves, and piping) shall be fabricated from materials (e.g., plastics or appropriate stainless steel) that do not interact chemically or physically with the concentrate so as to affect its purity, or with the germicides used to disinfect the equipment. The use of materials that are known to cause toxicity in hemodialysis such as copper, brass, galvanized material, and aluminum is prohibited.

(vii) Facility policies shall address means to protect stored acid concentrates from tampering or from degeneration due to exposure to extreme heat or cold.

(viii) Procedures to control the transfer of acid concentrates from the delivery container to the storage tank and prevent the inadvertent mixing of different concentrate formulations shall be developed, implemented, and enforced. The storage tanks shall be clearly labeled.

(ix) Concentrate mixing systems shall include a purified water source, a suitable drain, and a ground fault protected electrical outlet.

(I) Operators of mixing systems shall use personal protective equipment as specified by the manufacturer during all mixing processes.

(II) The manufacturer's instructions for use of a concentrate mixing system shall be followed, including instructions for mixing the powder with the correct amount of water. The number of bags or weight of powder added shall be determined and recorded.

(III) The mixing tank shall be clearly labeled to indicate the fill and final volumes required to correctly dilute the powder.

(IV) Systems for preparing either bicarbonate or acid concentrate from powder shall be monitored according to the manufacturer's instructions.

(V) Concentrates shall not be used, or transferred to holding tanks or distribution systems, until all tests are completed.

(VI) If a facility designs its own system for mixing concentrates, procedures shall be developed and validated using an independent laboratory to ensure proper mixing.

(x) Acid concentrate mixing tanks shall be designed to allow the inside of the tank to be rinsed when changing concentrate formulas.

(I) Acid mixing systems shall be designed and maintained to prevent rust and corrosion.

(II) Acid concentrate mixing tanks shall be emptied completely and rinsed with product water before mixing another batch of concentrate to prevent cross contamination between different batches.

(III) Acid concentrate mixing equipment shall be disinfected as specified by the equipment manufacturer or in the case where no specifications are given, as defined by facility policy.

(IV) Records of disinfection and rinsing of disinfectants to safe residual levels shall be maintained.

(xi) Bicarbonate concentrate mixing tanks shall have conical or bowl-shaped [~~bowl shaped~~] bottoms and shall drain from the lowest point of the base. The tank design shall allow all internal surfaces to be disinfected and rinsed.

(I) Bicarbonate concentrate mixing tanks shall not be prefilled the night before use.

(II) If disinfectant remains in the mixing tank overnight, this solution must be completely drained, the tank rinsed and tested for residual disinfectant before [~~prior to~~] preparing the first batch of that day of bicarbonate concentrate.

(III) Unused portions of bicarbonate concentrate shall not be mixed with fresh concentrate.

(IV) At a minimum, bicarbonate distribution systems shall be disinfected weekly. More frequent disinfection shall be done if required by the manufacturer, or if dialysate culture results are above the action level.

(V) If jugs are reused to deliver bicarbonate concentrate to individual hemodialysis machines:

(-a-) jugs shall be emptied of concentrate, rinsed and inverted to drain at the end of each treatment day;

(-b-) at a minimum, jugs shall be disinfected weekly, more frequent disinfection shall be considered by the medical director if dialysate culture results are above the action level; and

(-c-) following disinfection, jugs shall be drained, rinsed free of residual disinfectant, and inverted to dry and testing[~~. Testing~~] for residual disinfectant shall be done and documented.

(xii) All mixing tanks, bulk storage tanks, dispensing tanks and containers for single hemodialysis treatments shall be labeled as to the contents.

(I) Mixing tanks. Before [~~Prior to~~] batch preparation, a label shall be affixed to the mixing tank that includes the date of preparation and the chemical composition or formulation of the concentrate being prepared. This labeling shall remain on the mixing tank until the tank has been emptied.

(II) Bulk storage or dispensing tanks [~~Bulk storage/dispensing tanks~~]. These tanks shall be permanently labeled to identify the chemical composition or formulation of their contents.

(III) Single machine containers. At a minimum, single machine containers shall be labeled with sufficient information to differentiate the contents from other concentrate formulations used in the facility and permit positive identification by users of container contents.

(xiii) Permanent records of batches produced shall be maintained to include the concentrate formula produced, the volume of the batch, lot numbers [~~number(s)~~] of powdered concentrate packages, the manufacturer of the powdered concentrate, date and time of mixing, test results, person performing mixing, and expiration date (if applicable).

(xiv) If dialysate concentrates are prepared in the facility, the manufacturers' recommendations shall be followed regarding any preventive maintenance. Records shall be maintained indicating the date, time, person performing the procedure, and the results (if applicable).

(5) Prevention requirements concerning patients.

(A) Hepatitis B vaccination.

(i) With the advice and consent of a patient's attending nephrologist, facility staff shall make the hepatitis B vaccine available to a patient who is susceptible to hepatitis B, provided that the patient has coverage or is willing to pay for vaccination.

(ii) The facility shall make available to patients literature describing the risks and benefits of the hepatitis B vaccination.

(B) Serologic screening of patients.

(i) A patient new to dialysis shall have been screened for hepatitis B surface antigen (HBsAg) within one month before or at the time of admission to the facility or have a known hepatitis B surface antibody (anti-HBs) status of at least 10 milli-international units per milliliter no more than 12 months before [~~prior to~~] admission. The facility shall document how this screening requirement is met.

(ii) Repeated serologic screening shall be based on the antigen or antibody status of the patient.

(I) Monthly screening for HBsAg is required for patients whose previous test results are negative for HBsAg.

(II) Screening of HBsAg-positive or anti-HBs-positive patients may be performed on a less frequent basis, provided that the facility's policy on this subject remains congruent with Appendices i and ii of the National Surveillance of Dialysis Associated Disease in the United States, 2000, published by the United States Department of Health and Human Services.

(C) Isolation procedures for the HBsAg-positive patient.

(i) The facility shall treat patients positive for HBsAg in a segregated treatment area which includes a hand washing sink, a work area, patient care supplies and equipment, and sufficient space to prevent cross-contamination to other patients.

(ii) A patient who tests positive for HBsAg shall be dialyzed on equipment reserved and maintained for the HBsAg-positive patient's use only.

(iii) When a caregiver is assigned to both HBsAg-negative and HBsAg-positive patients, the HBsAg-negative patients assigned to this grouping must be Hepatitis B antibody positive. Hepatitis B antibody positive patients are to be seated at the treatment stations nearest the isolation station and be assigned to the same staff member who is caring for the HBsAg-positive patient.

(iv) If an HBsAg-positive patient is discharged, the equipment which had been reserved for that patient shall be given intermediate level disinfection before [~~prior to~~] use for a patient testing negative for HBsAg.

(v) In the case of patients new to dialysis, if these patients are admitted for treatment before results of HBsAg or anti-HBs testing are known, these patients shall undergo treatment as if the HBsAg test results were potentially positive, except that they shall not be treated in the HBsAg isolation room, area, or machine.

(I) The facility shall treat potentially HBsAg-positive patients in a location in the treatment area which is outside of traffic patterns until the HBsAg test results are known.

(II) The dialysis machine used by this patient shall be given intermediate level disinfection before [~~prior to~~] its use by another patient.

(III) The facility shall obtain HBsAg status results of the patient no later than three days from admission.

(u) Respiratory care services. The hospital shall meet the needs of the patients in accordance with acceptable standards of practice.

(1) Policies and procedures shall be adopted, implemented, and enforced which describe the provision of respiratory care services in the hospital.

(2) The organization of the respiratory care services shall be appropriate to the scope and complexity of the services offered.

(3) There shall be a medical director or clinical director of respiratory care services who is a physician with the knowledge, experience, and capabilities to supervise and administer the services properly. The medical director or clinical director may serve on either a full-time or part-time basis.

(4) There shall be adequate numbers of respiratory therapists, respiratory therapy technicians, and other personnel who meet the qualifications specified by the medical staff, consistent with the state law.

(5) Personnel qualified to perform specific procedures and the amount of supervision required for personnel to carry out specific procedures shall be designated in writing.

(6) If blood gases or other clinical laboratory tests are performed by the respiratory care services staff, the respiratory care staff shall comply with CLIA 1988 in accordance with the requirements specified in 42 CFR[;] Part 493.

(7) Services shall be provided only on, and in accordance with, the orders of a physician.

(v) Sterilization and sterile supplies.

(1) Supervision. The sterilization of all supplies and equipment shall be under the supervision of a person qualified by education, training, and experience. Staff responsible for the sterilization of supplies and equipment shall participate in a documented continuing education program; new employees shall receive initial orientation and on-the-job training.

(2) Equipment and procedures.

(A) Sterilization. Every hospital shall provide equipment adequate for sterilization of supplies and equipment as needed. Equipment shall be maintained and operated to perform, with accuracy, the sterilization of the various materials required.

(B) Written policy. Written policies and procedures for the decontamination and sterilization activities performed shall be adopted, implemented, and enforced. Policies shall include the receiving, cleaning, decontaminating, disinfecting, preparing and sterilization of reusable items, as well as those for the assembly, wrapping, storage, distribution and quality control of sterile items and equipment. These written policies shall be reviewed at least every other year and approved by the infection control practitioner or committee.

(C) Separation. Where cleaning, preparation, and sterilization functions are performed in the same room or unit, the physical facilities, equipment, and the policies and procedures for their use, shall be such as to effectively separate soiled or contaminated supplies and equipment from the clean or sterilized supplies and equipment. Hand washing facilities shall be provided and a separate sink shall be provided for safe disposal of liquid waste.

(D) Labeling. All containers for solutions, drugs, flammable solvents, ether, alcohol, and medicated supplies shall be clearly labeled to indicate contents. Those which are sterilized by the hospital shall be labeled so as to be identifiable both before and after sterilization. Sterilized items shall have a load control identification that indicates the sterilizer used, the cycle or load number, and the date of sterilization.

(E) Preparation for sterilization.

(i) All items to be sterilized shall be prepared to reduce the bioburden. All items shall be thoroughly cleaned, decontaminated, and prepared in a clean, controlled environment.

(ii) All articles to be sterilized shall be arranged so all surfaces will be directly exposed to the sterilizing agent for the prescribed time and temperature.

(F) Packaging. All wrapped articles to be sterilized shall be packaged in materials recommended for the specific type of sterilizer and material to be sterilized.

(G) External chemical indicators.

(i) External chemical indicators, also known as sterilization process indicators, shall be used on each package to be sterilized, including items being flash sterilized to indicate that items have been exposed to the sterilization process.

(ii) The indicator results shall be interpreted according to manufacturer's written instructions and indicator reaction specifications.

(iii) A log shall be maintained with the load identification, indicator results, and identification of the contents of the load.

(H) Biological indicators. Biological indicators are commercially-available microorganisms (e.g., United States Food and Drug Administration (FDA) approved strips or vials of Bacillus species endospores) which can be used to verify the performance of waste treatment equipment and processes (or sterilization equipment and processes).

(i) The efficacy of the sterilizing process shall be monitored with reliable biological indicators appropriate for the type of sterilizer used.

(ii) Biological indicators shall be included in at least one run each week of use for steam sterilizers, at least one run each day of use for low-temperature hydrogen peroxide gas sterilizers, and every load for ethylene oxide (EO) sterilizers.

(iii) Biological indicators shall be included in every load that contains implantable objects.

(iv) A log shall be maintained with the load identification, biological indicator results, and identification of the contents of the load.

(v) If a test is positive, the sterilizer shall immediately be taken out of service.

(I) Implantable items shall be recalled and reprocessed if a biological indicator test (spore test) is positive.

(II) All available items shall be recalled and reprocessed if a sterilizer malfunction is found and a list of those items not retrieved in the recall shall be submitted to infection control.

(III) A malfunctioning sterilizer shall not be put back into use until it has been serviced and successfully tested according to the manufacturer's recommendations.

(I) Sterilizers.

(i) Steam sterilizers (saturated steam under pressure) shall be utilized for sterilization of heat and moisture stable items. Steam sterilizers shall be used according to manufacturer's written instructions.

(ii) EO sterilizers shall be used for processing heat and moisture sensitive items. EO sterilizers and aerators shall be used and vented according to the manufacturer's written instructions.

(iii) Flash sterilizers shall be used for emergency sterilization of clean, unwrapped instruments and porous items only.

(J) Disinfection.

(i) Written policies, approved by the infection control committee, shall be adopted, implemented, and enforced for the use of chemical disinfectants.

(ii) The manufacturer's written instructions for the use of disinfectants shall be followed.

(iii) An expiration date, determined according to manufacturer's written recommendations, shall be marked on the container of disinfection solution currently in use.

(iv) Disinfectant solutions shall be kept covered and used in well-ventilated areas.

(v) Chemical germicides that are registered with the United States Environmental Protection Agency as "sterilants" may be used either for sterilization or high-level disinfection.

(vi) All staff personnel using chemical disinfectants shall have received training on their use.

(K) Performance records.

(i) Performance records for all sterilizers shall be maintained for each cycle. These records shall be retained and available for review for a minimum of five years.

(ii) Each sterilizer shall be monitored continuously during operation for pressure, temperature, and time at desired temperature and pressure. A record shall be maintained and shall include:

(I) the sterilizer identification;

(II) sterilization date;

(III) cycle number;

(IV) contents of each load;

(V) duration and temperature of exposure phase (if not provided on sterilizer recording charts);

(VI) identification of operators [~~operator(s)~~];

(VII) results of biological tests and dates performed;

(VIII) time-temperature recording charts from each sterilizer;

(IX) gas concentration and relative humidity (if applicable); and

(X) any other test results.

(L) Storage of sterilized items.

(i) Sterilized items shall be transported so as to maintain cleanliness and sterility and to prevent physical damage.

(ii) Sterilized items shall be stored in well-ventilated, limited access areas with controlled temperature and humidity.

(iii) The hospital shall adopt, implement, and enforce a policy which describes the mechanism used to determine the shelf life of sterilized packages.

(M) Preventive maintenance. Preventive maintenance of all sterilizers shall be performed according to individual adopted, implemented, and enforced policy on a scheduled basis by qualified personnel, using the sterilizer manufacturer's service manual as a reference. A preventive maintenance record shall be maintained for each sterilizer. These records shall be retained at least two years and shall be available for review.

(w) Surgical services. If a hospital provides surgical services, the services shall be well-organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered, the services shall be consistent in quality with inpatient care in accordance with the complexity of services offered. A special hospital may not offer surgical services.

(1) Organization and staffing. The organization of the surgical services shall be appropriate for the scope of the services offered.

(A) The operating rooms shall be supervised by an experienced RN or physician.

(B) Licensed vocational nurses (LVNs) and surgical technologists (operating room technicians) may serve as scrub nurses or technologists under the supervision of an RN.

(C) Circulating duties in the operating room must be performed by qualified RNs. In accordance with approved medical staff policies [~~polices~~] and procedures, LVNs and surgical technologists may assist in circulatory duties under the direct supervision of a qualified RN circulator.

(D) Surgical privileges shall be delineated for all physicians, podiatrists, and dentists performing surgery in accordance with the competencies of each. The surgical services shall maintain a roster specifying the surgical privileges of each.

(E) If the facility employs surgical technologists, the facility shall adopt, implement, and enforce policies and procedures to comply with HSC [~~Health and Safety Code,~~] Chapter 259 [(~~relating to Surgical Technologists at Health Care Facilities~~)].

(2) Delivery of service. Surgical services shall be consistent with needs and resources. Written policies governing surgical care which are designed to ensure the achievement and maintenance of high standards of medical practice and patient care shall be adopted, implemented, and enforced.

(A) There shall be a complete medical history and physical examination, as required under subsection (k)(3)(F) of this section, in the medical record of every patient before [~~prior to~~] surgery, except in emergencies. If this has been dictated, but not yet recorded in the patient's medical record, there shall be a statement to that effect and an admission note in the record by the individual who admitted the patient.

(B) A properly executed informed consent form for the operation shall be in the patient's medical record before surgery, except in emergencies.

(C) The following equipment shall be available in the operating room suites:

(i) communication system;

(ii) cardiac monitor;

(iii) resuscitator;

(iv) defibrillator;

(v) aspirator; and

(vi) tracheotomy set.

(D) There shall be adequate provisions for immediate postoperative care.

(E) The operating room register shall be complete and up-to-date and it[~~. The register~~] shall contain[~~, but not be limited to,~~] the following:

(i) patient's name and hospital identification number;

(ii) date of operation;

(iii) operation performed;

(iv) operating surgeon and assistants [~~assistant(s)~~];

(v) type of anesthesia used and name of person administering it;

(vi) time operation began and ended;

(vii) time anesthesia began and ended;

(viii) disposition of specimens;

(ix) names of scrub and circulating personnel;

(x) unusual occurrences; and

(xi) disposition of the patient.

(F) An operative report describing techniques, findings, and tissue removed or altered shall be written or dictated immediately following surgery and signed by the surgeon.

(x) Therapy services. If the hospital provides physical therapy, occupational therapy, audiology, or speech pathology services, the services shall be organized and staffed to ensure the health and safety of patients.

(1) Organization and staffing. The organization of the services shall be appropriate to the scope of the services offered.

(A) The director of the services shall have the necessary knowledge, experience, and capabilities to properly supervise and administer the services.

(B) Physical therapy, occupational therapy, speech therapy, or audiology services, if provided, shall be provided by staff who meet the qualifications specified by the medical staff, consistent with state law.

(2) Delivery of services. Services shall be furnished in accordance with a written plan of treatment. Services to be provided shall be consistent with applicable state laws and regulations, and in accordance with orders of the physician, podiatrist, dentist or other licensed practitioner who is authorized by the medical staff to order the services. Therapy orders shall be incorporated in the patient's medical record.

(y) Waste and waste disposal.

(1) Special waste and liquid/sewage waste management.

(A) The hospital shall comply with the requirements set forth by DSHS [~~the department~~] in Chapter 1, Subchapter K [~~§§1.131 - 1.137~~] of this title (relating to Definition, Treatment, and Disposition of Special Waste from Health Care-Related Facilities) and the TCEQ requirements in 30 TAC Chapter 326[~~, Medical Waste Management~~], Subchapter B [~~§326.17, §326.19, §326.21, and §326.23~~] (relating to Packaging, Labeling and Shipping Requirements) and §326.31 (relating to Exempt Medical Waste Operations).

(B) All sewage and liquid wastes shall be disposed of in a municipal sewerage system or a septic tank system permitted by the TCEQ in accordance with 30 TAC Chapter 285 (relating to On-Site Sewage Facilities).

(2) Waste receptacles.

(A) Waste receptacles shall be conveniently available in all toilet rooms, patient areas, staff work areas, and waiting rooms. Receptacles shall be routinely emptied of their contents at a central location [~~location(s)~~] into closed containers.

(B) Waste receptacles shall be properly cleaned with soap and hot water, followed by treatment of inside surfaces of the receptacles with a germicidal agent.

(C) All containers for other municipal solid waste shall be leak-resistant, have tight-fitting covers, and be rodent-proof.

(D) Nonreusable containers shall be of suitable strength to minimize animal scavenging or rupture during collection operations.

§133.49. Reporting Requirements.

(a) A hospital shall submit reports to the Texas Department of State Health Services (DSHS)[~~department~~] in accordance with the reporting requirements in Texas Health and Safety Code (HSC)[~~,~~] §98.103 and §98.1045 [~~(relating to Reportable Infections and Reporting of Preventable Adverse Events)~~].

(b) A hospital that donates human fetal tissue under HSC [~~Texas Health and Safety Code,~~] Chapter 173[~~,~~] shall submit an annual report to the Texas Health and Human Services Commission (HHSC) that includes for each donation the specific type of fetal tissue donated and the accredited public or private institution of higher learning that received the donation. The hospital shall submit the annual report no later than January 31st of the subsequent year.

(c) A hospital that diagnoses or treats an abortion complication, as defined in §139.2 of this title (relating to Definitions), shall comply with §139.5 of this title (relating to Additional Reporting Requirements).

(d) Pursuant to HSC §166.054, a hospital shall complete and submit to HHSC the Ethics or Medical Committee Reporting Form, which is located on the HHSC website, no later than the 180th day after the hospital delivers the written notice required under HSC §166.046(b)(1). The Ethics or Medical Committee Reporting Form collects the following information:

(1) the number of days that elapsed from the patient's admission to the hospital to the date notice was provided under HSC §166.046(b)(1);

(2) whether the ethics or medical committee met to review the case under HSC §166.046 and, if the committee did meet, the number of days that elapsed from the date notice was provided under HSC §166.046(b)(1) to the date the meeting was held;

(3) whether the patient was:

(A) transferred to a physician within the same hospital who was willing to comply with the patient's advance directive or a health care or treatment decision made by or on behalf of the patient;

(B) transferred to a different health care facility; or

(C) discharged from the hospital to a private residence or other setting that is not a health care facility;

(4) whether the patient died while receiving life-sustaining treatment at the hospital;

(5) whether life-sustaining treatment was withheld or withdrawn from the patient at the hospital after expiration of the time period described by HSC §166.046(e) and, if so, the disposition of the patient after the withholding or withdrawal of life-sustaining treatment at the hospital, as selected from the following categories:

(A) the patient died at the hospital;

(B) the patient is currently a patient at the hospital;

(C) the patient was transferred to a different health care facility; or

(D) the patient was discharged from the facility to a private residence or other setting that is not a health care facility;

(6) the age group of the patient selected from the following categories:

(A) 17 years of age or younger;

(B) 18 years of age or older and younger than 66 years of age; or

(C) 66 years of age or older;

(7) the health insurance coverage status of the patient selected from the following categories:

(A) private health insurance coverage;

(B) public health plan coverage; or

(C) uninsured;

(8) the patient's sex;

(9) the patient's race;

(10) whether the hospital was notified of and able to reasonably verify any public disclosure of the contact information for the hospital's personnel, physicians or health care professionals who provide care at the hospital, or members of the ethics or medical committee in connection with the patient's stay at the hospital; and

(11) whether the hospital was notified of and able to reasonably verify any public disclosure by hospital personnel of the contact information for the patient's immediate family members or the person responsible for the patient's health care decisions in connection with the patient's stay at the hospital.

(e) In accordance with HSC §166.054(c)-(e), HHSC publishes on its website an aggregate report of information submitted under subsection (d) of this section in the preceding year by April 1st of each year.

(f) Pursuant to HSC §166.054(g), information collected or submitted under subsection (d) of this section:

(1) is not admissible in a civil or criminal proceeding in which a physician, health care professional acting under the direction of a physician, or health care facility is a defendant;

(2) may not be used in relation to any disciplinary action by a licensing or regulatory agency with oversight over a physician, health care professional acting under the direction of a physician, or health care facility; and

(3) is not public information or subject to disclosure under Texas Government Code Chapter 552, except as permitted by Texas Government Code §552.008.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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Karen Ray
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Department of State Health Services
Earliest possible date of adoption: July 14, 2024
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CHAPTER 229. FOOD AND DRUG

The Executive Commissioner of the Texas Health and Human Services Commission (HHSC), on behalf of the Texas Department of State Health Services (DSHS), proposes amendments to §§229.40, 229.41, 229.241 - 229.252, and 229.419 - 229.430.

BACKGROUND AND PURPOSE

The purpose of the proposal is to amend Texas Administrative Code, Title 25, Chapter 229, Subchapters D, O, and W. The amendments reflect current federal law, statute, and rule references since the rules were last adopted. The amendments revise and add definitions to clarify intent and improve compliance, update agency addresses and websites, and include clarifying language to ensure consistency in interpretation of the rules.

SECTION-BY-SECTION SUMMARY

Subchapter D, Regulation of Cosmetics

The proposed amendment to §229.40 replaces wording for consistency throughout the chapter.

The proposed amendment to §229.41(a) adds a reference for consistency with federal references, adds federal citations, replaces a spelled out reference with the acronym defined in this section, and renumbers the paragraphs. The proposed amendment to §229.41(b) updates DSHS contact information. The proposed amendment to §229.41(c) replaces wording for consistency throughout the chapter.

Subchapter O, Licensing of Wholesale Distributors of Nonprescription Drugs--Including Good Manufacturing Practices

The proposed amendment to §229.241 replaces wording for consistency throughout the chapter.

The proposed amendment to §229.242(a) updates certain federal references, updates where copies of the laws and regulations can be found, and updates wording for clarity. The proposed amendment to §229.242(b) updates the DSHS website address. The proposed amendment to §229.242(c) replaces wording for consistency throughout the chapter.

The proposed amendment to §229.243 provides revised and new definitions, adds clarity to the rule language, and ensures consistency in interpretation of the rules.

The proposed amendment to §229.244 replaces wording for consistency throughout the chapter.

The proposed amendment to §229.245 replaces wording for consistency throughout the chapter and simplifies a reference.

The proposed amendment to §229.246 corrects references, edits language for clarity and consistency, and updates DSHS contact information.

The proposed amendment to §229.247 updates DSHS contact information, updates wording for clarity, and revises references.

The proposed amendment to §229.248 adds the time period by which DSHS must be notified of a change in a license application, updates wording for clarity, and updates DSHS contact information.

The proposed amendment to §229.249 replaces "amended" with "issued" throughout the rule for clarification concerning licenses, corrects references, and updates wording for clarity.

The proposed amendment to §229.250 updates wording and punctuation for clarity and grammar, specifies the name of the Department of Public Safety, and corrects references.

The proposed amendment to §229.251 adds new language for nonprescription drugs, updates references, and revises language for consistency and understanding.

The proposed amendment to §229.252 updates language for consistency and revises a reference.

Subchapter W, Licensing of Wholesale Distributors of Prescription Drugs--Including Good Manufacturing Practices

The proposed amendment to §229.419, concerning Purpose, removes a word for clarity.

The proposed amendment to §229.420 updates certain federal references, updates wording for clarity and consistency throughout the chapter, and updates the DSHS website address.

Proposed new amendment §229.421 provides revised and new definitions, adds clarity to the rule language, and ensures consistency in interpretation of the rules.

The proposed amendment to §229.422 replaces the term "giving" with "providing" for consistency in the chapter.

The proposed amendment to §229.423 adds the statement "local intellectual and developmental disability authorities, referred to as," which describes the facilities a state agency can distribute prescription drugs to, updates references, and revises wording for clarity and consistency.

The proposed amendment to §229.424 updates wording for clarity and consistency throughout the chapter.

The proposed amendment to §229.425 updates wording for clarity and consistency throughout the chapter and updates the DSHS website address.

The proposed amendment to §229.426 updates wording for clarity and consistency throughout this chapter and updates the DSHS mailing address and website address.

The proposed amendment to §229.427 corrects references and updates wording for clarity and consistency.

The proposed amendment to §229.428 updates wording for clarity and consistency throughout the chapter.

The proposed amendment to §229.429 updates wording for clarity and consistency in this chapter, updates certain federal references, and adds new language for prescription drug wholesalers.

The proposed amendment to §229.430 updates wording for clarity and consistency in this chapter and updates certain federal references.

FISCAL NOTE

Christy Havel Burton, Chief Financial Officer, has determined for each year of the first five years the rules will be in effect, enforcing or administering the rules does not have foreseeable implications relating to costs or revenues of state or local governments.

GOVERNMENT GROWTH IMPACT STATEMENT

DSHS has determined during the first five years the rules will be in effect:

(1) the proposed rules will not create or eliminate a government program;

(2) implementation of the proposed rules will not create new DSHS employee positions;

(3) implementation of the proposed rules will result in no assumed change in future legislative appropriations;

(4) the proposed rules will not affect fees paid to DSHS;

(5) the proposed rules will not create a new regulation;

(6) the proposed rules will not expand, limit, or repeal existing regulations;

(7) the proposed rules will not change the number of individuals subject to the rules; and

(8) the proposed rules will not affect the state's economy.

SMALL BUSINESS, MICRO-BUSINESS, AND RURAL COMMUNITY IMPACT ANALYSIS

Christy Havel Burton, Chief Financial Officer, has also determined there will be no adverse economic effect on small businesses, micro-businesses, or rural communities.

The rules do not impose any additional costs on small businesses, micro-businesses, or rural communities are required to comply with the rules.

LOCAL EMPLOYMENT IMPACT

The proposed rules will not affect a local economy.

COSTS TO REGULATED PERSONS

Texas Government Code §2001.0045 does not apply to these rules because the rules are necessary to protect the health, safety, and welfare of the residents of Texas.

PUBLIC BENEFIT AND COSTS

Timothy Stevenson, Associate Commissioner, Consumer Protection Division, has determined for each year of the first five years the rules are in effect, the public benefit will be transparent and efficient compliance actions resulting from the development of the cosmetic, nonprescription drug, and prescription drug rules.

Christy Havel Burton, Chief Financial Officer has also determined for the first five years the rules are in effect, there are no anticipated economic costs to persons who are required to comply with the proposed rules.

TAKINGS IMPACT ASSESSMENT

DSHS has determined the proposal does not restrict or limit an owner's right to his or her property that would otherwise exist

in the absence of government action and, therefore, does not constitute a taking under Texas Government Code §2007.043.

PUBLIC COMMENT

Written comments on the proposal may be submitted to Megan Snyder, Drugs and Medical Devices Branch, P.O. Box 149347, Mail Code 1987, Austin, Texas 78714-9347; or by e-mail to dmd.regulatory@dshs.texas.gov.

To be considered, comments must be submitted no later than 31 days after the date of this issue of the *Texas Register.* Comments must be (1) postmarked or shipped before the last day of the comment period; (2) hand-delivered at 8407 Wall Street, Austin, Texas 78754 before 5:00 p.m. on the last working day of the comment period; or (3) emailed before midnight on the last day of the comment period. If the last day to submit comments falls on a holiday, comments must be postmarked, shipped, or emailed before midnight on the following business day to be accepted. When emailing comments, please indicate "Comments on Proposed Rules 22R108" in the subject line.

SUBCHAPTER D. REGULATION OF COSMETICS

25 TAC §229.40, §229.41

STATUTORY AUTHORITY

The proposed amendments are authorized by Texas Health and Safety Code §431.241 and §431.244, which provides the Executive Commissioner of HHSC with authority to adopt rules to enforce the Texas Food, Drug, and Cosmetic Act and adopts specific rules under Code of Federal Regulations, Title 21 as a rule under this chapter; and Texas Government Code §531.0055, and Texas Health and Safety Code §1001.075, which authorize the Executive Commissioner of HHSC to adopt rules and policies necessary for the operation and provision of health and human services by DSHS and for the administration of Texas Health and Safety Code Chapter 1001, including Chapter 431, the Texas Food, Drug, and Cosmetic Act.

The proposed amendments implement Texas Government Code Chapter 531; and Texas Health and Safety Code Chapters 431 and 1001.

§229.40. Purpose.

(a) This subchapter sets [~~These sections set~~] forth the requirements for the sale of cosmetics in this state.

(b) Cosmetic [~~A "cosmetic"~~] means articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part of the human body for cleaning, beautifying, promoting attractiveness, or altering the appearance, and articles intended for use as a component of those articles. The term does not include soap.

§229.41. Applicable Laws and Regulations.

(a) The department adopts by reference the following laws and regulations:

(1) Federal Food, Drug, and Cosmetic Act, 21 United States Code (USC) §301, et seq., as amended;

(2) 21 Code of Federal Regulations (CFR) Part 70, Color Additives, as amended;

(3) 21 CFR Part 73, Listing of Color Additives Exempt From Certification, as amended;

(4) 21 CFR Part 74, Listing of Color Additives Subject to Certification, as amended;

(5) 21 CFR Part 81, General Specifications and General Restrictions for Provisional Color Additives for Use in Foods, Drugs, and Cosmetics, as amended;

(6) 21 CFR Part 82, Listing of Certified Provisionally Listed Colors and Specifications, as amended;

(7) [~~(2)~~] 21 CFR [~~Code of Federal Regulations (CFR)~~] Part 700, General, as amended;

(8) [~~(3)~~] 21 CFR Part 701, Cosmetic Labeling, as amended; and

(9) [~~(4)~~] 21 CFR Part 740, Cosmetic Product Warning Statements, as amended.

(b) [~~Copies of these laws and regulations are indexed and filed at the department, and are available for inspection during normal working hours, 8:00 a.m. - 5:00 p.m. (except weekends and holidays).~~] Electronic copies of these laws and regulations are available online at www.dshs.texas.gov [~~http://www.dshs.state.tx.us/license.shtm~~].

(c) Nothing in this subchapter relieves [~~these sections shall relieve~~] any person of the responsibility for compliance with other applicable Texas and federal laws and regulations.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on May 28, 2024.

TRD-202402359
Cynthia Hernandez
General Counsel
Department of State Health Services
Earliest possible date of adoption: July 14, 2024
For further information, please call: (512) 834-6755

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SUBCHAPTER O. LICENSING OF WHOLESALE DISTRIBUTORS OF NONPRESCRIPTION DRUGS--INCLUDING GOOD MANUFACTURING PRACTICES

25 TAC §§229.241 - 229.252

STATUTORY AUTHORITY

The proposed amendments are authorized by Texas Health and Safety Code §431.241 and §431.244, which provides the Executive Commissioner of HHSC with authority to adopt rules to enforce the Texas Food, Drug, and Cosmetic Act and adopts specific rules under Code of Federal Regulations, Title 21 as a rule under this chapter; and Texas Government Code §531.0055, and Texas Health and Safety Code §1001.075, which authorize the Executive Commissioner of HHSC to adopt rules and policies necessary for the operation and provision of health and human services by DSHS and for the administration of Texas Health and Safety Code Chapter 1001, including Chapter 431, the Texas Food, Drug, and Cosmetic Act.

The proposed amendments implement Texas Government Code Chapter 531; and Texas Health and Safety Code Chapters 431 and 1001.

§229.241. Purpose.

This subchapter provides [~~These sections provide for~~] the minimum licensing standards necessary to ensure the safety and efficacy of nonprescription drugs offered for sale by wholesale distributors.

§229.242. Applicable Laws and Regulations.

(a) The department adopts by reference the following laws and regulations:

(1) Federal Food, Drug, and Cosmetic Act, 21 United States Code (USC) §301, et seq., as amended;

(2) 9 Code of Federal Regulations (CFR)[~~,~~] Part 113, Standard Requirements, as amended;

(3) 21 CFR[~~,~~] Part 70, Color Additives, as amended;

(4) 21 CFR[~~,~~] Part 71, Color Additive Petitions, as amended;

(5) 21 CFR[~~,~~] Part 73, Listing of Color Additives Exempt From Certification, as amended;

(6) 21 CFR[~~,~~] Part 74, Listing of Color Additives Subject to Certification, as amended;

(7) 21 CFR [~~,~~] Part 80, Color Additive Certification, as amended;

(8) 21 CFR[~~,~~] Part 81, General Specifications and General Restrictions for Provisional Color Additives for Use [~~use~~] in Foods, Drugs, and Cosmetics, as amended;

(9) 21 CFR[~~,~~] Part 82, Listing of Certified Provisionally Listed Colors and Specifications, as amended;

(10) 21 CFR[~~,~~] Part 201, Labeling, as amended;

(11) 21 CFR[~~,~~] Part 206, Imprinting of Solid Oral Dosage Form Drug Products for Human Use, as amended;

(12) 21 CFR[~~,~~] Part 207, Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs, and the National Drug Code [~~Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution~~], as amended;

(13) 21 CFR[~~,~~] Part 210, Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General, as amended;

(14) 21 CFR[~~,~~] Part 211, Current Good Manufacturing Practice for Finished Pharmaceuticals, as amended;

(15) 21 CFR[~~,~~] Part 225, Current Good Manufacturing Practice for Medicated Feeds, as amended;

(16) 21 CFR[~~,~~] Part 226, Current Good Manufacturing Practice for Type A Medicated Articles, as amended;

(17) 21 CFR[~~,~~] Part 250, Special Requirements for [~~For~~] Specific Human Drugs, as amended;

(18) 21 CFR[~~,~~] Part 299, Drugs; Official Names and Established Names, as amended;

(19) 21 CFR[~~,~~] Part 300, General, as amended;

(20) 21 CFR[~~,~~] Part 310, New Drugs, as amended;

(21) 21 CFR[~~,~~] Part 312, Investigational New Drug Application, as amended;

(22) 21 CFR[~~,~~] Part 314, Applications for FDA Approval to Market a New Drug [~~or an Antibiotic Drug~~], as amended;

(23) 21 CFR[~~,~~] Part 316, Orphan Drugs, as amended;

(24) 21 CFR[~~,~~] Part 320, Bioavailability and Bioequivalence Requirements, as amended;

(25) 21 CFR[~~,~~] Part 328, Over-the-Counter [~~(OTC)~~] Drug Products Intended for Oral Ingestion that Contain Alcohol, as amended;

(26) 21 CFR Part 330, Over-the-Counter (OTC) Human Drugs Which Are [~~are~~] Generally Recognized as Safe and Effective and Not Misbranded, as amended;

(27) 21 CFR[~~,~~] Part 331, Antacid Products for Over-the-Counter (OTC) Human Use, as amended;

(28) 21 CFR[~~,~~] Part 332, Antiflatulent Products for Over-the-Counter [~~(OTC)~~] Human Use, as amended;

(29) 21 CFR[~~,~~] Part 333, Topical Antimicrobial Drug Products for Over-the-Counter [~~(OTC)~~] Human Use, as amended;

(30) 21 CFR[~~,~~] Part 335, Antidiarrheal Drug Products for Over-the-Counter [~~(OTC)~~] Human Use, as amended;

(31) 21 CFR[~~,~~] Part 336, Antiemetic Drug Products for Over-the-Counter [~~(OTC)~~] Human Use, as amended;

(32) 21 CFR[~~,~~] Part 338, Nighttime Sleep-Aid [~~Sleep-aid~~] Drug Products for Over-the-Counter [~~(OTC)~~] Human Use, as amended;

(33) 21 CFR[~~,~~] Part 340, Stimulant Drug Products for Over-the-Counter [~~(OTC)~~] Human Use, as amended;

(34) 21 CFR[~~,~~] Part 341, Cold, Cough, Allergy, Bronchodilator, and Anti-asthmatic Drug Products for Over-the-Counter [~~(OTC)~~] Human Use, as amended;

(35) 21 CFR[~~,~~] Part 343, Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-The-Counter [~~(OTC)~~] Human Use, as amended;

(36) 21 CFR[~~,~~] Part 344, Topical Otic [~~OTIC~~] Drug Products for Over-the-Counter [~~(OTC)~~] Human Use, as amended;

(37) 21 CFR[~~,~~] Part 346, Anorectal Drug Products for Over-the-Counter [~~(OTC)~~] Human Use, as amended;

(38) 21 CFR[~~,~~] Part 347, Skin Protectant Drug Products for Over-the-Counter [~~(OTC)~~] Human Use, as amended;

(39) 21 CFR[~~,~~] Part 348, External Analgesic Drug Products for Over-the-Counter [~~(OTC)~~] Human Use, as amended;

(40) 21 CFR[~~,~~] Part 349, Ophthalmic Drug Products for Over-the-Counter [~~(OTC)~~] Human Use, as amended;

(41) 21 CFR[~~,~~] Part 350, Antiperspirant Drug Products for Over-the-Counter [~~(OTC)~~] Human Use, as amended;

(42) 21 CFR[~~,~~] Part 352, Sunscreen Drug Products for Over-the-Counter [~~(OTC)~~] Human Use (Stayed Indefinitely), as amended;

(43) 21 CFR[~~,~~] Part 355, Anticaries Drug Products for Over-the-Counter [~~(OTC)~~] Human Use, as amended;

(44) 21 CFR[~~,~~] Part 357, Miscellaneous Internal Drug Products for Over-the-Counter [~~(OTC)~~] Human Use, as amended;

(45) 21 CFR[~~,~~] Part 358, Miscellaneous External Drug Products for Over-the-Counter [~~(OTC)~~] Human Use, as amended; [~~and~~]

(46) 21 CFR[,] Part 369, Interpretive Statements Re [~~Re:~~] Warnings on Drugs and Devices for Over-the-Counter Sale [~~(OTC) Sales~~], as amended; [~~.~~]

(47) 21 CFR Part 700, General, as amended;

(48) 21 CFR Part 701, Cosmetic Labeling, as amended; and

(49) 21 CFR Part 740, Cosmetic Product Warning Statements, as amended.

(b) [~~Copies of these laws and regulations are indexed and filed at the department, 1100 West 49th Street, Austin, Texas 78756, and are available for inspection during normal working hours, 8:00 a.m. - 5:00 p.m. (except weekends and holidays)~~]. Electronic copies of these laws and regulations are available online at www.dshs.texas.gov [~~http://www.dshs.state.tx.us/license.shtm~~].

(c) Nothing in this subchapter relieves [~~these sections shall relieve~~] any person of the responsibility for compliance with other applicable Texas and federal laws and regulations.

§229.243. Definitions.

The following words and terms, when used in this subchapter, [~~shall~~] have the following meanings, unless the context clearly indicates otherwise.

(1) Act--The Texas Food, Drug, and Cosmetic Act, Texas Health and Safety Code Chapter 431.

(2) Adulterated drug--Has the meaning specified in the Act at [~~Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431,~~] §431.111.

(3) Authorized agent--An employee of the department who is designated by the commissioner to enforce the provisions of the Act.

(4) Broker--A person engaged in offering or contracting for wholesale distribution sale or transfer of a nonprescription drug into, within, or out of Texas and who does not take title to or physical possession of the nonprescription drug.

(5) [~~(4)~~] Change of ownership--A sole proprietor who transfers all or part of the facility's ownership to another person or persons; the removal, addition, or substitution of a person or persons as a partner in a facility owned by a partnership; a corporate sale, transfer, reorganization, or merger of the corporation which owns the facility if sale, transfer, reorganization, or merger causes a change in the facility's ownership to another person or persons; or if any other type of association, the removal, addition, or substitution of a person or persons as a principal of such association.

(6) [~~(5)~~] Commissioner--Commissioner of the Texas Department of State Health Services.

(7) Component--Any ingredient intended for use in the manufacture of a drug product, including those that may not appear in such drug product.

(8) [~~(6)~~] Cosmetic--Articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part of the human body for cleaning, beautifying, promoting attractiveness, or altering the appearance, and articles intended for use as a component of those articles. The term does not include soap.

(9) [~~(7)~~] Department--The Texas Department of State Health Services.

(10) [~~(8)~~] Device--An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory[~~, that is~~]:

(A) recognized in the official United States Pharmacopoeia National Formulary or any supplement to it;

(B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in humans [~~man~~] or other animals; or

(C) intended to affect the structure or any function of the body of humans [~~man~~] or other animals and [~~that~~] does not achieve any of its principal intended purposes through chemical action within or on the body of humans [~~man~~] or other animals and is not dependent on metabolization for the achievement of any of its principal intended purposes.

(11) [~~(9)~~] Drug--Articles recognized in the official United States Pharmacopoeia National Formulary, or any supplement to it; [~~,~~] articles designated or intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans [~~man~~] or other animals; [~~,~~] articles, other than food, intended to affect the structure or any function of the body of humans [~~man~~] or other animals; [~~,~~] and articles intended for use as a component of any such article. The term does not include devices or their components, parts, or accessories. A food for which a claim is made in accordance with the Federal Act, §403(r), 21 USC §343, and for which the claim is approved by the United States [~~U.S.~~] Food and Drug Administration (FDA) [~~,~~] is not a drug solely because the label or labeling contains such a claim.

(12) [~~(10)~~] Federal Act--Federal Food, Drug, and Cosmetic Act, 21 USC §301, [~~United States Code~~] et seq., as amended.

(13) [~~(11)~~] Flea market--A location at which booths or similar spaces are rented or otherwise made available temporarily to two or more persons and at which the persons offer tangible personal property for sale.

(14) Inactive ingredient--Any component other than an active ingredient, including any excipient, flavor, fragrance, and color.

(15) [~~(12)~~] Labeling--All labels and other written, printed, or graphic matter:

(A) upon any drug or any of its containers or wrappers; or

(B) accompanying such drug.

(16) [~~(13)~~] Manufacturer--A person who manufactures, prepares, propagates, compounds, processes, packages, or repackages nonprescription drugs, or a person who changes the container, wrapper, or labeling of any nonprescription drug package.

(17) [~~(14)~~] Misbranded drug--Has the meaning specified in the Act at [~~Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431,~~] §431.112.

(18) [~~(15)~~] Nonprescription drug--Any drug that is not a prescription drug, including the terms Over-the-Counter Drug and Non-legend Drug. [~~and includes the term "Over the Counter Drug."~~]

(19) [~~(16)~~] Nonprescription drug product--A finished dosage form, for example, tablet, capsule, solution, etc., containing [~~that contains~~] an active nonprescription ingredient [~~drug ingredient generally, but not necessarily, in association with inactive ingredients~~]. The term also includes a finished dosage form that does not contain an active ingredient but is intended to be used as a placebo. Any nonprescription drug product that is also a cosmetic or device or component thereof is also subject to the applicable requirements of

the Federal Act, Chapters V and VI, and Subchapters E and F; and Subchapter D of this chapter (relating to Regulation of Cosmetics) and Subchapter X of this chapter (relating to Licensing of Device Distributors and Manufacturers).

(20) Over-the-Counter (OTC) drugs--Drugs that are safe and effective for use by the general public without seeking treatment by a health professional.

(21) [~~(17)~~] Person--An individual, corporation, business trust, estate, trust, partnership, association, or any other public or private legal entity.

(22) [~~(18)~~] Place of business--Each location at which a nonprescription drug for wholesale distribution is located.

(23) [~~(19)~~] Prescription drug--Any drug (including any biological product, except for blood and blood components intended for transfusion or biological products that are also medical devices) required by federal [~~Federal~~] law (including federal [~~Federal~~] regulation) to be dispensed only by a prescription, including finished dosage forms and bulk drug substances subject to the Federal Act at [~~,~~]§503(b).

(24) [~~(20)~~] Wholesale distribution--Distribution to a person other than a consumer or patient, including[~~, but not limited to~~] distribution to any person by a manufacturer, repackager, own label distributor, broker, jobber, warehouse, or wholesaler. This term does not include:

(A) intracompany sales of nonprescription drugs, which means transactions or transfers of nonprescription drugs between a division, subsidiary, parent, or affiliated or related company under common ownership and control or any transaction or transfer between co-license holders of a co-licensed product;

(B) the distribution of nonprescription drug samples by a representative of a manufacturer or wholesale drug distributor;

(C) the delivery of, or offer to deliver, a nonprescription drug by a common carrier solely in the common carrier's usual course of business of transporting nonprescription drugs, if the common carrier does not store, warehouse, or take legal ownership of the nonprescription drug; and

(D) the sale or transfer from a purchaser, other than a consumer, seller, or warehouser, of expired, damaged, returned, or recalled nonprescription drugs to the original manufacturer or to a reverse logistics provider.

§229.244. Sale of Nonprescription Drugs.

Any reference in this subchapter [~~these sections~~] to the sale of nonprescription drugs includes: [~~shall be considered to include~~]

(1) manufacturing [~~the manufacture~~], packaging, exposing, offering, possessing, or [~~exposure, offer, possession, and~~] holding [~~of~~] any nonprescription drug for sale;

(2) selling [~~the sale~~], dispensing, or providing [~~and giving of~~] any nonprescription drug; and

(3) supplying or applying [~~of~~] any nonprescription drug in the operation of any nonprescription drug place of business.

§229.245. Exemption.

(a) A person is exempt from licensing a place of business in accordance with §229.246 of this subchapter [~~title~~] (relating to Licensure Requirements) if the person holds a license for the place of business issued by the department under Subchapter W of this chapter (relating to Licensing of Wholesale Distributors of Prescription Drugs--Including Good Manufacturing Practices).

(b) An exemption from the licensing requirement granted in subsection (a) of this section does not constitute an exemption from other applicable requirements for nonprescription drugs in this subchapter [~~these sections~~] or under the Act [~~Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431~~].

§229.246. Licensure Requirements.

(a) General. Except as provided by §229.245 of this subchapter [~~title~~] (relating to Exemption), a person may not engage in the wholesale distribution of nonprescription drugs in Texas unless the person has a valid license from the department for each place of business.

(b) Out-of-state place of business. Except as provided by §229.245 of this subchapter [~~title~~], a person who engages in the wholesale distribution of nonprescription drugs from outside this state may only engage in the wholesale distribution of nonprescription drugs within [~~in~~] this state if the person holds a license as required under subsection (a) of this section.

(c) Combination product. If the United States Food and Drug Administration determines, with respect to a product that is a combination of a nonprescription drug and a device, that the primary mode of action of the product is as a nonprescription drug, the [~~a~~] wholesale distributor must obtain a license [~~of such a product is subject to licensure~~] as described in this section.

(d) Proof of licensure. The license holder must show proof of licensure in a format readily available at each place of business.

[~~(d) Display of License. The license shall be displayed in an open public area at each place of business.~~]

(e) New place of business. Each person acquiring or establishing a place of business for [~~the purpose of~~] wholesale distribution of nonprescription drugs after the effective date of this subchapter must obtain a license before [~~these sections shall apply to the department for a license of such business prior to~~] beginning operation.

(f) Two or more places of business. A [~~If the~~] wholesale distributor of nonprescription drugs must obtain a license for [~~operates more than one place of business, the wholesale distributor of nonprescription drugs shall license~~] each place of business [~~separately~~].

(g) Pre-licensing inspection. The applicant must [~~shall~~] cooperate with any pre-licensing inspection by the department of the applicant's place of business. The department may accept reports from authorities in other jurisdictions to determine the extent of compliance with the minimum standards in this subchapter [~~these sections~~] for applicants located out-of-state.

(h) Issuance of license. In accordance with §229.281 of this chapter [~~title~~] (relating to Processing License/Permit Applications Relating to Food and Drug Operations), the department may license a wholesale distributor of nonprescription drugs who meets the requirements in this subchapter [~~of these sections,~~] and pays all license fees under [~~in compliance with~~] §229.249 of this subchapter [~~title~~] (relating to Licensure Fees).

(i) Transfer of license. Licenses are not [~~shall not be be~~] transferable [~~from one person to another or from one place of business to another~~].

(j) License term. Unless the license is amended as provided in subsection (k) of this section, or suspended or revoked as provided in §229.250 of this subchapter [~~title~~] (relating to Refusal, Cancellation, Suspension, or Revocation of a License), the license is valid for two years.

(k) Amendment of license. A license that is amended, including a change of name [~~, ownership,~~] or a notification of a change in the location of a licensed place of business requires [~~will require~~] submission of an application as outlined in §229.247 of this subchapter [~~title~~] (relating to Licensing Procedures) and submission of fees as outlined in §229.249 of this subchapter [~~title~~].

(l) Renewal of license.

(1) The license application as outlined in §229.247 of this subchapter [~~title~~] and nonrefundable licensing fees as outlined in §229.249 of this subchapter [~~title~~] for each place of business must [~~shall~~] be submitted to the department before [~~prior to~~] the expiration date of the current license.

(2) A person who files a renewal application after the expiration date must pay an additional $100 [~~as a~~] delinquency fee.

(3) [~~(2)~~] A person [~~licensee~~] who fails to submit a renewal application before [~~prior to~~] the current license expires [~~licensure expiration date~~] and continues operations is [~~may be~~] subject to [~~the~~] enforcement and penalty provisions in §229.252 of this subchapter [~~title~~] (relating to Enforcement and Penalties), and [~~and/or~~] the refusal, cancellation, suspension, and revocation provisions in §229.250 of this subchapter [~~title~~].

(4) [~~(3)~~] A renewal license must [~~shall~~] only be issued when all past due administrative penalties, license fees, and delinquency fees are paid.

§229.247. Licensing Procedures.

(a) License application forms. License application forms may be obtained from the Texas Department of State Health Services [~~department~~], 1100 West 49th Street, Austin, Texas, 78756, or online at www.dshs.texas.gov [~~http:/www.dshs.state.tx.us/license.shtm~~].

(b) Contents of license application. The application for licensure as a wholesale distributor of nonprescription drugs must [~~shall~~] be signed and verified, submitted on a license application form furnished by the department, and contain the following information:

(1) the name of the legal entity to be licensed, including the name under which the business is conducted;

(2) the address of each place of business to be [~~that is~~] licensed;

(3) if a proprietorship, the name and residence address of the proprietor; if a partnership, the names and residence addresses of all partners; if a corporation, the date and place of incorporation and name and address of its registered agent in the state and corporation charter number; or if any other type of association, the names of the principals of such association;

(4) the name[~~, residence address,~~] and valid driver license number for each individual in an actual administrative capacity which, in the case of proprietorship, must [~~shall~~] be the managing proprietor; partnership, the managing partner; corporation, the officers and directors; or those in a managerial capacity in any other type of association;

(5) for each place of business, the residence address of the individual in charge [~~thereof~~];

(6) a list of categories which must be marked and adhered to in the determination and payment of the fee as described in §229.249 of this subchapter (relating to Licensure Fees); and

(7) a statement verified by the applicant's signature acknowledging [~~that acknowledges~~] the applicant [~~has~~] read, understood, and agrees to abide by the provisions of this subchapter [~~these sections~~] and those of the Act [~~Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431~~].

(c) Renewal license application. The renewal application for licensure as a wholesale distributor of nonprescription drugs must [~~shall~~] be made on a license application form furnished by the department.

[~~(d) Texas Online. Applicants may submit initial and renewal license applications under these sections electronically by the Internet through Texas Online at www.texasonline.state.tx.us. The department is authorized to collect fees, in amounts determined by the Texas Online Authority, to recover costs associated with application and renewal application processing through Texas Online.~~]

§229.248. Report of Changes.

(a) Change in the content of a license application. The license holder must [~~shall~~] notify the department of any change in the information on the license application in writing within 10 [~~ten~~] days of the [~~any~~] change [~~which would render the information contained in the application for the license, reported pursuant to §229.247 of this title (relating to Licensing Procedures), no longer accurate~~]. Failure to inform the department within 10 [~~no later than ten~~] days of a change in the information required in the application for a license may result in an enforcement action, including [~~a~~] suspension or revocation of the license.

(b) Change in location of place of business. The license holder must notify the department at least [~~Not fewer than~~] 30 days in advance of an intended [~~the~~] change of address of the[~~, the licensee shall notify the department in writing of the licensee's intent to change the location of a~~] licensed place of business. The notice must [~~shall~~] include the address of the new location[~~,~~] and the name [~~and residence address~~] of the individual in charge of the business at the new location. Within [~~Not more than~~] 10 days of beginning operations at the new location [~~after the completion of the change of location~~], the license holder must [~~licensee shall~~] notify the department in writing to confirm the move [~~completion of the change of location,~~] and provide verification or correction of the information provided on [~~previously provided or correct and confirm any information that has changed since providing~~] the notice of intent. The license holder must simultaneously return the original license to the department. The notice and confirmation required by this subsection will be deemed adequate if the license holder submits [~~licensee sends~~] the notices by certified mail, return receipt requested, to the Texas Department of State Health Services [~~department~~] at 1100 West 49th Street, Austin, Texas 78756, or submits notices [~~them~~] electronically through www.texas.gov [~~the Texas Online Internet website~~].

§229.249. Licensure Fees.

(a) License fee. Except as provided by §229.245 of this subchapter [~~title~~] (relating to Exemption), no person may operate or conduct business as a wholesale distributor of nonprescription drugs without first obtaining a license from the department. All applicants for an initial wholesale distributor of nonprescription drugs license or a renewal license must [~~shall~~] pay a licensing fee unless otherwise exempt as provided by subsection (c) of this section. All fees are nonrefundable. Licenses are issued for two-year terms. A license shall only be issued when all past due administrative penalties, license fees, and delinquency fees are paid.

(1) In-state wholesale distributors of nonprescription drugs who are not manufacturers must [~~shall~~] pay a two-year license fee based on the gross annual sales of all nonprescription drugs.

(A) For a wholesale distributor with gross annual nonprescription drug sales of $0 - $199,999.99, the fees are:

(i) $1,040 for a two-year license;

(ii) $1,040 for a two-year license issued [~~that is amended~~] due to a change of ownership; and

(iii) $520 for a license issued [~~that is amended~~] during the current licensure period due to minor changes.

(B) For a wholesale distributor with gross annual nonprescription drug sales of $200,000 - $19,999,999.99, the fees are:

(i) $1,690 for a two-year license;

(ii) $1,690 for a two-year license issued [~~that is amended~~] due to a change of ownership; and

(iii) $845 for a license issued [~~that is amended~~] during the current licensure period due to minor changes.

(C) For a wholesale distributor with gross annual nonprescription drug sales greater than or equal to $20 million, the fees are:

(i) $2,210 for a two-year license;

(ii) $2,210 for a two-year license issued [~~that is amended~~] due to a change of ownership; and

(iii) $1,105 for a license issued [~~that is amended~~] during the current licensure period due to minor changes.

(2) In-state wholesale distributors of nonprescription drugs who are not manufacturers and who also are required to be licensed as a device distributor under §229.439(a) of this chapter [~~title~~] (relating to Licensure Fees) or as a wholesale food distributor under §229.182(a)(3) of this chapter [~~title~~] (relating to Licensing/Registration Fee and Procedures) must [~~shall~~] pay a combined two-year license fee for each place of business. License fees are based on the combined gross annual sales of these regulated products (foods, drugs, and [~~and/or~~] devices).

(A) For each place of business having combined gross annual sales of $0 - $199,999.99, the fees are:

(i) $520 for a two-year license;

(ii) $520 for a two-year license issued [~~that is amended~~] due to a change of ownership; and

(iii) $260 for a license [~~that is~~] amended during the current licensure period due to minor changes.

(B) For each place of business having combined gross annual sales of $200,000 - $499,999.99, the fees are:

(i) $780 for a two-year license;

(ii) $780 for a two-year license issued [~~that is amended~~] due to a change of ownership; and

(iii) $390 for a license [~~that is~~] amended during the current licensure period due to minor changes.

(C) For each place of business having combined gross annual sales of $500,000 - $999,999.99, the fees are:

(i) $1,040 for a two-year license;

(ii) $1,040 for a two-year license issued [~~that is amended~~] due to a change of ownership; and

(iii) $520 for a license [~~that is~~] amended during the current licensure period due to minor changes.

(D) For each place of business having combined gross annual sales of $1 million - $9,999,999.99, the fees are:

(i) $1,300 for a two-year license;

(ii) $1,300 for a two-year license issued [~~that is amended~~] due to a change of ownership; and

(iii) $650 for a license [~~that is~~] amended during the current licensure period due to minor changes.

(E) For each place of business having combined gross annual sales greater than or equal to $10 million, the fees are:

(i) $1,950 for a two-year license;

(ii) $1,950 for a two-year license issued [~~that is amended~~] due to a change of ownership; and

(iii) $975 for a license [~~that is~~] amended during the current licensure period due to minor changes.

(3) In-state wholesale distributors of nonprescription drugs who are manufacturers must [~~shall~~] pay a two-year license fee based on the gross annual sales of all nonprescription drugs.

(A) For a wholesale distributor with gross annual nonprescription drug sales of $0 - $199,999.99, the fees are:

(i) $1,040 for a two-year license;

(ii) $1,040 for a two-year license issued [~~that is amended~~] due to a change of ownership; and

(iii) $520 for a license [~~that is~~] amended during the current licensure period due to minor changes.

(B) For a wholesale distributor with gross annual nonprescription drug sales of $200,000 - $1,999,999.99, the fees are:

(i) $1,235 for a two-year license;

(ii) $1,235 for a two-year license issued [~~that is amended~~] due to a change of ownership; and

(iii) $620 for a license [~~that is~~] amended during the current licensure period due to minor changes.

(C) For a wholesale distributor with gross annual nonprescription drug sales of $2 million to $9,999,999.99, the fees are:

(i) $1,560 for a two-year license;

(ii) $1,560 for a two-year license issued [~~that is amended~~] due to a change of ownership; and

(iii) $780 for a license [~~that is~~] amended during the current licensure period due to minor changes.

(D) For a wholesale distributor with gross annual nonprescription drug sales of $10 million to $19,999,999.99, the fees are:

(i) $1,885 for a two-year license;

(ii) $1,885 for a two-year license issued [~~that is amended~~] due to a change of ownership; and

(iii) $940 for a license [~~that is~~] amended during the current licensure period due to minor changes.

(E) For a wholesale distributor with gross annual nonprescription drug sales greater than or equal to $20 million, the fees are:

(i) $2,210 for a two-year license;

(ii) $2,210 for a two-year license issued [~~that is amended~~] due to a change of ownership; and

(iii) $1,105 for a license [~~that is~~] amended during the current licensure period due to minor changes.

(4) Out-of-state wholesale distributors of nonprescription drugs must [~~shall~~] pay a two-year license fee based on all gross annual sales of nonprescription drugs delivered into Texas.

(A) For each wholesale distributor with gross annual nonprescription drug sales of $0 - $19,999,999.99, the fees are:

(i) $1,300 for a two-year license;

(ii) $1,300 for a two-year license issued [~~that is amended~~] due to a change of ownership; and

(iii) $650 for a license [~~that is~~] amended during the current licensure period due to minor changes.

(B) For each wholesale distributor with gross annual nonprescription drug sales of greater than or equal to $20 million, the fees are:

(i) $1,950 for a two-year license;

(ii) $1,950 for a two-year license issued [~~that is amended~~] due to a change of ownership; and

(iii) $975 for a license [~~that is~~] amended during the current licensure period due to minor changes.

(b) Proration of license fees. A person having [~~that has~~] more than one place of business may request a one-time proration of the license fees when applying for a license for each new place of business. Upon approval by the department, the license for the new place of business will have a renewal date [~~that is~~] the same as the firm's other licensed places of business.

(c) Exemption from license fees. A person is exempt from the license fees required by this section if the person is a charitable organization, as described in the Internal Revenue Code of 1986, 26 USC §501(c)(3), or a nonprofit affiliate of the organization, to the extent otherwise permitted by law.

§229.250. Refusal, Cancellation, Suspension, or Revocation of License.

(a) The department [~~commissioner~~] may refuse an application for a wholesale distributor of nonprescription drugs license or may suspend or revoke such a license if the applicant or license holder [~~licensee~~]:

(1) has been convicted of a felony or misdemeanor involving [~~that involves~~] moral turpitude;

(2) is an association, partnership, or corporation and the managing officer or [~~and/or~~] any officer or director of the corporation has been convicted of a felony or misdemeanor involving [~~that involves~~] moral turpitude;

(3) is an association, partnership, or corporation and the managing officer or [~~and/or~~] any officer or director of the corporation has been convicted of a felony or misdemeanor involving the illegal use, sale, or transportation of intoxicating liquors, narcotic drugs, barbiturates, amphetamines, desoxyephedrine, their compounds or derivatives, or any other dangerous or habit-forming drugs;

(4) has violated any of the provisions of the Texas, Food, Drug, and Cosmetic Act, Texas Health and Safety Code[~~,~~] Chapter 431 (Act), or this subchapter [~~these sections~~].

(5) has violated the Texas Health and Safety Code[~~,~~] §431.021(l)(3) [~~§431.021(1)(3)~~], concerning the counterfeiting of a drug or the sale or holding for sale of a counterfeit drug;

(6) has violated the Controlled Substance Act, Texas Health and Safety Code[~~,~~] Chapter 481 [~~(Texas Controlled Substance Act)~~], or the Dangerous Drug Act, Texas Health and Safety Code[~~,~~] Chapter 483 [~~(Dangerous Drug Act)~~];

(7) has violated the rules of the director of the Department of Public Safety, including being responsible for a significant discrepancy in the records that state law requires the applicant or license holder [~~licensee to~~] maintain;

(8) has failed to complete a license application or submits an application containing [~~that contains~~] false, misleading, or incorrect information, or [~~contains~~] information that cannot be verified by the department;

(9) has failed to pay a license fee or a renewal fee for a license; or

(10) has obtained or attempted to obtain a license by fraud or deception.

(b) The department may, after providing opportunity for hearing, refuse to license a wholesale distributor of nonprescription drugs, or may suspend or revoke a license for violations of the requirements in this subchapter [~~these sections~~] or for any of the reasons described in the Act.

(c) Any hearings for the refusal, suspension, or revocation of a license are governed by §§1.21, 1.23, 1.25, and 1.27 of this title (relating to Formal Hearing Procedures).

(d) If the department suspends a license, the suspension must [~~shall~~] remain in effect until the department determines [~~that~~] the reason for the suspension no longer exists. If the suspension overlaps a renewal date, the suspended license holder must [~~shall~~] comply with the renewal procedures in §229.247 of this subchapter [~~title~~] (relating to Licensing Procedures); however, the department may choose not to renew the license until the department determines [~~that~~] the reason for suspension no longer exists.

(e) If the department revokes or does not renew a license, a person may reapply for a license by complying with the requirements and procedures in §229.247 of this subchapter [~~title~~] at the time of reapplication. The department may refuse to issue a license if the reason for revocation or non-renewal continues to exist.

(f) A license issued under this subchapter must [~~these sections shall~~] be returned to the department if the person's place of business:

(1) ceases business or otherwise ceases operation on a permanent basis;

(2) relocates; or

(3) changes name or ownership. For a corporation, an ownership change is deemed to have occurred, requiring return of [~~resulting in the necessity to return~~] the license to the department, when 5.0 percent [~~%~~] or more of the share of stock of a corporation is transferred from one person to another.

§229.251. Minimum Standards for Licensure.

(a) General requirements.

(1) All persons engaged in the wholesale distribution of nonprescription drugs must comply with the applicable minimum standards in this section, in addition to the statutory requirements contained in the Act [~~Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431 (Act)~~] and [~~those requirements adopted~~] in §229.242 of this subchapter [~~title~~] (relating to Applicable Laws and Regulations).

(2) For the purpose of this section, the policies that apply to nonprescription drugs as described in the United States Food and Drug Administration's (FDA) Compliance Policy Guides are the policies of

the department. [For the purpose of this section, the policies described in the United States Food and Drug Administration's (FDA's) Compliance Policy Guides as they apply to nonprescription drugs shall be the policies of the department.]

(3) Nonprescription drug wholesalers must not purchase or receive drugs in this state other than from drug distributors licensed by the department.

(b) Federal establishment registration and drug listing.

(1) All persons who operate as nonprescription drug manufacturers in Texas must [shall] meet the requirements in 21 Code of Federal Regulations (CFR)[,] Part 207, Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs, and the National Drug Code. [titled "Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution."]

(2) New nonprescription drugs offered for sale by wholesale distributors must [shall] have met, if applicable, the requirements of 21 CFR[,] Part 314, [titled "]Applications for FDA Approval to Market a New Drug.["]

(c) Good manufacturing practices. Manufacturers of nonprescription drug products must comply [be in compliance] with the applicable requirements in:

(1) 21 CFR[,] Part 210, [titled "]Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General, as amended["];

(2) 21 CFR[,] Part 211, [titled "] Current Good Manufacturing Practice for Finished Pharmaceuticals, as amended [; General"];

(3) 21 CFR[,] Part 225, [titled "] Current Good Manufacturing Practice for Medicated Feeds, as amended ["; and]

(4) 21 CFR[,] Part 226, [titled "] Current Good Manufacturing Practice for Type A Medicated Articles, as amended; and [Article."]

(5) the [The] regulations in this subsection governing [these parts govern] the methods used in, and the facilities or controls used for, the manufacture, processing, packing, or holding of a drug to ensure [assure that] each drug meets the requirements of the Federal Food, Drug, and Cosmetic Act, 21 USC §301, et seq., as amended, (Federal Act) [Federal Act] as to safety, and has the identity and strength meeting [and meets] the quality and purity characteristics [that] it purports or is represented to possess.

(d) Buildings and facilities.

(1) All manufacturing, processing, packing, or holding of drugs by nonprescription drug manufacturers must [shall] take place in buildings and facilities described in subsection (c) of this section.

(2) Manufacturing [No manufacturing], processing, packing, or holding of nonprescription drugs must not [shall] be conducted in any personal residence.

(3) Sale [No sale] of nonprescription drugs must not [shall] be conducted in any flea market.

(4) Any place of business used by a wholesale distributor of nonprescription drugs who is not a manufacturer to store, warehouse, hold, offer, transport, or display drugs must [shall]:

(A) be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(B) have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, and space;

(C) be maintained in a clean and orderly condition and in good repair, including the walls, ceilings, windows, doors, and floors of the premises;

(D) be free from infestation by insects, rodents, birds, or vermin of any kind; and

(E) utilize [have] a quarantine area for storage of drugs that are outdated, damaged, deteriorated, returned, recalled, misbranded, or adulterated, that is clearly designated and separated from other sections where drugs are stored so drugs in this subchapter are not confused with usable drugs.

(e) Storage of nonprescription drugs. All nonprescription drugs stored by wholesale distributors must [shall] be held at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs and the standards set forth in the latest edition of the United States Pharmacopeia/National Formulary (USP/NF). If no storage requirements are established for a nonprescription drug, the nonprescription drug may be held at controlled room temperature, as defined in the USP/NF, to help ensure that its identity, strength, quality, and purity are not adversely affected. Prior to storage in inventory, a wholesale distributor must:

(1) upon receipt, visually examine each outside shipping container for identity and to prevent the acceptance of contaminated drugs otherwise unfit for distribution; and

(2) carefully inspect each outgoing shipment for identity of the drug and to prevent delivery of drugs that have been damaged in storage, including drugs held under improper conditions.

(f) Operating procedures for wholesale distributors who are not manufacturers. Written procedures describing the holding of nonprescription drug products by wholesale distributors of nonprescription drugs who are not manufacturers must [shall] be established and followed and [shall] include:

(1) a procedure for identifying and retrieving nonprescription drug products [that are] subject to a recall; and

(2) a quarantine procedure for nonprescription drug products that have expired; are subject to recall; or are otherwise determined to be adulterated or misbranded, for the return, destruction, or other disposal of those items.

(g) Nonprescription drug labeling. Nonprescription drugs sold by wholesale distributors must [shall] meet the labeling requirements of the Act and 21 CFR[,] Part 201, [titled "]Labeling.["]

(h) Nonprescription drugs that are combination products. Any nonprescription drug that is a combination product as described in §229.246(c) of this title (relating to Licensure Requirements) is also subject to the applicable requirements in Subchapter X of this chapter (relating to Licensing of Device Distributors and Manufacturers).

(i) Nonprescription drugs that are also cosmetics. Any nonprescription drug that is also a cosmetic or component thereof is also subject to the applicable requirements of Subchapter D of this chapter (relating to Regulation of Cosmetics).

§229.252. Enforcement and Penalties.

(a) Inspection. To enforce this subchapter [these sections] or the Act [Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431 (Act)], the commissioner, an authorized agent, or a health authority, may, on presenting appropriate credentials to the owner, operator, or agent in charge of a place of business:

(1) enter at reasonable times a place of business, including a factory or warehouse, in which a nonprescription drug is manufactured, packed, or held for introduction into commerce or held after the introduction;

(2) enter a vehicle being used to transport or hold a nonprescription drug in commerce; or

(3) inspect at reasonable times, within reasonable limits, and in a reasonable manner, the place of business or vehicle and all equipment, finished and unfinished materials, containers, and labeling of any item, and obtain samples necessary for the enforcement of this subchapter [these sections] or the Act.

(b) Receipt for samples. An authorized agent or health authority who inspects [makes an inspection of] a place of business, including a factory or warehouse, and obtains a sample during or on completion of the inspection and before leaving the place of business, must [shall] give [to] the owner, operator, or the owner's or operator's agent a receipt describing the sample.

(c) Access to records.

(1) A person who is required to maintain records referenced in this subchapter [these sections] or under the Act [Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431 (Act)], or Federal Food, Drug, and Cosmetic Act (Federal Act), Chapter V, or a person who is in charge or custody of those records, must [shall], at the request of an authorized agent or health authority, permit the authorized agent or health authority at all reasonable times access to [and to copy and verify the] records for verification and copying.

(2) A person, including a carrier engaged in commerce, or other person receiving a nonprescription drug in commerce or holding a nonprescription drug received in commerce must [shall], at the request of an authorized agent, permit the authorized agent at all reasonable times to have access to and to copy and verify all records showing:

(A) the movement in commerce of any nonprescription drug;

(B) the holding of any nonprescription drug after movement in commerce; and

(C) the quantity, shipper, and consignee of any nonprescription drug.

(d) Retention of records. Records required by this subchapter must [these sections shall] be maintained at the place of business or other location that is reasonably accessible for a period of at least three years following disposition of the nonprescription drug unless a greater period of time is required by [laws and regulations adopted in] §229.242 of this subchapter [title] (relating to Applicable Laws and Regulations).

(e) Adulterated and misbranded nonprescription drug. If the department identifies an adulterated or misbranded nonprescription drug, the department may impose the applicable provisions of Subchapter C of the Act, including[, but not limited to:] detention, emergency order, recall, and [condemnation, destruction, injunction, civil penalties, criminal penalties, and/or] administrative penalties. Administrative [and civil] penalties will be assessed using the Severity Levels contained in §229.261 of this chapter (relating to Assessment of Administrative Penalties). The department may request the attorney general or local law enforcement institute an action for criminal penalties, collection of civil penalties, condemnation, destruction, and injunction under the Act [§229.251 of this title (relating to Minimum Standards for Licensure)].

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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Cynthia Hernandez
General Counsel
Department of State Health Services
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For further information, please call: (512) 834-6755

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SUBCHAPTER W. LICENSING OF WHOLESALE DISTRIBUTORS OF PRESCRIPTION DRUGS--INCLUDING GOOD MANUFACTURING PRACTICES

25 TAC §§229.419 - 229.430

STATUTORY AUTHORITY

The proposed amendments are authorized by Texas Health and Safety Code §431.241 and §431.244, which provides the Executive Commissioner of HHSC with authority to adopt rules to enforce the Texas Food, Drug, and Cosmetic Act and adopts specific rules under Code of Federal Regulations, Title 21 as a rule under this chapter; and Texas Government Code §531.0055, and Texas Health and Safety Code §1001.075, which authorize the Executive Commissioner of HHSC to adopt rules and policies necessary for the operation and provision of health and human services by DSHS and for the administration of Texas Health and Safety Code Chapter 1001, including Chapter 431, the Texas Food, Drug, and Cosmetic Act.

The proposed amendments implement Texas Government Code Chapter 531; and Texas Health and Safety Code Chapters 431 and 1001.

§229.419. Purpose.

This subchapter provides [for] the minimum licensing requirements necessary to ensure the safety and efficacy of prescription drugs offered for sale by wholesale distributors.

§229.420. Applicable Laws and Regulations.

(a) The department adopts by reference the following laws and regulations:

(1) Federal Food, Drug, and Cosmetic Act, 21 United States Code (USC) [(U.S.C.),] §301 et seq., as amended;

(2) 9 Code of Federal Regulations (CFR)[,] Part 113, Standard Requirements, as amended;

(3) 21 CFR[,] Part 70, Color Additives, as amended;

(4) 21 CFR[,] Part 71, Color Additive Petitions, as amended;

(5) 21 CFR[,] Part 73, Listing of Color Additives Exempt From Certification, as amended;

(6) 21 CFR[,] Part 74, Listing of Color Additives Subject to Certification, as amended;

(7) 21 CFR[,] Part 80, Color Additive Certification, as amended;

(8) 21 CFR[,] Part 81, General Specifications and General Restrictions for Provisional Color Additives for Use [~~use~~] in Foods, Drugs, and Cosmetics, as amended;

(9) 21 CFR[,] Part 82, Listing of Certified Provisionally Listed Colors and Specifications, as amended;

(10) 21 CFR[,] Part 200, General, as amended;

(11) 21 CFR[,] Part 201, Labeling, as amended;

(12) 21 CFR[,] Part 202, Prescription Drug Advertising, as amended;

(13) 21 CFR[,] Part 203, Prescription Drug Marketing, as amended;

(14) 21 CFR[,] Part 205, Guidelines for State Licensing of Wholesale Prescription Drug Distributors, as amended;

(15) 21 CFR[,] Part 206, Imprinting of Solid Oral Dosage Form Drug Products for Human Use, as amended;

(16) 21 CFR[,] Part 207, Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs, and the National Drug Code [~~Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution~~], as amended;

(17) 21 CFR[,] Part 210, Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General, as amended;

(18) 21 CFR[,] Part 211, Current Good Manufacturing Practice for Finished Pharmaceuticals, as amended;

(19) 21 CFR Part 212, Current Good Manufacturing Practice for Positron Emission Tomography Drugs, as amended;

(20) [~~(19)~~] 21 CFR[,] Part 216, Human Drug [~~Pharmacy~~] Compounding, as amended;

(21) [~~(20)~~] 21 CFR[,] Part 225, Current Good Manufacturing Practice for Medicated Feeds, as amended;

(22) [~~(21)~~] 21 CFR[,] Part 226, Current Good Manufacturing Practice for Type A Medicated Articles, as amended;

(23) [~~(22)~~] 21 CFR[,] Part 250, Special Requirements For Specific Human Drugs, as amended;

(24) 21 CFR Part 251, §804, Importation Program, as amended;

(25) [~~(23)~~] 21 CFR[,] Part 290, Controlled Drugs, as amended;

(26) [~~(24)~~] 21 CFR[,] Part 299, Drugs; Official Names and Established Names, as amended;

(27) [~~(25)~~] 21 CFR[,] Part 300, General, as amended;

(28) [~~(26)~~] 21 CFR[,] Part 310, New Drugs, as amended;

(29) [~~(27)~~] 21 CFR[,] Part 312, Investigational New Drug Application, as amended;

(30) [~~(28)~~] 21 CFR[,] Part 314, Applications for FDA Approval to Market a New Drug [~~or an Antibiotic Drug~~], as amended;

(31) [~~(29)~~] 21 CFR[,] Part 315, Diagnostic Radiopharmaceuticals, as amended;

(32) [~~(30)~~] 21 CFR[,] Part 316, Orphan Drugs, as amended;

(33) [~~(31)~~] 21 CFR[,] Part 320, Bioavailability and Bioequivalence Requirements, as amended;

(34) [~~(32)~~] 21 CFR[,] Part 361, Prescription Drugs for Human Use Generally Recognized as Safe and Effective and Not Misbranded: Drugs Used in [~~In~~] Research, as amended;

(35) [~~(33)~~] 21 CFR[,] Part 500, General, as amended;

(36) [~~(34)~~] 21 CFR[,] Part 510, New Animal Drugs, as amended;

(37) [~~(35)~~] 21 CFR[,] Part 511, New Animal Drugs for Investigational Use, as amended;

(38) [~~(36)~~] 21 CFR[,] Part 514, New Animal Drug Applications, as amended;

(39) [~~(37)~~] 21 CFR[,] Part 515, Medicated Feed Mill License, as amended;

(40) 21 CFR Part 516, New Animal Drugs for Minor Use and Minor Species, as amended;

(41) [~~(38)~~] 21 CFR[,]Part 520, Oral Dosage Form New Animal Drugs, as amended;

(42) [~~(39)~~] 21 CFR[,] Part 522, Implantation or Injectable Dosage Form New Animal Drugs, as amended;

(43) [~~(40)~~] 21 CFR[,] Part 524, Ophthalmic and Topical Dosage Form New Animal Drugs, as amended;

(44) [~~(41)~~] 21 CFR[,] Part 526, Intramammary Dosage Form New Animal Drugs [~~Forms~~], as amended;

(45) 21 CFR Part 528, New Animal Drugs in Genetically Engineered Animals, as amended;

(46) [~~(42)~~] 21 CFR[,] Part 529, Certain Other Dosage Form New Animal Drugs, as amended;

(47) [~~(43)~~] 21 CFR[,] Part 530, Extralabel Drug Use in Animals, as amended;

(48) [~~(44)~~] 21 CFR[,] Part 556, Tolerances for Residues of New Animal Drugs in Food, as amended;

(49) [~~(45)~~] 21 CFR[,] Part 558, New Animal Drugs for Use in Animal Feeds, as amended;

(50) [~~(46)~~] 21 CFR[,] Part 589, Substances Prohibited From Use in Animal Food or Feed, as amended;

(51) [~~(47)~~] 21 CFR[,] Part 600, Biological Products: General, as amended;

(52) [~~(48)~~] 21 CFR[,] Part 601, Licensing, as amended;

(53) [~~(49)~~] 21 CFR[,] Part 610, General Biological Products Standards, as amended;

(54) [~~(50)~~] 21 CFR[,] Part 660, Additional Standards for Diagnostic Substances for Laboratory Tests, as amended;

(55) [~~(51)~~] 21 CFR[,] Part 680, Additional Standards for Miscellaneous Products, as amended;

(56) 21 CFR Part 700, General, as amended;

(57) 21 CFR Part 701, Cosmetic Labeling, as amended;

(58) 21 CFR Part 740, Cosmetic Product Warning Statements, as amended;

(59) 21 CFR Part 1271, Human Cells, Tissues, and Cellular and Tissue-Based Products, as amended;

(60) [~~(52)~~] 21 CFR[~~,~~] Part 1300, Definitions, as amended;

(61) [~~(53)~~] 21 CFR[~~,~~] Part 1301, Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances, as amended;

(62) [~~(54)~~] 21 CFR[~~,~~] Part 1302, Labeling and Packaging Requirements For Controlled Substances, as amended;

(63) [~~(55)~~] 21 CFR[~~,~~] Part 1304, Records and Reports of Registrants, as amended;

(64) [~~(56)~~] 21 CFR[~~,~~] Part 1305, Orders for Schedule I and Schedule II Controlled Substances, as amended;

(65) [~~(57)~~] 21 CFR[~~,~~] Part 1306, Prescriptions, as amended; [~~and~~]

(66) [~~(58)~~] 21 CFR[~~,~~] Part 1307, Miscellaneous; and

(67) 21 CFR Part 1317, Disposal, as amended.

(b) Copies of these laws and regulations are indexed and filed at the Texas Department of State Health Services [~~department~~], 1100 West 49th Street, Austin, Texas 78756, and are available for inspection during normal working hours. Electronic copies of these laws and regulations are available online at www.dshs.texas.gov [~~http://www.dshs.state.tx.us/license.shtm~~].

(c) Nothing in this subchapter relieves [~~shall relieve~~] any person of the responsibility for complying with other applicable Texas and federal laws and regulations.

§229.421. Definitions.

The following words and terms, when used in this subchapter, [~~must~~] have the following meanings, unless the context clearly indicates otherwise.

(1) Act--The Texas Food, Drug, and Cosmetic Act, Texas Health and Safety Code[~~,~~] Chapter 431.

(2) Adulterated drug--Has the meaning specified in the Act [~~Texas Food, Drug, and Cosmetic Act, Health and Safety Code, §431.111~~].

(3) Authorized agent--An employee of the department who is designated by the commissioner to enforce the provisions of the Act.

(4) Broker--A person engaged in the offering or contracting for wholesale distribution; sale or [~~and/or~~] transfer of a prescription drug into, within, or out of Texas; and, who does not take title to or physical possession of the prescription drug.

(5) Change of ownership--A sole proprietor who transfers all or part of the facility's ownership to another person or persons; the removal, addition, or substitution of a person or persons as a partner in a facility owned by a partnership; a corporate sale, transfer, reorganization, or merger of the corporation which owns the facility if sale, transfer, reorganization, or merger causes a change in the facility's ownership to another person or persons; or if any other type of association, the removal, addition, or substitution of a person or persons as a principal of such association.

(6) Co-licensed product partner--One of two or more parties having [~~that have~~] the right to engage in the manufacturing or marketing of a prescription drug consistent with the United States Food and Drug Administration's (FDA) regulations and guidance [~~guidances~~] implementing the Prescription Drug Marketing Act of 1987 (Pub. L. No. 100 - 293).

(7) Commissioner--Commissioner of the Texas Department of State Health Services.

(8) Component--Any ingredient intended for use in the manufacture of a drug product, including those that might not appear in such drug product.

(9) [~~(8)~~] Department--The Texas Department of State Health Services.

(10) [~~(9)~~] Device--An instrument apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory[~~, that is~~]:

(A) recognized in the official United States Pharmacopoeia National Formulary or any supplement to it;

(B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in humans [~~man~~] or other animals; or

(C) intended to affect the structure or any function of the body of humans [~~man~~] or other animals and that does not achieve any of its principal intended purposes through chemical action within or on the body of humans [~~man~~] or other animals and is not dependent on metabolization for the achievement of any of its principal intended purposes.

(11) [~~(10)~~] Drop shipment--The sale of a prescription drug to a wholesale distributor by the manufacturer of the prescription drug, or by the manufacturer's co-licensed product partner, third-party logistics provider, or exclusive distributor, in which:

(A) the wholesale distributor takes title but not physical possession of the prescription drug;

(B) the wholesale distributor invoices the pharmacy, pharmacy warehouse, or other person authorized by law to dispense or administer the drug to a patient; and

(C) the pharmacy, pharmacy warehouse, or other authorized person receives delivery of the prescription drug directly from the manufacturer or the manufacturer's third-party logistics provider or exclusive distributor.

(12) [~~(11)~~] Drug--Articles recognized in the official United States Pharmacopoeia National Formulary, or any supplement to it;[~~,~~] articles designated or intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans [~~man~~] or other animals; [~~,~~] articles, other than food, intended to affect the structure or any function of the body of humans [~~man~~] or other animals; [~~,~~] and articles intended for use as a component of any such article. The term does not include devices or their components, parts, or accessories. A food for which a claim is made in accordance with the Federal Food, Drug, and Cosmetic Act, §403(r) and 21 United States Code (USC) §301, et seq. [~~Federal Act, §403(r)~~], and for which the claim is approved by the FDA [~~United States Food and Drug Administration~~], is not a drug solely because the label or labeling contains such a claim.

(13) [~~(12)~~] Emergency medical reasons--Includes transfers of a prescription drug between a wholesale distributor or pharmacy to alleviate a temporary shortage of a prescription drug arising from delays in or interruption of regular distribution schedules; sales to nearby emergency medical services, i.e., ambulance companies and firefighting organizations in the same state or same marketing or service area, or nearby licensed practitioners of drugs for use in the treatment of acutely ill or injured persons; provision of minimal emergency supplies of drugs to nearby nursing homes for use in emergencies or during hours of the day when necessary drugs cannot be obtained; and transfers of prescription drugs by a retail pharmacy to alleviate a temporary shortage.

(14) [~~(13)~~] Federal Act--Federal Food, Drug, and Cosmetic Act, 21 USC [~~United States Code (U.S.C.)~~], §301, et seq., as amended.

(15) [~~(14)~~] Flea market--A location at which booths or similar spaces are rented or otherwise made available temporarily to two or more persons and at which the persons offer tangible personal property for sale.

(16) Inactive ingredient--Any component, other than an active ingredient, including excipient, flavor, fragrance, and color.

(17) [~~(15)~~] Labeling--All labels and other written, printed, or graphic matter:

(A) upon any drug or any of its containers or wrappers; or

(B) accompanying such drug.

(18) [~~(16)~~] Manufacturer--A person who manufactures, prepares, propagates, compounds, processes, packages, or repackages prescription drugs, or a person who changes the container, wrapper, or labeling of any prescription drug package. A person licensed or approved by the FDA [~~United States Food and Drug Administration~~] to engage in the manufacture of drugs or devices, consistent with the federal agency's definition of manufacturer [~~"manufacturer"~~] under the agency's regulations and guidance [~~guidances~~] implementing the Prescription Drug Marketing Act of 1987 (Pub. L. No. 100 - 293). The term does not include a pharmacist engaged in compounding [~~that is~~] done within the practice of pharmacy and pursuant to a prescription drug order or initiative from a practitioner for a patient or prepackaging [~~that is~~] done in accordance with Texas Occupations Code[~~,~~] §562.154.

(19) [~~(17)~~] Manufacturer's exclusive distributor--A person who holds a wholesale distributor license under this subchapter, who contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of the manufacturer, and who takes title to, but does not have general responsibility to direct the sale or disposition of, the manufacturer's prescription drug. A manufacturer's exclusive distributor must be an authorized distributor of record to be considered part of the normal distribution channel.

(20) [~~(18)~~] Misbranded drug--Has the meaning specified in the Act at [~~Texas Food, Drug, and Cosmetic Act, Health and Safety Code,~~] §431.112.

(21) [~~(19)~~] Nonprescription drug--Any drug that is not a prescription drug, including the terms Over-the-Counter Drug and Non-legend Drug.

(22) [~~(20)~~] Normal distribution channel--A chain of custody for a prescription drug, either directly or by drop shipment, from the manufacturer of the prescription drug, the manufacturer to the manufacturer's co-licensed product partner, the manufacturer to the manufacturer's third-party logistics provider, or the manufacturer to the manufacturer's exclusive distributor, to:

(A) a pharmacy to:

(i) a patient; or

(ii) another designated person authorized by law to dispense or administer the drug to a patient;

(B) an authorized distributor of record to:

(i) a pharmacy to a patient; or

(ii) another designated person authorized by law to dispense or administer the drug to a patient;

(C) an authorized distributor of record to a wholesale distributor licensed under this subchapter to another designated person authorized by law to administer the drug to a patient;

(D) an authorized distributor of record to a pharmacy warehouse to the pharmacy warehouse's intracompany pharmacy;

(E) a pharmacy warehouse to the pharmacy warehouse's intracompany pharmacy or another designated person authorized by law to dispense or administer the drug to a patient;

(F) a person authorized by law to prescribe a prescription drug that by law may be administered only under the supervision of the prescriber; or

(G) an authorized distributor of record to one other authorized distributor of record to a licensed practitioner for office use.

(23) [~~(21)~~] Person--An individual, corporation, business trust, estate, trust, partnership, association, or any other public or private legal entity.

(24) [~~(22)~~] Pharmacy warehouse--A location for which a person holds a wholesale drug distribution license under this subchapter, serving [~~that serves~~] as a central warehouse for drugs or devices, and from which intracompany sales or transfers of drugs or devices are made to a group of pharmacies under common ownership and control.

(25) [~~(23)~~] Prescription drug--Any drug (including any biological product, except for blood and blood components intended for transfusion or biological products that are also medical devices) required by federal [~~Federal~~] law (including federal [~~Federal~~] regulation) to be dispensed only by a prescription, including finished dosage forms and bulk drug substances subject to the Federal Act, §503(b).

(26) [~~(24)~~] Repackage--Repackaging or otherwise changing the container, wrapper, or labeling of a drug to further the distribution of a prescription drug. The term does not include repackaging by a pharmacist to dispense a drug to a patient or prepackaging in accordance with Texas Occupations Code[~~,~~] §562.154.

(27) [~~(25)~~] Repackager--A person who engages in repackaging.

(28) [~~(26)~~] Third-party logistics provider--A person who holds a wholesale distributor license under this subchapter, who contracts with a prescription drug manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of the manufacturer, and who does not take title to the prescription drug or have general responsibility to direct the prescription drug's sale or disposition. A third-party logistics provider must be an authorized distributor of record to be considered part of the normal distribution channel.

(29) [~~(27)~~] Verification--A person who is engaged in the wholesale distribution of a prescription drug, and who is in possession of a pedigree for a prescription drug must [~~shall~~], before distributing the prescription drug, authenticate and certify, in accordance with the Act at Texas Food, Drug, and Cosmetic Act, Health and Safety Code[~~,~~] §431.412 and [~~,~~] §431.413, and §229.429(f)(3)(G) of this subchapter (relating to Minimum Standards of Licensure), [~~title, that~~] each transaction listed on the pedigree has occurred.

(30) [~~(28)~~] Wholesale distribution--Distribution of prescription drugs to a person other than a consumer or patient. The term does not include:

(A) intracompany sales of prescription drugs, which means transactions or transfers of prescription drugs between a division, subsidiary, parent, or affiliated or related company [~~that is~~] under common ownership and control or any transaction or transfer between co-license holders of a co-licensed product;

(B) the sale, purchase, trade, or transfer of prescription drugs or the offer to sell, purchase, trade, or transfer a prescription drug for emergency medical reasons including a transfer of a prescription drug by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;

(C) the distribution of prescription drug samples by a representative of a manufacturer;

(D) the return of drugs by a hospital, health care entity, or charitable institution in accordance with 21 Code of Federal Regulations (CFR) [~~CFR,~~] §203.23;

(E) the sale of reasonable quantities by a retail pharmacy of a prescription drug to a licensed practitioner for office use;

(F) the sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug under a prescription;

(G) the sale, transfer, merger, or consolidation of all or part of the business of a pharmacy from or with another pharmacy, whether accomplished as a purchase and sale of stock or business assets;

(H) the delivery of, or offer to deliver, a prescription drug by a common carrier solely in the common carrier's usual course of business of transporting prescription drugs, if the common carrier does not store, warehouse, or take legal ownership of the prescription drug;

(I) the sale or transfer from a retail pharmacy or pharmacy warehouse of expired, damaged, returned, or recalled prescription drugs to the original manufacturer or to a third-party returns processor in accordance with the procedures set out in [~~Title~~] 21[~~,~~] CFR [~~Code of Federal Regulations,~~] §203.23(a)(1) - (5) for other returns;

(J) the purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;

(K) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in [~~§501(c)(3) of~~] the Internal Revenue Code of 1986, 26 USC §501(c)(3), [~~1954~~] to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(L) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities [~~that are~~] under common control; for purposes of this subchapter, common control means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract, or otherwise; or

(M) the sale, purchase, or trade of blood and blood components intended for transfusion.

(31) [~~(29)~~] Wholesale distributor--A person engaged in the wholesale distribution of prescription drugs, including[~~, but not limited to,~~] a manufacturer, repackager, own-label distributor, private-label distributor, jobber, broker, manufacturer warehouse, distributor warehouse, or other warehouse, manufacturer's exclusive distributor, authorized distributor of record, drug wholesaler or distributor, independent wholesale drug trader, specialty wholesale distributor, third-party logistics provider, retail pharmacy that conducts wholesale distribution, and pharmacy warehouse that conducts wholesale distribution.

§229.422. Sale of a Prescription Drug.

Any reference in this subchapter to the sale of a prescription drug must be considered to include the manufacture, packaging, exposure, offer, possession, and holding of any prescription drug for sale; the sale, dispensing, and providing [~~giving~~] of any prescription drug; and supplying or applying of any prescription drug in the operation of any prescription drug place of business.

§229.423. Exemptions.

(a) General. A person who engages in the wholesale distribution of prescription drugs in this state for use in humans is exempt from this subchapter if the person is exempt under:

(1) the Prescription Drug Marketing Act of 1987 (PDMA Act) [~~(Act)~~], (21 United States Code (USC) [~~U.S.C.,~~] §353(c)(3)(B));

(2) the regulations adopted by the secretary to administer and enforce the PDMA Act [~~that Act~~];

(3) the interpretations of the PDMA Act [~~that Act~~] set forth in the compliance policy manual of the United States Food and Drug Administration; or

(4) the Texas Occupations Code[~~,~~] §562.154.

(b) Exemptions from licensing. Persons who engage in the following types of distribution of prescription drugs are exempt from the licensing requirements of this subchapter, to the extent [~~that~~] it does not violate provisions of the Texas Controlled Substances Act, Texas Health and Safety Code[~~,~~] Chapter 481, or the Texas Dangerous Drug Act, Texas Health and Safety Code[~~,~~] Chapter 483:

(1) intracompany sales of prescription drugs, which means transactions or transfers of prescription drugs between a division, subsidiary, parent, or affiliated or related company [~~that is~~] under common ownership and control, or any transaction or transfer between co-license holders of a co-licensed product;

(2) the sale, purchase, trade, or transfer of prescription drugs or the offer to sell, purchase, trade, or transfer a prescription drug for emergency medical reasons; including a transfer of a prescription drug by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;

(3) the distribution of prescription drug samples by a representative of a manufacturer;

(4) the return of drugs by a hospital, health care entity, or charitable institution in accordance with Title 21, Code of Federal Regulations (CFR) [~~,~~] §203.23;

(5) the sale of reasonable quantities by a retail pharmacy of a prescription drug to a licensed practitioner for office use;

(6) the sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug under a prescription;

(7) the sale, transfer, merger, or consolidation of all or part of the business of a pharmacy from or with another pharmacy, whether accomplished as a purchase and sale of stock or business assets;

(8) the delivery of, or offer to deliver, a prescription drug by a common carrier solely in the common carrier's usual course of business of transporting prescription drugs, if the common carrier does not store, warehouse, or take legal ownership of the prescription drug; [~~or~~]

(9) the sale or transfer from a retail pharmacy or pharmacy warehouse of expired, damaged, returned, or recalled prescription drugs to the original manufacturer or to a third-party returns processor in accordance with procedures set out in 21 CFR [~~Title 21, Code of Federal Regulations,~~] §203.23(a)(1) - (5) for returns;

(10) the purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;

(11) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in [~~§501(c)(3) of~~] the Internal Revenue Code of 1986, 26 USC §501(c)(3), [~~1954~~] to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(12) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control; for purposes of this subchapter, common control means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, [~~by~~] contract, or otherwise; or

(13) the sale, purchase, or trade of blood and blood components intended for transfusion.

(c) Applicability of other requirements. An exemption from the licensing requirements granted in subsection (b) of this section does not constitute an exemption from other applicable requirements for prescription drugs under this subchapter or under the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431.

(d) Exemption from certain requirements for certain wholesale distributors.

(1) A wholesale distributor that distributes only prescription drugs that are medical gases is exempt from the following requirements: §229.424(d) of this subchapter [~~title~~] (relating to Licensure Requirements), §229.425(b)(4) - (5), (c) and (d) of this subchapter [~~title~~] (relating to Licensing Procedures); and §229.424(n) and §229.425(h) of this subchapter [~~title~~] concerning bonds.

(2) A wholesale distributor that is a manufacturer or a third-party logistics provider on behalf of a manufacturer is exempt from the following requirements: §229.424(d) of this title; §229.425(b)(4) - (5), (c) and (d) of this subchapter [~~title~~]; and §229.424(n) and §229.425(h) of this subchapter [~~title~~] concerning bonds.

(3) A state agency or a political subdivision of this state that distributes prescription drugs using federal or state funding to nonprofit health care facilities or local intellectual and developmental disability authorities, referred to as local mental health or mental retardation authorities, for distribution to a pharmacy, practitioner, or patient is exempt from §229.424(d) and (n) and §229.425(d) and (h) of this subchapter [~~title~~] concerning bonds, and §229.429(f) [~~229.429(f)~~] of this subchapter [~~title~~] (relating to Minimum Standards of Licensure) concerning pedigree.

(4) The executive commissioner [~~Executive Commissioner~~] of the Texas Health and Human Services Commission by rule may exempt specific purchases of prescription drugs by state agencies and political subdivisions of this state if the executive commissioner [~~Executive Commissioner~~] determines [~~that~~] the requirements of this subchapter would result in a substantial cost to the state or a political subdivision of the state.

§229.424. Licensure Requirements.

(a) General. Except as provided in §229.423 of this subchapter [~~title~~] (relating to Exemptions), a person may not engage in the wholesale distribution of prescription drugs in Texas, as defined in §229.421(30) - (31) [~~§229.421(28) - (29)~~] of this subchapter [~~title~~] (relating to Definitions), unless the person has a valid license from the commissioner of the department for each place of business.

(b) Out-of-state place of business.

(1) Except as provided by §229.423 of this subchapter [~~title~~], a person who engages in the wholesale distribution of prescription drugs from outside this state may only engage in the wholesale distribution of prescription drugs in this state if the person holds a license as required in subsection (a) of this section.

(2) The department may accept reports from authorities in other jurisdictions to determine the extent of compliance with the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431 and this subchapter [~~these sections~~].

(3) The department may issue a license to a person who engages in the wholesale distribution of prescription drugs outside this state to engage in the wholesale distribution of prescription drugs in this state if, after an examination of the reports of the person's compliance history and current compliance record, the department determines [~~that~~] the person is in compliance with the Act and this subchapter [~~these sections~~].

(4) The department considers [~~shall consider~~] each license application and any related documents or reports filed by or in connection with a person who wishes to engage in the wholesale distribution of prescription drugs in this state on an individual basis.

(c) Combination product. If the United States Food and Drug Administration determines, with respect to a product that is a combination of a prescription drug and a device, [~~that~~] the primary mode of action of the product is as a prescription drug, a wholesale distributor of such a product is subject to licensure as described in this section.

(d) Applicant qualifications. To qualify for the issuance or renewal of a wholesale distributor license under this subchapter, the designated representative of an applicant or license holder must:

(1) be at least 21 years of age;

(2) have been employed full-time for at least three years by a pharmacy or a wholesale distributor in a capacity related to the dispensing or distributing of prescription drugs, including recordkeeping for the dispensing or distributing of prescription drugs;

(3) be employed by the applicant full-time in a managerial-level position;

(4) be actively involved in and aware of the actual daily operation of the wholesale distributor;

(5) be physically present at the applicant's place of business during regular business hours, except when the absence of the designated representative is authorized, including sick leave and vacation leave;

(6) serve as a designated representative for only one applicant at any one time, except in a circumstance, as the department determines reasonable, in which more than one licensed wholesale distributor is co-located in the same place of business at the same address and the wholesale distributors are members of an affiliated group, as defined by the Internal Revenue Code of 1986, 26 USC §1504;

(7) not have been convicted of a violation of any federal, state, or local laws relating to wholesale or retail prescription drug distribution or the distribution of controlled substances; and

(8) not have been convicted of a felony under a federal, state, or local law.

(e) Proof of licensure. The license holder must show proof of licensure in a format readily available to the public and at each place of business.

[(e) Display of license. The license shall be displayed in an open public area at each place of business.]

(f) New place of business. Each person acquiring or establishing a place of business for the purpose of wholesale distribution of prescription drugs must [after the effective date of these sections shall] apply to the department for a license of such business before [prior to] beginning operation.

(g) Two or more places of business. If the wholesale distributor of prescription drugs operates more than one place of business, the wholesale distributor of prescription drugs must [shall] license each place of business separately.

(h) Pre-licensing inspection. The applicant must [shall] cooperate with any pre-licensing inspection by the department of the applicant's place of business.

(i) Issuance of license. In accordance with §229.281 of this chapter [title] (relating to Processing License/Permit Applications Relating to Food and Drug Operations), the department may license a wholesale distributor of prescription drugs who meets the requirements of this subchapter [these sections] and pays all license fees under [in compliance with] §229.427 of this subchapter [title] (relating to Licensure Fees).

(j) Transfer of license. Licenses are [shall] not [be] transferable from one person to another or from one place of business to another.

(k) License term. Unless the license is amended as provided in subsection (l) [(m)] of this section or suspended or revoked as provided in §229.428 of this subchapter [title] (relating to Refusal, Cancellation, Suspension, or Revocation of License), the license is valid for two years.

(l) Amendment of license. A license that is amended, including a change of name, [ownership ,] or a notification of a change in the location of a licensed place of business will require submission of an application as outlined in §229.425 of this subchapter [title] (relating to Licensing Procedures) and submission of fees as outlined in §229.427 of this subchapter [title].

(m) Renewal of license.

(1) The license application as outlined in §229.425 of this subchapter [title] and nonrefundable licensing fees as outlined in §229.427 of this subchapter [title] for each place of business must [shall] be submitted to the department not later than the 30th day after the date the wholesale distributor receives a renewal notification form from the department. A person who files a renewal application after the expiration date must [shall] pay an additional $100 as a delinquency fee.

(2) A license holder [licensee] who fails to submit a renewal application before [prior to] the current licensure expiration date and continues operations may be subject to the enforcement and penalty provisions in §229.430 of this subchapter [title] (relating to Enforcement and Penalties), and [and/or] the refusal, cancellation, suspension, and revocation provisions in §229.428 of this subchapter [title].

(3) A renewal license is [shall] only [be] issued when all past due license fees and delinquency fees are paid.

(n) Bond.

(1) A wholesale distributor applying for or renewing a license must [shall] submit, payable to this state, a bond or other equivalent security acceptable to the department, including an irrevocable letter of credit or a deposit in a trust account or financial institution, in the amount of $100,000 [payable to this state].

(2) The bond or equivalent security submitted under paragraph (1) of this subsection must secure payment of any fines or penalties imposed by the department or imposed in connection with an enforcement action by the attorney general, any fees or other enforcement costs, including attorney's fees payable to the attorney general, and any other fees and costs incurred by this state related to that license holder, [that are] authorized under the laws of this state and not paid by [that] the license holder [fails to pay] before the 30th day after the date a fine, penalty, fee, or cost is assessed.

(3) The department or this state may make a claim against a bond or security submitted under paragraph (1) of this subsection before the first anniversary of the date a license expires or is revoked under this subchapter.

(4) The department must [shall] deposit the bonds and equivalent securities received under this section in a separate account.

(5) A pharmacy warehouse [that is] not engaged in wholesale distribution is exempt from the bond requirement under paragraph (1) of this subsection.

(6) A single bond is sufficient to cover all places of business operated by a wholesale distributor in this state.

§229.425. Licensing Procedures.

(a) License application forms. License application forms may be obtained from the Texas Department of State Health Services [department], 1100 West 49th Street, Austin, Texas, 78756, or online at www.dshs.texas.gov [http://www.dshs.state.tx.us/license.shtm].

(b) Contents of license application. The application for licensure as a wholesale distributor of prescription drugs must [shall] be signed and verified, submitted on a license application form furnished by the department, and contain the following information:

(1) the name, full business address, and telephone number of the applicant;

(2) all trade or business names under which the business is conducted;

(3) the address, telephone number, and name of a contact person for each of the applicant's places of business;

(4) the type of business entity:

(A) if a person, the name of the person;

(B) if the business is a sole proprietorship, the name of the proprietor;

(C) if the business is a partnership, the name of the partnership and each of the partners; or

(D) if the business is a corporation, the name of the corporation, the place of incorporation, and the name and title of each corporate office and director;

(5) the name, date of birth, residence address, telephone number, and any information necessary to complete a criminal history record check on a designated representative of each place of business;

(6) a list of all licenses and permits issued to the applicant by any other state under which the applicant is permitted to purchase or possess prescription drugs;

(7) the name of the manager, if different from the designated representative, for each place of business;

(8) a list of categories which must be marked and adhered to in the determination and paying of the fee; and

(9) a statement verified by the applicant's signature acknowledging [~~that acknowledges~~] the applicant [~~has~~] read, understood, and agrees to abide by the provisions of this subchapter and those of the Texas Food, Drug, and Cosmetic Act, Texas Health and Safety Code[~~,~~] Chapter 431.

(c) Designated representatives.

(1) For each person who is a designated representative of each place of business, the applicant must [~~shall~~] provide the following to the department:

(A) the person's places [~~place(s)~~] of residence for the past seven years;

(B) the person's date and place of birth;

(C) the person's occupations, positions of employment, and offices held during the past seven years;

(D) the business name and address of any business, corporation, or other organization in which the person held an office under subsection (b)(4) of this section or in which the person conducted an occupation or held a position of employment;

(E) a statement of whether, during the preceding seven years, the person was the subject of a proceeding to revoke a license or a criminal proceeding and the nature and disposition of the proceeding;

(F) a statement of whether, during the preceding seven years, the person has been enjoined, either temporarily or permanently, by a court from violating any federal or state law regulating the possession, control, or distribution of prescription drugs, including the details concerning the event;

(G) a written description of any involvement by the person as an officer or director with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund, during the past seven years, that manufactured, administered, prescribed, distributed, or stored pharmaceutical products and any lawsuits in which the businesses were named as a party;

(H) a description of any misdemeanor or felony offense for which the person, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the person pled guilty or nolo contendere;

(I) a description of any criminal conviction of the person under appeal, a copy of the notice of appeal for that criminal offense, and a copy of the final written order of an appeal not later than the 15th day after the date of the appeal's disposition; and

(J) a photograph of the person taken not earlier than 180 days before the date the application was submitted.

(2) The information submitted under paragraph (1) of this subsection must be attested to under oath.

(d) Criminal history. The department will obtain an applicant's criminal history record information and may forward the fingerprints to the Federal Bureau of Investigation for a federal criminal history check.

(e) Renewal license application. The renewal application for licensure as a wholesale distributor of prescription drugs must be made on a license application form furnished by the department. Not later than the 30th day after the date the wholesale distributor receives the form, the wholesale distributor must [~~shall~~] identify and state under oath to the department any change in or correction to the information.

(f) Replacement license. In the event a current and valid license is lost, stolen, or destroyed, the license holder must [~~licensee shall~~] request a replacement license from the department by submitting an application and non-refundable fee as outlined in §229.427 of this subchapter [~~title~~] (relating to Licensing Fees). A replacement license is [~~shall~~] only [~~be~~] issued if the lost, stolen, or destroyed license was current and valid at the time of the request, and no changes in business name, location, or ownership have occurred.

(g) Texas.gov [~~texas.gov~~]. Applicants may submit initial and renewal license applications under this subchapter electronically [~~by the Internet~~] through texas.gov [~~at www.texas.gov~~]. The department is authorized to collect fees, in amounts determined by §229.427(a) of this subchapter [~~texas.gov,~~] to recover costs associated with application and renewal application processing through texas.gov.

(h) Bond. Applicants will submit a bond in a manner prescribed by the department.

§229.426. Report of Changes.

(a) Change in the content of a license application. The license holder must [~~shall~~] notify the department in writing within 10 [~~ten~~] days of any change which would render the information contained in the application for the license, reported pursuant to §229.425 of this subchapter [~~title~~] (relating to Licensing Procedures), no longer accurate. Failure to inform the department no later than 10 [~~ten~~] days of a change in the information required in the application for a license may result in an enforcement action, including [a] suspension or revocation of the license.

(b) Change in location of place of business. The license holder must notify the department at least [~~Not fewer than~~] 30 days in advance of an intended [~~the~~] change of address of the [~~, the licensee shall notify the department in writing of the licensee's intent to change the location of a~~] licensed place of business. The notice must include the address of the new location[~~,~~] and the name [~~and residence address~~] of the individual in charge of the business at the new location. Within [~~Not more than~~] 10 days of beginning operations at the new location [~~after the completion of the change of location~~], the license holder must [~~licensee shall~~] notify the department in writing to confirm the move [~~completion of the change of location~~], and provide verification or correction of the information provided on [~~previously provided or correct and confirm any information that has changed since providing~~] the notice of intent. The notice and confirmation required by this subchapter will be deemed adequate if the license holder submits [~~licensee sends~~] the notices by certified mail, return receipt requested, to the Texas Department of State Health Services, 1100 West 49th Street, Austin, Texas, 78756, or electronically through texas.gov [~~department at P.O. Box 149347, Austin, Texas 78714-9347, or submits them electronically through texas.gov at www.texas.gov~~].

§229.427. Licensure Fees

(a) License fee. Except as provided by §229.423 of this subchapter [~~title~~] (relating to Exemptions), no person may operate or conduct business as a wholesale distributor of prescription drugs without first obtaining a license from the department. All applicants for an initial wholesale distributor of prescription drugs license or a renewal license must [~~shall~~] pay a licensing fee unless otherwise exempt as provided by subsection (c) of this section. All fees are nonrefundable. Licenses are issued for two-year terms. A license shall only be issued when all past due license fees and delinquency fees are paid.

(1) In-state and out-of-state wholesale distributors of prescription drugs who are not manufacturers must [~~shall~~] pay a two-year license fee based on the gross annual sales of all drugs.

(A) For a wholesale distributor of only medical gases, the fees are:

(i) $675 for a two-year license;

(ii) $675 for a two-year license issued [~~that is~~] to a change of ownership; and

(iii) $337 for a license [~~that is~~] amended during the current licensure period due to minor changes.

(B) For a wholesale distributor with gross annual drug sales of $0 - $199,999.99, the fees are:

(i) $1,080 for a two-year license;

(ii) $1,080 for a two-year license issued [~~that is~~] due to a change of ownership; and

(iii) $540 for a license [~~that is~~] amended during the current licensure period due to minor changes.

(C) For a wholesale distributor with gross annual drug sales of $200,000 - $19,999,999.99, the fees are:

(i) $1,755 for a two-year license;

(ii) $1,755 for a two-year license issued [~~that is~~] due to a change of ownership; and

(iii) $877 for a license [~~that is~~] amended during the current licensure period due to minor changes.

(D) For a wholesale distributor with gross annual drug sales greater than or equal to $20 million, the fees are:

(i) $2,295 for a two-year license;

(ii) $2,295 for a two-year license issued [~~that is~~] due to a change of ownership; and

(iii) $1,147 for a license [~~that is~~] amended during the current licensure period due to minor changes.

(2) In-state and out-of-state wholesale distributors of medical gases who are not manufacturers and who also are required to be licensed as a device distributor under §229.439(a) of this chapter [~~title~~] (relating to Licensure Fees) or as a wholesale food distributor under §229.182(a)(3) of this chapter [~~title~~] (relating to Licensing/Registration Fee and Procedures) must [~~shall~~] pay a combined two-year license fee for each place of business. License fees are based on the combined gross annual sales of these regulated products (medical gases, foods, drugs, and [~~and/or~~] devices) as follows:

(A) For combined gross annual sales of $0 - $199,999.99, the fees are:

(i) $540 for a two-year license;

(ii) $540 for a two-year license [~~that is~~] issued due to a change of ownership; and

(iii) $270 for a license [~~that is~~] amended during the current licensure period due to minor changes.

(B) For combined gross annual sales of $200,000 - $499,999.99, the fees are:

(i) $810 for a two-year license;

(ii) $810 for a two-year license issued [~~that is~~] due to a change of ownership; and

(iii) $405 for a license [~~that is~~] amended during the current licensure period due to minor changes.

(C) For combined gross annual sales of $500,000 - $999,999.99, the fees are:

(i) $1,080 for a two-year license;

(ii) $1,080 for a two-year license issued [~~that is~~] due to a change of ownership; and

(iii) $540 for a license [~~that is~~] amended during the current licensure period due to minor changes.

(D) For combined gross annual sales of $1 million - $9,999,999.99, the fees are:

(i) $1,350 for a two-year license;

(ii) $1,350 for a two-year license issued [~~that is~~] due to a change of ownership; and

(iii) $675 for a license issued [~~that is amended~~] during the current licensure period due to minor changes.

(E) For combined gross annual sales greater than or equal to $10 million, the fees are:

(i) $2,025 for a two-year license;

(ii) $2,025 for a two-year license issued [~~that is~~] due to a change of ownership; and

(iii) $1,012 for a license [~~that is~~] amended during the current licensure period due to minor changes.

(3) In-state and out-of-state manufacturers of only medical gases must [~~shall~~] pay a two-year license fee based on the gross annual sales of all prescription drugs as follows.

(A) For gross annual drug sales of $0 - $199,999.99, the fees are:

(i) $1,080 for a two-year license;

(ii) $1,080 for a two-year license issued [~~that is~~] due to a change of ownership; and

(iii) $540 for a license [~~that is~~] amended during the current licensure period due to minor changes.

(B) For gross annual drug sales of $200,000 - $19,999,999.99, the fees are:

(i) $1,755 for a two-year license;

(ii) $1,755 for a two-year license issued [~~that is~~] due to a change of ownership; and

(iii) $877 for a license [~~that is~~] amended during the current licensure period due to minor changes.

(C) For gross annual drug sales greater than or equal to $20 million, the fees are:

(i) $2,295 for a two-year license;

(ii) $2,295 for a two-year license issued [~~that is~~] due to a change of ownership; and

(iii) $1,147 for a license [~~that is~~] amended during the current licensure period due to minor changes.

(4) In-state and out-of-state manufacturers of prescription drugs must [~~shall~~] pay a two-year license fee based on the gross annual sales of all drugs as follows.

(A) For gross annual drug sales of $0 - $199,999.99, the fees are:

(i) $1,080 for a two-year license;

(ii) $1,080 for a two-year license issued [~~that is~~] due to a change of ownership; and

(iii) $540 for a license [~~that is~~] amended during the current licensure period due to minor changes.

(B) For gross annual drug sales of $200,000 - $1,999,999.99, the fees are:

(i) $1,350 for a two-year license;

(ii) $1,350 for a two-year license issued [~~that is~~] due to a change of ownership; and

(iii) $697 for a license [~~that is~~] amended during the current licensure period due to minor changes.

(C) For gross annual drug sales of $2 million - $9,999,999.99, the fees are:

(i) $1,620 for a two-year license;

(ii) $1,620 for a two-year license issued [~~that is~~] due to a change of ownership; and

(iii) $847 for a license [~~that is~~] amended during the current licensure period due to minor changes.

(D) For gross annual drug sales of $10 million to $19,999,999.99, the fees are:

(i) $1,890 for a two-year license;

(ii) $1,890 for a two-year license issued [~~that is~~] due to a change of ownership; and

(iii) $997 for a license [~~that is~~] amended during the current licensure period due to minor changes.

(E) For gross annual drug sales greater than or equal to $20 million, the fees are:

(i) $2,295 for a two-year license;

(ii) $2,295 for a two-year license issued [~~that is~~] due to a change of ownership; and

(iii) $1,147 for a license [~~that is~~] amended during the current licensure period due to minor changes.

(b) Replacement license fee. The replacement license fee is $100.

(c) Proration of license fees. A person having [~~that has~~] more than one place of business may request a one-time proration of the license fees when applying for a license for each new place of business. Upon approval by the department, the license for the new place of business will have a renewal date [~~that is~~] the same as the firm's other licensed places of business.

(d) Exemption from license fees. A person is exempt from the license fees required by this section if the person is a charitable organization, as described in the Internal Revenue Code of 1986, 26 USC §501(c)(3), or a nonprofit affiliate of the organization, to the extent otherwise permitted by law.

§229.428. Refusal, Cancellation, Suspension, or Revocation of License.

(a) The commissioner may refuse an application for a wholesale distributor of prescription drugs license or may suspend or revoke such a license if the applicant or license holder [~~licensee~~]:

(1) has been convicted of a felony or misdemeanor involving [~~that involves~~] moral turpitude;

(2) is an association, partnership, or corporation and the managing officer or [~~and/or~~] any officer or director of a corporation has been convicted of a felony or misdemeanor involving [~~that involves~~] moral turpitude;

(3) is an association, partnership, or corporation and the managing officer or [~~and/or~~] any officer or director of a corporation has been convicted of a felony or misdemeanor involving the illegal use, sale, or transportation of intoxicating liquors, narcotic drugs, barbiturates, amphetamines, desoxyephedrine, their compounds or derivatives, or any other dangerous or habit-forming drugs;

(4) has violated any of the provisions of the Texas, Food, Drug, and Cosmetic Act, Texas Health and Safety Code[~~,~~] Chapter 431 (Act) or this subchapter;

(5) has violated the Texas Health and Safety Code[~~,~~] §431.021(l)(3), (jj), and (kk), concerning the counterfeiting of a drug or the sale or holding for sale of a counterfeit drug;

(6) has violated the Texas Controlled Substances Act, Texas Health and Safety Code[~~,~~] Chapter 481, or the Texas Dangerous Drug Act, Texas Health and Safety Code[~~,~~] Chapter 483;

(7) has violated the rules of the director of the Department of Public Safety, including being responsible for a significant discrepancy in the records that state law requires the applicant or license holder [~~licensee~~] to maintain;

(8) fails to complete a license application or submits an application containing [~~that contains~~] false, misleading, or incorrect information or containing [~~contains~~] information not verifiable [~~that cannot be verified~~] by the department;

(9) has furnished false or fraudulent information in any application made in connection with drug manufacturing or distribution;

(10) has failed to pay a license fee or a renewal fee for a license; or

(11) has obtained or attempted to obtain a license by fraud or deception.

(b) The department may, after providing opportunity for hearing, refuse to license a wholesale distributor of prescription drugs, or may suspend or revoke a license for violations of the requirements in this subchapter [~~these sections~~] or for any of the reasons described in the Act.

(c) Any hearings for the refusal, suspension, or revocation of a license are governed by §§1.21, 1.23, 1.25, and 1.27 of this title (relating to Formal Hearing Procedures).

(d) If the department suspends a license, the suspension remains [~~shall remain~~] in effect until the department determines [~~that~~] the reason for the suspension no longer exists. If the suspension overlaps a renewal date, the suspended license holder must [~~shall~~] comply with the renewal procedures in §229.425 of this subchapter [~~title~~] (relating to Licensing Procedures); however, the department may choose not to renew the license until the department determines [~~that~~] the reason for suspension no longer exists.

(e) If the department revokes or does not renew a license, a person may reapply for a license by complying with the requirements and procedures in §229.425 of this subchapter [~~title~~] at the time of reapplication. The department may refuse to issue a license if the reason for revocation or non-renewal continues to exist.

(f) A license issued under this subchapter must [~~these sections shall~~] be returned to the department if the person's place of business:

(1) ceases business or otherwise ceases operation on a permanent basis;

(2) relocates; or

(3) changes name or ownership. For a corporation, an ownership change is deemed to have occurred, resulting in the necessity to return the license to the department, when 5.0 percent [%] or more of the share of stock of a corporation is transferred from one person to another.

(g) The commissioner may suspend or revoke a license if the license holder no longer meets the qualification for obtaining a license under Texas Health and Safety Code[,] §431.405.

§229.429. Minimum Standards for Licensure.

(a) General requirements.

(1) All persons engaged in the wholesale distribution of prescription drugs must comply with the applicable minimum standards in this section, in addition to the statutory requirements contained in the Texas Food, Drug, and Cosmetic Act, Health and Safety Code[,] Chapter 431 (Act) and the [~~those~~] requirements in §229.420 of this subchapter [~~title~~] (relating to Applicable Laws and Regulations).

(2) For the purpose of this section, the policies described in the United States Food and Drug Administration (FDA) [~~United States Food and Drug Administration's (FDA's)~~] Compliance Policy Guides as they apply to prescription drugs are [~~shall be~~] the policies of the department.

(3) Prescription drug wholesalers must not purchase or receive drugs in this state other than from drug distributors licensed by the department.

(b) Federal establishment registration and drug listing. All persons who operate as prescription drug manufacturers in Texas must [~~shall~~] meet the requirements in 21 Code of Federal Regulations (CFR)[,] Part 207, titled Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That are Regulated Under a Biologics License Application, and Animal Drugs, and the National Drug Code. [~~"Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution."~~] New prescription drugs offered for sale by wholesale distributors must meet [~~shall have met~~], if applicable, the requirements of 21 CFR[,] Part 314, [~~titled "~~]Applications for FDA Approval to Market a New Drug.[~~"~~]

(c) Good manufacturing practices. Manufacturers of prescription drug products must comply [~~be in compliance~~] with the applicable requirements in:

(1) 21 CFR[,] Part 210, [~~titled "~~]Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General[~~"~~];

(2) 21 CFR[,] Part 211, [~~titled "~~]Current Good Manufacturing Practice for Finished Pharmaceuticals[~~; General"~~];

(3) 21 CFR[,] Part 225, [~~titled "~~]Current Good Manufacturing Practice for Medicated Feeds[~~"~~]; [~~and~~]

(4) 21 CFR[,] Part 226, [~~titled "~~]Current Good Manufacturing Practice for Type A Medicated Articles; and[~~."~~]

(5) the [~~The~~] regulations in this subsection governing [~~these parts govern~~] the methods used in, and the facilities or controls used for, the manufacture, processing, packing, or holding of a drug to ensure [~~assure that~~] each drug meets the requirements of the Federal Food, Drug, and Cosmetic Act, 21 United States Code (USC) §301, et seq., as amended, (Federal Act) [~~Federal Act~~] as to safety, and has the identity and strength and meets the quality and purity characteristics [~~that~~] it purports or is represented to possess.

(d) Buildings and facilities.

(1) All manufacturing, processing, packing, or holding of drugs by prescription drug manufacturers must [~~shall~~] take place in buildings and facilities described in subsection (c) of this section.

(2) Manufacturing [~~No manufacturing~~], processing, packing, or holding of prescription drugs must not [~~shall~~] be conducted in any personal residence.

(3) Sale [~~No sale~~] of prescription drugs must not [~~shall~~] be conducted in any flea market.

(4) Any place of business used by a wholesale distributor of prescription drugs who is not a manufacturer to store, warehouse, hold, offer, transport, or display drugs must [~~shall~~]:

(A) comply [~~be in compliance~~] with [~~the requirements adopted in~~] §229.420(a)(14) of this subchapter [~~title~~];

(B) be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(C) have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, and space;

(D) be maintained in a clean and orderly condition;

(E) be free from infestation by insects, rodents, birds, or vermin of any kind; and

(F) have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, or adulterated.

(e) Storage of prescription drugs. All prescription drugs stored by wholesale distributors must [~~shall~~] be held at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs.

(f) Minimum restrictions on transactions.

(1) Returns.

(A) A wholesale distributor must receive prescription drug returns or exchanges from a pharmacy or pharmacy warehouse in accordance with the terms and conditions of the agreement between the wholesale distributor and the pharmacy or pharmacy warehouse. An expired, damaged, recalled, or otherwise nonsalable prescription drug [~~that is~~] returned to the wholesale distributor may be distributed by the wholesale distributor only to either the original manufacturer or a third party returns processor. The returns or exchanges, salable or otherwise, received by the wholesale distributor as provided by this subsection, including any redistribution of returns or exchanges by the wholesale distributor, are not subject to the pedigree requirement under Texas Health and Safety Code[,] §431.412, if the returns or exchanges are exempt from pedigree under:

(i) §503, Prescription Drug Marketing Act of 1987 (21 USC [~~U.S.C.~~] §353(c)(3)(B));

(ii) the regulations adopted by the Secretary of the U.S. Department of Health and Human Services to administer and enforce the [~~that~~] Act in clause (i) of this subsection; or

(iii) the interpretations of the [~~that~~] Act in clause (i) of this subsection, set out in the compliance policy guide of the FDA [~~United States Food and Drug Administration~~].

(B) Each wholesale distributor and pharmacy must [~~shall~~] administer the process of drug returns and exchanges to ensure [~~that~~] the process is secure and does not permit the entry of adulterated or counterfeit drugs into the distribution channel.

(C) Notwithstanding any provision of state or federal law to the contrary, a person [~~that has~~] not otherwise [~~been~~] required

to obtain a wholesale license under this subchapter and that is a pharmacy engaging in the sale or transfer of expired, damaged, returned, or recalled prescription drugs to the originating wholesale distributor or manufacturer and pursuant to federal statute, rules, and regulations, including the FDA [~~United States Food and Drug Administration's~~] applicable guidance [~~guidances~~] implementing the Prescription Drug Marketing Act of 1987 (Pub. L. No. 100 - 293), is exempt from wholesale licensure requirements under this subchapter.

(D) All other returns must comply with the requirements of 21 CFR [~~Title 21, Code of Federal Regulations,~~] §203.23(a)(1) - (5).

(2) Distributions. A manufacturer or wholesale distributor may distribute prescription drugs only to a person licensed under this subchapter, or the appropriate state licensing authorities, if an out-of-state wholesaler or retailer, or to a person authorized by federal law to receive the drug. Before furnishing prescription drugs to a person not known to the manufacturer or wholesale distributor, the manufacturer or wholesale distributor must [~~shall~~] verify [~~that~~] the person is legally authorized by the department or the appropriate state licensing authority to receive the prescription drugs or is authorized by federal law to receive the drugs. Wholesale distributors physically located and conducting operations in another state must [~~shall~~] verify, before [~~prior to~~] purchasing or receiving product, [~~that~~] the suppliers of drugs are licensed under this subchapter and physically located in Texas; and must [~~, shall~~] notify the department of unlicensed wholesale distributors.

(3) Pedigree.

(A) A person, who is engaged in the wholesale distribution of a prescription drug, including a repackager but excluding the original manufacturer, must [~~shall~~] provide a pedigree for each prescription drug for human consumption that leaves or at any time [~~has~~] left the normal distribution channel and is sold, traded, or transferred to any other person.

(B) A retail pharmacy or pharmacy warehouse is required to comply with this section only if the pharmacy or warehouse engages in the wholesale distribution of a prescription drug.

(C) A person who is engaged in the wholesale distribution of a prescription drug, including a repackager, but excluding the original manufacturer of the finished form of a prescription drug, and who is in possession of a pedigree for a prescription drug must [~~shall~~] verify before distributing the prescription drug that each transaction listed on the pedigree has occurred.

(D) A pedigree must include all necessary identifying information concerning each sale in the product's chain of distribution from the manufacturer, through acquisition and sale by a wholesale distributor or repackager, until final sale to a pharmacy or other person dispensing or administering the drug. At a minimum, the chain of distribution information must include:

(i) the name, address, telephone number, and, if available, the e-mail address of each person who owns the prescription drug and each wholesale distributor of the prescription drug;

(ii) the name and address of each location from which the product was shipped, if different from the owner's name and address;

(iii) the transaction dates; and

(iv) certification that each recipient has authenticated the pedigree.

(E) The pedigree must include, at a minimum, the:

(i) name of the prescription drug;

(ii) dosage form and strength of the prescription drug;

(iii) size of the container;

(iv) number of containers;

(v) lot number of the prescription drug; and

(vi) name of the manufacturer of the finished dosage form.

(F) Each pedigree statement must be:

(i) maintained by the purchaser and the wholesale distributor for at least three years; and

(ii) available for inspection and duplication [~~photocopying~~] not later than the second business day after the date a request is submitted by the department or a peace officer in this state.

(G) Verification procedures.

(i) Each transaction listed on the pedigree must be affirmatively authenticated before [~~prior to~~] any wholesale distribution of a prescription drug.

(ii) A person who is engaged in the wholesale distribution of a prescription drug, and who is in possession of a pedigree for a prescription drug must [~~shall~~] certify, using the following methods, [~~that~~] each transaction listed on the pedigree has occurred.

(I) Invoice confirmation. Receipt of an invoice (or shipping document) from the seller to the purchaser, which may have the prices redacted. Documentation requirements include, at a minimum, a copy of the invoice or shipping document. If this method is used to authenticate a pedigree, the wholesaler must [~~shall~~] review the document received for signs of tampering, incompleteness, or inconsistency with other invoices or shipping documents from that manufacturer or wholesaler, and must [~~shall~~] randomly verify the authenticity of the invoice or shipping document with the seller or shipping point reflected on that document using one of the methods in the subsections below. Each wholesaler must [~~shall~~] establish policies and procedures for the random verification of the authenticity of the invoices or shipping documents according to statistically sound standards. Each wholesaler must [~~shall~~] establish policies and procedures for verification with those wholesalers in the distribution chain with which the wholesaler performing the authentication does not have an established prescription drug vendor relationship.

(II) Telephonic confirmation. Documentation requirements include a signed statement by the person placing the telephone call identifying the person's name and position title representing the seller who provides the information, the date the information was provided, and verification of the sales transaction between the parties, including verification of the date of the transaction and the quantity of prescription drugs involved in the transaction.

(III) Electronic mail confirmation. Documentation requirements include a copy of the e-mail identifying [~~that identifies~~] the person's name and position title representing the seller who provides the information, the date the information was provided, and verification of the sales transaction between the parties, including verification of the date of the transaction and quantity of prescription drugs involved in the transaction.

(IV) Electronic web-based confirmation. Verification of the transaction per a web-based system established by the seller or an independent person [~~that is~~] secure from intentional or unintentional tampering or manipulation to conceal an accurate and complete history of the prescription drug transactions [~~transaction(s)~~].

Documentation requirements include a written representation from the seller or independent person that the seller or independent person, as applicable, is responsible for the information included on the website and has adequate security on the information posted to prevent unauthorized tampering, manipulation, or modification of the information and a copy of the dated website page confirming [~~that confirms~~] the sales transaction between the parties, including the date of the transaction and quantity of prescription drugs involved in the transaction.

(V) Notarized copy confirmation. Receipt of a legible and unaltered copy of a previous transaction's pedigree paper [~~that had been~~] signed under oath at the time of the previous transaction to support the transaction to which the pedigree paper relates. If this method is used to authenticate a pedigree, the wholesaler must [~~shall~~] review the document received for signs of tampering, incompleteness, or inconsistency, and must [~~shall~~] randomly verify the authenticity of pedigrees using one of the methods in [~~the~~] this subparagraph. Each wholesaler must [~~shall~~] establish policies and procedures for the random verification of the authenticity of these copies of pedigree according to statistically sound standards.

(VI) Exclusive purchasing. A wholesale distributor may use a written agreement between the wholesale distributor and an authorized distributor of record requiring [~~that requires that~~] all prescription drugs distributed to the wholesale distributor by the authorized distributor of record, [~~must~~] be purchased by the authorized distributor of record from the manufacturer. If this method is used to authenticate a pedigree, the wholesale distributor must [~~shall~~] establish policies and procedures for the random verification of the authenticity of the pedigrees that disclose the authorized distributor of record purchased the prescription drug from the manufacturer according to statistically sound standards.

(VII) Other methods. Any other method approved by the department.

(4) Premises. Prescription drugs distributed by a manufacturer or wholesale distributor may be delivered only to the premises listed on the license, except as listed in paragraph (5) of this subsection. A manufacturer or wholesale distributor may distribute prescription drugs to an authorized person or agent of that person at the premises of the manufacturer or wholesale distributor if:

(A) the identity and authorization of the recipient is properly established; and

(B) delivery is made only to meet the immediate needs of a particular patient of the authorized person.

(5) Delivery to hospital pharmacies. Prescription drugs may be distributed to a hospital pharmacy receiving area if a pharmacist or an authorized receiving person signs, at the time of delivery, a receipt showing the type and quantity of the prescription drug received. Any discrepancy between the receipt and the type and quantity of the prescription drug actually received must [~~shall~~] be reported to the delivering manufacturer or wholesale distributor not later than the next business day after the date of delivery to the pharmacy receiving area.

(g) Prescription drug labeling. Prescription drugs sold by wholesale distributors must [~~shall~~] meet the labeling requirements of the Act and those adopted in §229.420(a) of this subchapter [~~title~~].

(h) Prescription drugs that are combination products. Any prescription drug that is a combination product as described in §229.424(c) of this subchapter [~~title~~] (relating to Licensure Requirements) is also subject to the applicable requirements in Subchapter X of this chapter (relating to Licensing of Device Distributors and Manufacturers).

(i) Prescription drugs that are also cosmetics. Any prescription drug that is also a cosmetic or component thereof is also subject to the applicable requirements of Subchapter D of this chapter (relating to Regulation of Cosmetics).

(j) Nonprescription drugs. Nonprescription drugs offered for sale by wholesale distributors of prescription drugs must comply [~~shall be in compliance~~] with the applicable requirements of Subchapter O of this chapter (relating to Licensing of Wholesale Distributors of Nonprescription Drugs--Including Good Manufacturing Practices).

§229.430. Enforcement and Penalties.

(a) Inspection.

(1) To enforce this subchapter or the Texas Food, Drug, and Cosmetic Act, Texas Health and Safety Code[~~,~~] Chapter 431 (Act), the commissioner, an authorized agent, or a health authority may, on presenting appropriate credentials to the owner, operator, or agent in charge of a place of business:

(A) enter at reasonable times a place of business, including a factory or warehouse, in which a prescription drug is manufactured, packed, or held for introduction into commerce or held after the introduction;

(B) enter a vehicle being used to transport or hold a prescription drug in commerce; or

(C) inspect at reasonable times, within reasonable limits, and in a reasonable manner, the place of business or vehicle and all equipment, finished and unfinished materials, containers, and labeling of any item and obtain samples necessary for the enforcement of this subchapter or the Act.

(2) The inspection of a place of business, including a factory, warehouse, or consulting laboratory, in which a prescription drug is manufactured, processed, packed, or held for introduction into commerce extends to any place or thing, including a record, file, paper, process, control, or facility, [~~in order~~] to determine whether the drug:

(A) is adulterated or misbranded;

(B) may not be manufactured, introduced into commerce, sold, or offered for sale under the Act; or

(C) is otherwise in violation of this subchapter or the Act.

(3) An inspection under paragraph (2) of this subsection does [~~may~~] not extend to:

(A) financial data;

(B) sales data other than shipment data;

(C) pricing data;

(D) personnel data other than data relating to the qualifications of technical and professional personnel performing functions under the Act;

(E) research data other than data:

(i) relating to new drugs and antibiotic drugs; and

(ii) subject to reporting and inspection under regulations issued under §505(i) or (j) of the Federal Food, Drug, and Cosmetic Act, 21 United States Code (USC) §301, et seq., as amended, (Federal Act) [~~Federal Act~~]; or

(F) data relating to other drugs [~~that~~], in the case of a new drug, [~~would be~~] subject to reporting or inspection under regulations issued under §505(j) of the Federal Act.

(4) An inspection under paragraph (2) of this subsection must [~~shall~~] be started and completed with reasonable promptness.

(b) Receipt for samples. An authorized agent or health authority who inspects [~~makes an inspection of~~] a place of business, including a factory or warehouse, and obtains a sample during or on completion of the inspection and before leaving the place of business, must [~~shall~~] give [~~to~~] the owner, operator, or the owner's or operator's agent a receipt describing the sample.

(c) Access to records.

(1) A person [~~who is~~] required to maintain records referenced in this subchapter or under the Act [~~Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431 (Act)~~] or Chapter V of the Federal Act [~~Federal Food, Drug, and Cosmetic Act (Federal Act)~~] or a person [~~who is~~] in charge or custody of those records must [~~shall~~], at the request of an authorized agent or health authority, permit the authorized agent or health authority at all reasonable times, access to and to copy and verify the records.

(2) A person, including a carrier engaged in commerce, or other person receiving a prescription drug in commerce or holding a prescription drug received in commerce must [~~shall~~], at the request of an authorized agent, permit the authorized agent at all reasonable times to have access to and to copy and verify all records showing:

(A) the movement in commerce of any prescription drug;

(B) the holding of any prescription drug after movement in commerce; and

(C) the quantity, shipper, and consignee of any prescription drug.

(d) Retention of records. Records required by this subchapter must [~~shall~~] be maintained at the place of business or other location [~~that is~~] reasonably accessible for a period of at least three years following disposition of the prescription drug unless a greater period of time is required by [~~laws and regulations adopted in~~] §229.420 of this subchapter [~~title~~] (relating to Applicable Laws and Regulations).

(e) Adulterated or misbranded prescription drug. If the department identifies an adulterated or misbranded prescription drug, the department may impose the applicable enforcement provisions of Subchapter C of the Act including [~~, but not limited to:~~] detention, emergency order, recall, and [~~condemnation, destruction, injunction, civil penalties, criminal penalties, and/or~~] administrative penalties. The department may request the attorney general or local law enforcement institute an action for criminal penalties, collection of civil penalties, condemnation, destruction, and injunction under the Act.

(f) Order to cease distribution.

(1) The commissioner must [~~shall~~] issue an order requiring a person, including a manufacturer, distributor, or retailer of a prescription drug, to immediately cease distribution of the drug if the commissioner determines there is a reasonable probability [~~that~~]:

(A) a wholesale distributor has:

(i) violated this subchapter or the Act; or

(ii) sold, distributed, transferred, manufactured, repackaged, handled, or held a counterfeit prescription drug intended for human use that could cause serious adverse health consequences or death; and

(B) other procedures would result in unreasonable delay.

(2) An order under this subsection must provide the person subject to the order [~~with~~] an opportunity for an informal hearing on the actions required by the order to be held not later than the 10th day after [~~the date of~~] issuance of the order.

(3) If, after providing an opportunity for a hearing, the commissioner determines [~~that~~] inadequate grounds exist to support the actions required by the order, the commissioner must [~~shall~~] vacate the order.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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TRD-202402361
Cynthia Hernandez
General Counsel
Department of State Health Services
Earliest possible date of adoption: July 14, 2024
For further information, please call: (512) 834-6755

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CHAPTER 289. RADIATION CONTROL

(Editor's note: In accordance with Texas Government Code, §2002.014, which permits the omission of material which is "cumbersome, expensive, or otherwise inexpedient," the figures in 25 TAC §§289.201, 289.202, 289.253 and 289.255 - 289.257 are not included in the print version of the Texas Register. The figures are available in the on-line version of the June 14, 2024, issue of the Texas Register.)

The Executive Commissioner of the Texas Health and Human Services Commission (HHSC), on behalf of the Department of State Health Services (DSHS), proposes amendments to §289.201, concerning General Provisions for Radioactive Material; §289.202, concerning Standards for Protection Against Radiation from Radioactive Material; §289.253, concerning Radiation Safety Requirements for Well Logging Service Operations and Tracer Studies; §289.255, concerning Radiation Safety Requirements and Licensing and Registration Procedures for Industrial Radiography; §289.256, concerning Medical and Veterinary Use of Radioactive Material; §289.257, concerning Packaging and Transportation of Radioactive Material; and §289.258, concerning the Licensing and Radiation Safety Requirements for Irradiators.

BACKGROUND AND PURPOSE

The proposed amendments are necessary for Texas (an Agreement State) to comply with United States Nuclear Regulatory Commission (NRC) requirements, as identified in the Review Summary Sheets for Regulation Amendments (RATS Identification). The amendments update NRC information and result from the NRC's adoption of rules related to the use of digital output personnel dosimeters as an acceptable individual monitoring device.

Additional updates to NRC rules involve miscellaneous corrections, including references to the Council on Postdoctoral Training of the American Osteopathic Association and the Accreditation Council for Pharmacy Education, Exempt Material Activity Concentrations, and Exempt Consignment Activity Limits for Radionuclides. Updates also include the requirement to report transactions involving nationally tracked sources, the reference

to the list of addresses of the governors' designees receiving advance notification of transportation of nuclear waste, and references to master material licensees and removal of permits issued under an NRC master material broad scope license.

The proposed amendments establish new definitions; qualify training requirements; and update license application processes, concerning use of field stations, material storage, and approved methods for waste disposal. Amendments update Radiation Safety Committee (RSC) requirements and transportation exemptions for medical and veterinary licensees, identify conditions under which medical licensees may revise their radiation protection programs without the department's approval, and update contamination control criteria and methods. Amendments clarify record retention requirements related to the receipt, transfer, and disposal of radioactive material and devices and ensure compatibility with NRC requirements not specifically mentioned in the RATS Identification.

The proposed amendments update, correct, improve, and clarify the rule language and incorporate plain language where appropriate.

SECTION-BY-SECTION SUMMARY

Proposed amendment to §289.201(b)(7) deletes the definition of "agency." Proposed new §289.201(b)(33) adds the definition "department." Subsequent paragraphs in the definition subsection are renumbered.

Proposed amendments to §289.201(b)(21) and (22) and §289.201(b)(63) update the definitions to specify "permission to engage in regulated activities" as described in the certificate of registration or license.

Proposed amendment to renumbered §289.201(b)(27) updates the definition of "consortium" to meet HHSC plain language guidelines.

Proposed amendment to §289.201(b)(46) updates the definition of "exposure" to remove the obsolete term "negatrons" and conforms with the International Commission on Radiation Units and Measurements definition.

Proposed amendment to §289.201(b)(57) modifies the definition of "individual monitoring device" to ensure compatibility with NRC language and account for the accepted use of digital output personnel dosimeters by the NRC. The references to "pocket dosimeter" and "personal air sampling devices" are removed to mitigate confusion regarding acceptable personnel monitoring devices for well logging and irradiator operations.

Proposed amendment to §289.201(b)(66) deletes the definition of "licensing state," which is an obsolete term. Subsequent paragraphs in the definition subsection are renumbered.

Proposed amendments to renumbered §289.201(b)(84) and §289.201(b)(143) update the definitions of "physician" and "veterinarian" by specifying the Texas Occupations Code chapters extending the authority to practice medicine and veterinary medicine, respectively.

Proposed new §289.201(b)(85) adds the definition of "pocket dosimeter" based on the proposed update to the definition of "individual monitoring device." Adding a discrete definition will mitigate confusion regarding acceptable personnel monitoring devices to be used during well logging and irradiator operations.

Proposed amendment to §289.201(b)(114) changes the definition of "sealed source" to maintain compatibility with NRC language.

Proposed new §289.201(b)(129) adds a definition for "temporary job site" as it is also defined in §289.253 and §289.255. Subsequent paragraphs in the definition subsection are renumbered.

Proposed amendment to renumbered §289.201(b)(137), Type A quantity, removes the repeated "A_2" value and replaces it with the "A_1" value as necessary to maintain NRC compatibility.

Proposed amendment to §289.201(d)(1)(B), Records, clarifies the record retention requirement for the receipt, transfer, and disposal of radioactive material. The update differentiates receipt and transfer from disposal record requirements and maintains compatibility with NRC language.

Proposed amendment to §289.201(d)(5) modifies data retention requirements to account for all media types used to store records.

Proposed amendment to §289.201(g)(1)(A), Tests for leakage or contamination of sealed sources, corrects exception reference from §289.253(i) to §289.253(j) of this chapter.

Proposed amendment to §289.201(m), Open records, removes subsection (m) in its entirety because Texas Government Code and DSHS policy prescribe open records request procedures. Removing subsection (m) also removes Figure: 25 TAC §289.201(m)(2)(A)(ii). Subsequent subsections are renumbered accordingly, Figure: 25 TAC §289.201(n)(1) is renumbered as Figure: 25 TAC §289.201(m)(1), and Figure: 25 TAC §289.201(n)(2) is renumbered as Figure: 25 TAC §289.201(m)(2).

Proposed amendment to §289.202(p)(4) ensures compatibility with NRC language and accounts for the NRC's accepted use of digital output personnel dosimeters. Individual monitoring devices requiring processing are qualified, and the requirement they be processed and evaluated by an accredited laboratory is retained.

Proposed amendment to §289.202(r)(1)(F) ensures compatibility with NRC language and accounts for the accepted use of digital output personnel dosimeters by the NRC. The change specifies wear periods for individual monitoring devices requiring processing.

Proposed new §289.202(r)(1)(G) accounts for digital output personnel dosimeters not requiring processing and establishes the evaluation periodicity.

Proposed amendment to §289.202(r)(2) adds the term "as applicable" to account for devices not requiring processing.

Proposed new §289.202(ff)(1)(F) accounts for NRC regulation allowing for alternative radioactive material waste disposal procedures when reviewed and approved by DSHS. Subsequent clauses outline documentation and conditions required to be submitted for DSHS's review.

Proposed amendment to §289.202(fff)(1)(A) and (B) ensures compatibility with NRC language by removing unnecessary references to "iodine-125" and "in vitro clinical or in vitro laboratory testing."

Proposed amendment to §289.202(ggg)(2)(B)(vi) removes Figure: 25 TAC §289.202(ggg)(2)(B)(vi) and replaces the figure with new rule text describing the use of stochastic and non-stochastic annual limits on intake (ALIs). The subsequent

clauses of the subparagraph are renumbered and Figure: 25 TAC §289.202(ggg)(2)(B)(viii) is renumbered as Figure: 25 TAC §289.202(ggg)(2)(B)(vii).

Proposed amendment to §289.202(ggg)(5), in Figure: 25 TAC §289.202(ggg)(5), changes "(ll)(4)" to "(ll)(5)" in the left-hand column of the table and changes "Entries at no > 1 year intervals" to "Entries at not > 1 year intervals" in the right-hand column of the table.

Proposed amendment to §289.202(ggg)(6) adds that the sample area for acceptable surface contamination levels is "(per 100 cm^2)." The proposed amendment removes current Figure: 25 TAC §289.202(ggg)(6) and replaces it with a new Figure: 25 TAC §289.202(ggg)(6) that is based on Regulatory Guide 8.23 and is formatted similarly to Table R-3 of Consolidated Guidance About Material Licenses: Program-Specific Guidance About Medical Use Licenses, Final Report (NUREG 1556, Volume 9, Revision 3). Acceptable surface contamination levels are updated to coincide with NRC guidelines.

Proposed amendment deletes §289.202(hhh)(1)(H) and subsequent clauses are removed due to NRC compatibility requirements.

Proposed amendment to §289.253(g)(4), Storage precautions, removes language not included in the NRC rule and adds language consistent with NRC guidelines to ensure material may only be stored in locations "specifically authorized by the department."

Proposed amendment to §289.253(i)(1) and (3) ensure language is consistent with NRC rule by moving the language "capable of detecting beta and gamma radiation" from paragraph (3) and moving it to paragraph (1).

Proposed amendment to §289.253(o)(4) removes the reference to "licensing state," which is an obsolete term.

Proposed amendments to §289.253(p)(1)(A), Training requirements, and §289.255(e)(1)(A), Requirements for qualifications of radiographic personnel, remove the inference that the department accredits training courses by deleting the language requiring courses to be "accepted by the agency, another agreement state, or the NRC."

Proposed amendments to §289.253(r)(1) and §289.255(p)(2)(I) ensure compatibility with updated NRC regulations removing the requirement for an accredited laboratory to process individual monitoring devices. Individual monitoring devices are qualified as those "requiring replacement" and those "requiring processing" to account for NRC acceptance of digital output personnel dosimeters not requiring processing. A requirement for all individual monitoring devices to "be evaluated at least quarterly or promptly after replacement, whichever is more frequent," is retained to account for devices not requiring processing.

Proposed amendment to §289.253(r)(2) changes "exposure to concentrations" to "intake" to clarify the requirement for circumstances requiring internal monitoring or bioassay.

Proposed amendment to §289.253(z)(3), Energy compensation source, replaces erroneous reference to subsection (cc)(4) with (ee)(4)(A), which ensures compatibility with the NRC equivalent requirement for operations not using a surface casing.

Proposed amendment to §289.253(dd)(4)(B), Notification of incidents and lost sources, updates well monitoring requirements to clarify the acceptable methods, and uses a "what/when/why/how" structure. This update meets compatibility requirements with the NRC.

Proposed amendment to Figure: 25 TAC §289.253(ee)(5) distinguishes the receipt and transfer records from the disposal records retention requirements and adds the reference to §289.201(d).

Proposed amendment to §289.255(c)(1) removes the definition of "additional authorized use/storage site" and places the definition of "field station" in §289.255(c)(16). Adopting "field station" directly from NRC rules with an additional reference to "radiation machines" ensures compatibility with NRC rules. Subsequent paragraphs are renumbered.

Proposed amendment to §289.255(c)(17) removes the definition of "fluoroscopic imaging assembly," as it does not exist in these rules.

Proposed amendment to §289.255(c)(18) removes the definition of "GED" due to proposed deletion of the General Education Development (GED) from the Radiation Safety Office training requirements of §289.255(e)(4)(B). Subsequent paragraphs are renumbered.

Proposed amendment to §289.255(c)(27) removes the definition of "permanent storage site," as it is no longer used in the rule based on the proposed deletion of the definition of "storage facility" in §289.255(c)(48). Subsequent paragraphs are renumbered.

Proposed amendment to renumbered §289.255(c)(30) updates the compatibility with NRC language by clarifying that an individual "who provides visual surveillance of industrial radiographic operations while in attendance during transport or at the site where the sealed source or sources are being used" is defined as a radiographer.

Proposed amendment to renumbered §289.255(c)(43) for the definition of "storage area" replaces "used for radiographic operations" with "in use" to ensure compatibility with NRC language.

Proposed amendment to §289.255(c)(48) removes the unnecessary definition of "storage facility," which is not defined in NRC rules. Subsequent paragraphs are renumbered.

Proposed amendment to renumbered §289.255(c)(45) modifies the definition of "temporary job site" to ensure compatibility with the NRC definition.

Proposed amendment to §289.255(d)(4), Exemptions, updates several applicable references. Reference to subsection (k) is added to account for the exemption of radiation machines utilized for industrial radiography at permanent radiographic installations. Inventories of those machines must be conducted under §289.226(m)(9) as now specified in proposed amendment to §289.255(k).

Proposed amendment to §289.255(e)(2)(A)(ii), Requirements for qualifications of radiographic personnel, removes reference to "radiographer trainers authorized on a license or certificate of registration" as trainers are not listed on a license or certificate of registration. A reference to subsection "(e)(3) of this section" is added to clarify training requirements.

Proposed amendment to §289.255(e)(3)(A)(i)(II), Radiographer trainer, clarifies the training requirement by specifying "2000 hours of documented direct experience" instead of "one year" to qualify the necessary training for trainers.

Proposed amendment to §289.255(e)(4)(A) and (B), RSO for industrial radiography, revises training requirements to conform with 10 Code of Federal Regulations (CFR) §34.42 format and language. Changes and additions ensure compatibility with NRC rule. Language describing RSO designation on DSHS-issued licenses and certificates of registration has been moved to paragraph (4) of this subsection.

Proposed amendments to §289.255(i) and §289.255(i)(1), "industrial radiography sealed" and "radiography exposure" have been added to the subsection title and paragraph to clarify the applicability of the rule to industrial sources and devices using depleted uranium (DU) as shielding.

Proposed amendment to §289.255(k), changes the heading to "Inventory" to account for addition of exemption for radiation machines used in industrial radiography. Proposed amendment to §289.255(k)(1) adds language specifying the exemption of machines and prescribes inventory and record retention requirements of §289.226(m)(9).

Proposed amendment to §289.255(o), changes the heading to "Notifications" as the proposed additions of notifications to §289.255(o)(4) and (5) are not limited to incidents.

Proposed new §289.255(o)(4) and (5) adds requirements to notify DSHS when using or storing radioactive material at a location not listed on a license beyond 180 days in a calendar year or when using or storing radiation machines at a location not listed on a certificate of registration beyond 90 days in a calendar year. Proposed amendment to §289.255(t) - (u) deletes the notification language and moves it to subsection (o).

Proposed amendments to §289.255(p)(2)(A)(i) and §289.255(s)(1)(B), regarding the use of individual monitoring devices, updates the incorrect reference to §289.202(p)(3) and (4) and changes it to §289.202(p)(4) and (5).

Proposed amendment to §289.255(p)(2)(E)(i), Individual monitoring, adds "use or" storage "site" and removes the term "location" to clarify and maintain consistency with subsequent rules in the section.

Proposed amendment to §289.255(p)(2)(G), Individual monitoring, adjusts processing and evaluation requirements for an off-scale reading during industrial radiography operations. Devices are distinguished as those requiring processing and those not requiring processing to account for NRC acceptance of digital output personnel dosimeters.

Proposed amendment to §289.255(p)(6)(B), Individual monitoring, removes "received from the device processor" to comply with NRC acceptance of digital output personnel dosimeters.

Proposed amendment to §289.255(t)(1)(B)(iv), Registration requirements for industrial radiographic operations, adds a reference to "all field stations" being listed on the application for a certificate of registration. This precludes the need for the remaining language in clause (iv) and subclauses (I) - (III) of this clause. Language from subclause (IV) is moved to subsection (o).

Proposed amendment to §289.255(u)(1)(B)(iv), Licensing requirements for industrial radiographic operations, adds a reference to "all field stations" being listed on the application for a certificate of registration. This precludes the need for the remaining language in clause (iv) and subclauses (I) - (III) of this clause. Language from subclause (IV) is moved to subsection (o).

Proposed amendments to §289.255(u)(1)(B)(viii)(II) and §289.255(u)(9)(G) replace the terms "storage facilities" and "storage location" with "storage areas" and "storage area," respectively. The definition of "storage facility" is removed from subsection (c). "Storage area" is defined in the rule.

Proposed amendment to §289.255(u)(4)(B), Permanent storage precautions for the use of sealed sources, removes language not included in the equivalent NRC rule and adds the language "specifically authorized by the department," consistent with NRC guidelines, to ensure material is only stored at locations specifically authorized by the department.

Proposed amendment to §289.255(u)(5)(D)(iv), Performance requirements for industrial radiography equipment, adds the term "lock box," included in the equivalent NRC rule. To clarify language found in 10 CFR §34.20, the clause is restructured, and language is added to specify safety plugs or covers "be installed during storage and transportation to" protect the source assembly.

Proposed amendment to §289.255(u)(7)(D), Labeling and storage, adds the term "legible" to describe the required vehicle label used when transporting radioactive material.

Proposed amendments to §289.255(u)(8)(G) and §289.255(u)(8)(J), Operating and internal audit requirements for the use of sealed sources of radiation, updates the subparagraphs to meet compatibility requirements with equivalent NRC rule, specifically 10 CFR §34.41(a) and (b).

Proposed amendments to Figure: 25 TAC §289.255(v)(1), Record/document requirements, adds a separate requirement to retain material and device "disposal" records "until license termination." This is distinguished from "receipt and transfer" records and is updated for consistency with NRC rules, allowing agreement states to be more restrictive.

Proposed amendments to §289.255(x)(2)(B)(iv) and (v) and §289.255(x)(2)(C)(viii) and (ix), General requirements for inspection of industrial radiographic equipment, remove the requirement to inspect for the "presence of radioactive contamination" as this procedure is not included in the NRC guidelines. Additionally, paragraph (2)(A)(i) already requires licensees to survey the guide tube for radiation levels.

Proposed amendment to §289.256(h)(3)(C), Training for an RSO and ARSO, changes the language, "a NRC master material license" to "an NRC master material licensee," under NRC compatibility requirements.

Proposed amendment to §289.256(i), Radiation Safety Committee, adds a requirement that licensees authorized for two or more different types of radioactive material use requiring a "written directive" or two or more "therapeutic" units under subsection "(q)" must establish an RSC. This is consistent with the requirement to establish an RSC applicable to other licensees or registrants practicing under provisions of subsections (kk), (rr), and (ddd) of this section. This addition is consistent with agreement state authorization to be more restrictive than the NRC.

Proposed amendment to §289.256(i)(2), Radiation Safety Committee, removes paragraph (2) of this subsection and adjusts paragraph (1) to ensure uniform membership requirements apply to all licensees requiring a radiation safety committee.

Proposed amendment to §289.256(l)(5)(B), Training for experienced RSO, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized

nuclear pharmacist, is adjusted to replace "by" with "in accordance with" and reference to "NRC master material license of broad scope" is changed to "NRC master material broad scope license." This change ensures compatibility with equivalent NRC rule.

Proposed amendment to §289.256(p)(7), replaces "name and/or number" with "designation" to clarify the rule and remove use of "and/or."

Proposed amendment to §289.256(r)(2)(E), License amendments and notifications, corrects a typographical error by adding a new sentence beginning with "Other." This ensures compatibility with NRC language and clarifies the rule.

Proposed amendment to §289.256(r)(2)(G), License amendments and notifications, adds conditions under which a medical licensee may revise its radiation protection program without the department's approval as is consistent with 10 CFR §35.26.

Proposed amendment to §289.256(cc)(1), Release of individuals containing radioactive drugs or implants containing radioactive material, removes the obsolete requirement allowing release of patients treated with temporary eye plaques based on a less than 5 mrem per hour "exposure rate" at a distance of 1 meter from the plaque location.

Proposed amendment to §289.256(ii)(4), Permissible molybdenum-99, strontium-82, and strontium-85 concentrations, replaces reference to subsection "(www)" with "(xxx)" based on comment received from the NRC identifying the error.

Proposed amendment to §289.256(ii)(5), Permissible molybdenum-99, strontium-82, and strontium-85 concentrations, replaces the reference to subsection "(xxx)" with "(www)" based on comment received from the NRC identifying the error.

Proposed amendments to §§289.256(nn)(1)(A), 289.256(zz)(1)(A), 289.256(zz)(2)(B), 289.256(ttt)(1)(A), and 289.256(ttt)(2)(A)(iii) update the accrediting body reference to "the Council on Postdoctoral Training of the American Osteopathic Association" when referring to training requirements for Doctor of Osteopathic Medicine. This update ensures compatibility with the equivalent NRC rules.

Proposed amendment to §289.256(qq)(2)(C)(i) removes the redundant phrase, "and shall have experience in administering dosages in the same category or categories as the individual requesting authorized user status; or." This ensures compatibility with the equivalent NRC rule.

Proposed amendment to §289.256(tt)(3)(B), Brachytherapy sealed sources accountability, updates the last sentence to clarify that the date sealed sources "were returned to storage" must be recorded.

Proposed amendments to Figure: 25 TAC §289.256(xxx), Records/documents for department inspection, removes reference to "receipt, transfer, and disposal" of radioactive material and changes to distinguish "Records of receipt and transfer" from "Records of disposal of radioactive material." Time intervals are updated to "Until disposal of the records is authorized by the department" and "Until termination of the radioactive material license," respectively. Additionally, cross-references related to RSC meetings, procedures for administrations requiring a written directive, and service provider documentation have been updated or corrected. These changes clarify retention requirements and are compatible with NRC rules.

Proposed amendment to §289.257(g), Exemptions of physicians, adds "and veterinarians" to the title and updates references to "veterinarian" and "veterinary medicine" to include veterinarians to the exemption as they are licensed under the medical rule, §289.256.

Proposed amendment to §289.257(i)(1)(C)(iii), General license, adds "U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001" to the Document Control Desk address to correct omitted information.

Proposed amendment to §289.257(q)(4)(C)(i) removes the clause as required by NRC RATS ID 2020-3. Subsequent clauses to this subparagraph have been renumbered.

Proposed amendment to Figure: 25 TAC §289.257(ee)(6), Appendices for determination of A_1 and A_2, updates the "Specific activity" of Samarium-147 (Sm-147) in TBq/g (Terabecquerels/gram) from "$8.5X10^{-1}$" to "$8.5X10^{-10}$" as required to maintain NRC compatibility.

Proposed amendments to §§289.258(e)(8), 289.258(w)(1), and 289.258(w)(3) remove the reference to "licensing state," which is an obsolete term.

Proposed amendment to §289.258(u)(1), Personnel monitoring, is required to ensure compatibility with updated NRC regulations removing the requirement for an accredited laboratory to process individual monitoring devices. The previous requirement that the "personnel dosimeter processor must be accredited for" is replaced with "must be capable of detecting" photons in the normal and accident dose ranges. The term "personnel dosimeter" is replaced with "individual monitoring device" to maintain consistency. Individual monitoring devices are qualified as those "requiring replacement" and those "requiring processing" to account for NRC acceptance of digital output personnel dosimeters not requiring processing. A requirement for all individual monitoring devices to "be evaluated at least quarterly or promptly after replacement, whichever is more frequent," is retained to account for devices not requiring processing.

Proposed amendment to §289.258(u)(2), Personnel monitoring, updates reference to "the paragraph" with "this paragraph."

Proposed amendment to §289.258(w)(1), Detection of leaking sources, replaces "the commission" with "the NRC" to maintain consistency when referencing the U.S. Nuclear Regulatory Commission (NRC).

Proposed amendment to §289.258(cc)(5), Records/documents, changes reference to "film badge, TLD, or OSL" to "individual monitoring device" so the record retention requirements will apply to digital output personnel dosimeters not requiring processing.

FISCAL NOTE

Christy Havel Burton, Chief Financial Officer, has determined that for each year of the first five years the rules will be in effect, enforcing or administering the rules does not have foreseeable implications relating to costs or revenues of state or local governments.

GOVERNMENT GROWTH IMPACT STATEMENT

DSHS has determined that during the first five years the rules will be in effect:

(1) the proposed rules will not create or eliminate a government program;

(2) implementation of the proposed rules will not affect the number of DSHS employee positions;

(3) implementation of the proposed rules will result in no assumed change in future legislative appropriations;

(4) the proposed rules will not affect fees paid to DSHS;

(5) the proposed rules will not create a new regulation;

(6) the proposed rules will not expand existing regulations;

(7) the proposed rules will not change the number of individuals subject to the rules; and

(8) the proposed rules will not affect the state's economy.

SMALL BUSINESS, MICRO-BUSINESS, AND RURAL COMMUNITY IMPACT ANALYSIS

Christy Havel Burton, Chief Financial Officer, has also determined there will be no significant adverse economic impact on small businesses, micro-businesses, or rural communities required to comply with the rules as proposed. Small businesses, micro-businesses, and rural communities may be required to make minor changes to their business practices to comply with the rules when license conditions are applicable.

LOCAL EMPLOYMENT IMPACT

The proposed rules will not affect the local economy.

COSTS TO REGULATED PERSONS

Texas Government Code §2001.0045 does not apply to these rules because these rules are necessary to protect the health, safety, and welfare of the residents of Texas.

PUBLIC BENEFITS AND COSTS

Dr. Timothy Stevenson, Associate Commissioner, Consumer Protection Division, has determined that for each year of the first five years the rules are in effect, the public will benefit from adopting the rules. The public benefit anticipated as the result of enforcing or administering the rules is to ensure continued enhanced protection of the public, patients, workers, and the environment from unnecessary exposure to ionizing radiation. This is accomplished when rules are understandable, effective, specific, and harmonious with NRC rules.

Christy Havel Burton, Chief Financial Officer, has also determined that for the first five years the rules are in effect, there are no anticipated economic costs to persons required to comply with the proposed rules because those persons are already required to follow NRC regulations.

TAKINGS IMPACT ASSESSMENT

DSHS has determined the proposal does not restrict or limit an owner's right to their property that would otherwise exist in the absence of government action and, therefore, does not constitute a taking under Texas Government Code §2007.043.

PUBLIC COMMENT

Written comments on the proposal may be submitted to Radiation Section, Consumer Protection Division, DSHS, Mail Code 1986, P.O. Box 149347, Austin, Texas 78714-9347, or street address 1100 West 49th Street, Austin, Texas, 78756; by fax to (512) 483-3430; or emailed to CPDRuleComments@dshs.texas.gov.

To be considered, comments must be submitted no later than 31 days after the date of this issue of the *Texas Register.* Comments must be (1) postmarked or shipped before the last day of the comment period; (2) hand-delivered before 5:00 p.m. on the last working day of the comment period; or (3) faxed or emailed before midnight on the last day of the comment period. If the last day to submit comments falls on a holiday, comments must be postmarked, shipped, or emailed before midnight or hand-delivered before 5:00 p.m. on the following business day to be accepted. When faxing or emailing comments, please indicate "Comments on Proposed Rule 23R011" in the subject line.

SUBCHAPTER D. GENERAL

25 TAC §289.201, §289.202

STATUTORY AUTHORITY

The amendments are authorized by Texas Health and Safety Code Chapter 401 (the Texas Radiation Control Act), which provides for DSHS radiation control rules and regulatory program to be compatible with federal standards and regulation; §401.051, which provides the required authority to adopt rules and guidelines relating to the control of sources of radiation; §401.052, which provides authority for rules providing for transportation and routing of radioactive material and waste in Texas; §401.103, which provides authority for licensing and registration for transportation of sources of radiation; §401.104 which provides for rulemaking authority for general or specific licensing of radioactive material and devices or equipment using radioactive material; §401.224, which provides rulemaking authority relating to the packaging of radioactive waste; Chapter 401, Subchapter J, which authorizes enforcement of the Act; Texas Government Code §531.0055; and Texas Health and Safety Code §1001.075, which authorizes the Executive Commissioner of HHSC to adopt rules and policies for the operation and provision of health and human services by DSHS and for the administration of Texas Health and Safety Code Chapter 1001.

The amendments also implement Texas Health and Safety Code Chapters 401 and 1001, and Texas Government Code Chapter 531.

§289.201. General Provisions for Radioactive Material.

(a) Scope. Except as otherwise specifically provided, this section applies to all persons who receive, possess, use, transfer, or acquire any radioactive material unless the [~~provided, however, that nothing in this section shall apply to any person to the extent such~~] person is subject to regulation by the United States Nuclear Regulatory Commission (NRC). This section does not apply [~~or~~] to radioactive material in the possession of federal agencies. State regulation [~~Attention is directed to the fact that regulation by the state~~] of source material, byproduct material, and special nuclear material in quantities not sufficient to form a critical mass is subject to the provisions of the agreement between the state and NRC and to Part 150 of NRC regulations (10 Code of Federal Regulations (CFR) Part 150) [~~(Title 10, Code of Federal Regulations (CFR), Part 150)~~]. A person who receives, possesses, uses, owns, transfers, or acquires radioactive material before [~~prior to~~] receiving a license is subject to the requirements of this chapter.

(b) Definitions. The following words and terms when used in this chapter [~~shall~~] have the following meanings[~~,~~] unless the context clearly indicates otherwise.

(1) Absorbed dose--The energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the gray (Gy) and the rad.

(2) Accelerator-produced material--Any material made radioactive by exposing it to the radiation from a particle accelerator.

(3) Access control--A system for allowing only approved individuals to have unescorted access to the security zone and for ensuring that all other individuals are subject to escorted access.

(4) Act--Texas Radiation Control Act, Texas Health and Safety Code (HSC)[,] Chapter 401.

(5) Activity--The rate of disintegration or transformation or decay of radioactive material. The units of activity are the becquerel (Bq) and the curie (Ci).

(6) Adult--An individual 18 or more years of age.

[(7) Agency--The Department of State Health Services.]

(7) [(8)] Aggregated--Accessible by the breach of a single physical barrier that would allow access to radioactive material in any form, including any devices that contain the radioactive material, when the total activity equals or exceeds a category 2 quantity of radioactive material.

(8) [(9)] Agreement state--Any state with which NRC has entered into an effective agreement under Section 274 [§274b] of the Atomic Energy Act of 1954, as amended [(73 Stat. 689)].

(9) [(10)] Airborne radioactive material--Any radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

(10) [(11)] Airborne radioactivity area--A room, enclosure, or area in which airborne radioactive materials exist in concentrations:

(A) over [in excess of] the derived air concentrations (DACs) specified in Table I, Column 3 of §289.202(ggg)(2)(F) of this subchapter [title] (relating to Standards for Protection Against Radiation from Radioactive Materials); or

(B) to such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent [0.6%] of the annual limit on intake (ALI) or 12 derived air concentration-hours (DAC-hours) [DAC-hours].

(11) [(12)] Approved individual--An individual whom the licensee has determined to be trustworthy and reliable for unescorted access as specified in §289.252(ii)(2) - (8) [in accordance with §289.252(ii)(2) - (8)] of this chapter [title] (relating to Licensing of Radioactive Material) and who has completed the training required by §289.252(ii)(10)(C) of this chapter [title].

(12) [(13)] As low as is reasonably achievable (ALARA)--Making every reasonable effort to maintain exposures to radiation as far below the dose limits in these regulations as is practical, consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of ionizing radiation and licensed sources of radiation in the public interest.

(13) [(14)] Background investigation--The investigation conducted by a licensee or applicant to support the determination of trustworthiness and reliability.

(14) [(15)] Background radiation--Radiation from cosmic sources; non-technologically enhanced, naturally occurring radioactive material, including radon, except as a decay product of source or special nuclear material;[,] and [including] global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents, such as Chernobyl, contributing [that contribute] to background radiation and [are] not under the control of the licensee. "Background radiation" does not include radiation from sources of radiation regulated by the department [agency].

(15) [(16)] Becquerel (Bq)--The International System of Units (SI) unit of activity. One becquerel is equal to one [1] disintegration or transformation per second (dps or tps). Commonly used multiples of the becquerel are the kBq (kilobecquerel, 10^3Bq), MBq (megabecquerel, 10^6Bq), GBq (gigabecquerel, 10^9Bq), and TBq (terabecquerel, 10^{12}Bq). 1 Ci = 37 GBq.

(16) [(17)] Bioassay--The determination of kinds, quantities, or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement, in vivo counting, or by analysis and evaluation of materials excreted or removed from the human body. For purposes of this chapter, "radiobioassay" is an equivalent term.

(17) [(18)] Brachytherapy--A method of radiation therapy in which sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, or interstitial application.

(18) [(19)] Byproduct material--Byproduct material is defined as:

(A) any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material;

(B) the tailings or wastes produced by or resulting from the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition;

(C) any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; [or]

(D) any material that has been made radioactive by use of a particle accelerator; and is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or [and]

(E) any discrete source of naturally occurring radioactive material, other than source material, that is extracted or converted after extraction before, on, or after August 8, 2005, for use in a commercial, medical, or research activity and that the United States NRC, in consultation with the Administrator of the United States Environmental Protection Agency (EPA), the United States Secretary of Energy, the United States Secretary of Homeland Security, and the head of any other appropriate federal [Federal] agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security.

(19) [(20)] Category 1 quantity of radioactive material--A quantity of radioactive material meeting or exceeding the category 1 threshold in §289.252(jj)(9) of this chapter [title]. This is determined by calculating the ratio of the total activity of each radionuclide to the category 1 threshold for that radionuclide and adding the ratios together. If the sum is equal to or exceeds one [1], the quantity would be considered a category 1 quantity. Category 1 quantities of radioactive material do not include the radioactive material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.

(20) [(21)] Category 2 quantity of radioactive material--A quantity of radioactive material meeting or exceeding the category 2 threshold but less than the category 1 threshold in §289.252(jj)(9) of

this chapter [~~title~~]. This is determined by calculating the ratio of the total activity of each radionuclide to the category 2 threshold for that radionuclide and adding the ratios together. If the sum is equal to or exceeds one [~~1~~], the quantity would be considered a category 2 quantity. Category 2 quantities of radioactive material do not include the radioactive material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.

(21) [~~(22)~~] Certificate of registration--A form of permission to engage in regulated activities given by the department [~~agency~~] to an applicant who has met the requirements for registration or mammography system certification set out in the Act and this chapter.

(22) [~~(23)~~] Certification of mammography systems (state certification)--A form of permission to engage in regulated activities given by the department [~~agency~~] to an applicant who has met the requirements for mammography system certification set out in the Act and this chapter.

(23) [~~(24)~~] Collective dose--The sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

(24) [~~(25)~~] Commercial--Having financial profit as the primary aim.

(25) [~~(26)~~] Committed dose equivalent ($H_{T,50}$) [~~($H_{T,50}$)~~]--The dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

(26) [~~(27)~~] Committed effective dose equivalent ($H_{E,50}$) [~~($H_{E,50}$)~~]--The sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues ($H_{E,50} = W_T H_{T,50}$) [~~($H_{E,50} = \Sigma W_T H_{T,50}$)~~].

(27) [~~(28)~~] Consortium--An association of medical use licensees and a Positron Emission Tomography (PET) radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance costs of the PET radionuclide production facility. The PET radionuclide production facility produces [~~that produces PET~~] radionuclides [~~for use in producing radioactive drugs~~] [~~within the consortium~~] for production and noncommercial distribution of radioactive drugs [~~distributions~~] among consortium members [~~its associated members~~] for medical use and is [~~. The PET radionuclide production facility within the consortium shall be~~] located at an educational institution or a medical facility.

(28) [~~(29)~~] Constraint (dose constraint)--A value above which specified licensee actions are required.

(29) [~~(30)~~] Critical group--The group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

(30) [~~(31)~~] Curie (Ci)--A unit of measurement of radioactivity. One curie (Ci) is the [~~that~~] quantity of radioactive material that decays at the rate of 3.7×10^{10} disintegrations per second (dps). Commonly used submultiples of the curie are the millicurie (mCi) and the microcurie (Ci). One mCi = 1×10^{-3} Ci = 3.7×10^{7} dps. One Ci = 1×10^{-6} Ci = 3.7×10^{4} dps. One nanocurie (nCi) = 1×10^{-9} Ci = 3.7×10^{1} dps. One picocurie (pCi) = 1 x 10-12Ci = 3.7 x 10-2dps.

(31) [~~(32)~~] Decommission--To remove a facility or site safely from service and reduce residual radioactivity to a level that permits the following:

(A) release of the property for unrestricted use or [~~and/or~~] termination of license; or

(B) release of the property under alternate requirements for license termination.

(32) [~~(33)~~] Deep dose equivalent (H_d) [~~(H_d)~~], that applies to external whole body exposure--The dose equivalent at a tissue depth of 1 centimeter (cm) (1,000 milligrams per square centimeter (mg/cm^2) [~~(mg/cm^2)~~]).

(33) Department--The Department of State Health Services.

(34) Depleted uranium--The source material uranium in which the isotope uranium-235 is less than 0.711 weight percent of the total uranium present. Depleted uranium does not include special nuclear material.

(35) Discrete source--A radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.

(36) Distinguishable from background--The detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site, or, in the case of structures or equipment, in similar materials using adequate measurement technology, survey, and statistical techniques.

(37) Distribution--The physical conveyance and authorized transfer of commodities from producers to consumers and any intermediate persons involved in that conveyance.

(38) Diversion--The unauthorized movement of radioactive material subject to §289.252(ii) of this chapter [~~title~~] to a location different from the material's authorized destination inside or outside of the site at which the material is used or stored.

(39) Dose--A generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, total organ dose equivalent, or total effective dose equivalent. For purposes of this chapter, "radiation dose" is an equivalent term.

(40) Dose equivalent (H_T) [~~(H_T)~~]--The product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert (Sv) and rem.

(41) Dose limits--The permissible upper bounds of radiation doses established as specified in [~~accordance with~~] this chapter. For purposes of this chapter, "limits" is an equivalent term.

(42) Effective dose equivalent (H_E) [~~(H_E)~~]--The sum of the products of the dose equivalent to each organ or tissue (H_T) [~~(H_T)~~] and the weighting factor (W_T) [~~(W_T)~~] applicable to each of the body organs or tissues that are irradiated ($H_E = W_T H_T$) [~~($H_E = \Sigma W_T H_T$)~~].

(43) Embryo/fetus--The developing human organism from conception until the time of birth.

(44) Entrance or access point--Any opening through which an individual or extremity of an individual could gain access to radiation areas or to licensed sources of radiation. This includes portals of sufficient size to permit human access, irrespective of their intended use.

(45) Escorted access--Accompaniment while in a security zone by an approved individual who maintains continuous direct visual surveillance, at all times over an individual who is not approved for unescorted access.

(46) Exposure--The quotient of dQ by dm where "dQ" is the absolute value of the total charge of the ions of one sign produced in air when all the electrons and positrons [~~(negatrons and positrons)~~]

liberated by photons in a volume element of air having mass "dm" are completely stopped in air. The SI unit of exposure is the coulomb per kilogram (C/kg). The roentgen is the special unit of exposure. For purposes of this chapter, this term is used as a noun.

(47) Exposure rate--The exposure per unit of time.

(48) External dose--That portion of the dose equivalent received from any source of radiation outside the body.

(49) Extremity--Hand, elbow, arm below the elbow, foot, knee, and leg below the knee. The arm above the elbow and the leg above the knee are considered part of the whole body.

(50) Fingerprint orders--The orders issued by the NRC or the legally binding requirements issued by agreement states that require fingerprints and criminal history records checks for individuals with unescorted access to category 1 and category 2 quantities of radioactive material or Safeguards Information-Modified Handling files [~~safeguards information-modified handling~~].

(51) Generally applicable environmental radiation standards--Standards issued by the EPA [~~United States Environmental Protection Agency (EPA)~~] under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

(52) Gray (Gy)--The SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (J/kg) or 100 rad.

(53) High radiation area--An area, accessible to individuals, in which radiation levels from sources of radiation external to the body could result in an individual receiving a dose equivalent more than [~~in excess of~~] 0.1 rem (1 millisievert (mSv)) in one hour at 30 cm from any source of radiation or from any surface that the radiation penetrates.

(54) Human use--The internal or external administration of radiation or radioactive material to human beings for healing arts purposes or research and [~~and/or~~] development specifically authorized by the department [~~agency~~].

(55) Individual--Any human being.

(56) Individual monitoring--The assessment of:

(A) dose equivalent to an individual using [~~by the use of~~] individual monitoring devices; or

(B) committed effective dose equivalent to an individual by bioassay or by determination of the time-weighted air concentrations to which an individual has been exposed, that is, DAC-hours. (See the definition for DAC-hours in §289.202(c) of this subchapter [~~title~~]); or

(C) dose equivalent to an individual using [~~by the use of~~] survey data.

(57) Individual monitoring device [~~devices~~]--Device [~~Devices~~] designed to be worn by a single individual (such as a film badge, thermoluminescent dosimeter (TLD), optically stimulated luminescence dosimeter (OSL), or digital output personnel dosimeter) used for the assessment of dose equivalent. For purposes of this chapter, "personnel dosimeter" and "dosimeter" are equivalent terms. [~~Examples of individual monitoring devices include, but are not limited to, film badges, thermoluminescence dosimeters (TLDs), optically stimulated luminescence dosimeters (OSLs), pocket ionization chambers (pocket dosimeters), electronic personal dosimeters, and personal air sampling devices.~~]

(58) Inspection--An official examination or [~~and/or~~] observation, including [~~, but not limited to,~~] records, tests, surveys, and monitoring to determine compliance with the Act and rules, orders, requirements, and conditions of the department [~~agency~~].

(59) Internal dose--That portion of the dose equivalent received from radioactive material taken into the body.

(60) Ionizing radiation--Any electromagnetic or particulate radiation capable of producing ions, directly or indirectly, in its passage through matter. Ionizing radiation includes gamma rays and x-rays [~~x rays~~], alpha and beta particles, high-speed electrons, neutrons, and other nuclear particles.

(61) Land disposal facility--The land, buildings, and equipment that are intended to be used for the disposal of low-level radioactive waste (LLRW) into the subsurface of the land.

(62) Lens dose equivalent--The external dose equivalent to the lens of the eye at a tissue depth of 0.3 cm (300 mg/cm^2) [~~(300 mg/cm^2)~~].

(63) License--A form of permission to engage in regulated activities given by the department [~~agency~~] to an applicant who has met the requirements for licensing set out in the Act and this chapter.

(64) Licensed material--Radioactive material received, possessed, used, or transferred under a general or specific license issued by the department [~~agency~~].

(65) Licensee--Any person who is licensed by the department as specified in [~~agency in accordance with~~] the Act and this chapter.

[~~(66) Licensing state--Any state with rules equivalent to the Suggested State Regulations for Control of Radiation relating to, and having an effective program for, the regulatory control of naturally occurring or accelerator-produced radioactive material (NARM) and has been designated as such by the Conference of Radiation Control Program Directors, Inc. For the purposes of evaluation and/or distribution of sealed sources, this includes Licensing State Status: Product Review Only.~~]

(66) [~~(67)~~] Local law enforcement agency (LLEA)--A public or private organization that has been approved by a federal, state, or local government to carry firearms and make arrests, and is authorized and has the capability to provide an armed response in the jurisdiction where the licensed category 1 or category 2 quantity of radioactive material is used, stored, or transported.

(67) [~~(68)~~] Lost or missing radioactive material--Radioactive material whose location is unknown. This definition includes licensed material that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.

(68) [~~(69)~~] Low-level radioactive waste (LLRW)--Radioactive material that meets the following criteria:

(A) LLRW includes [~~is radioactive material that is~~]:

(i) discarded or unwanted radioactive material [~~and is~~] not exempt by rule adopted under the Texas Radiation Control Act (Act), specifically, HSC, §401.106;

(ii) waste, as that term is defined in 10 CFR §61.2 [~~Title 10, CFR, §61.2~~]; and

(iii) radioactive material subject to:

(I) concentration limits established in 10 CFR §61.55 [~~Title 10, CFR, §61.55~~], or compatible rules adopted by the

department [~~agency~~] or the Texas Commission on Environmental Quality (TCEQ), as applicable; and

(II) disposal criteria established in Title 10 of the CFR[~~, CFR,~~] or established by the department [~~agency~~] or TCEQ, as applicable.

(B) LLRW does not include:

(i) high-level radioactive waste as defined by 10 CFR §60.2 [~~Title 10, CFR, §60.2~~];

(ii) spent nuclear fuel as defined by 10 CFR §72.3 [~~Title 10, CFR, §72.3~~];

(iii) byproduct material defined in HSC §401.003(3)(B) [~~the Act, HSC, §401.003(3)(B)~~];

(iv) naturally occurring radioactive material (NORM) waste that is not oil and gas NORM waste;

(v) oil and gas NORM waste; or

(vi) transuranics greater than 100 nanocuries per gram.

(69) [~~(70)~~] Manufacture--To fabricate or mechanically produce.

(70) [~~(71)~~] Member of the public--Any individual, except when that individual is receiving an occupational dose.

(71) [~~(72)~~] Minor--An individual less than 18 years of age.

(72) [~~(73)~~] Mobile device--A piece of equipment containing licensed radioactive material that either is mounted on a permanent base with wheels or [~~and/or~~] casters, or otherwise equipped for moving while completely assembled and without dismounting; or is a portable device. Mobile devices do not include stationary equipment installed in a fixed location.

(73) [~~(74)~~] Monitoring--The measurement of radiation, radioactive material concentrations, surface area activities, or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of this chapter, "radiation monitoring" and "radiation protection monitoring" are equivalent terms.

(74) [~~(75)~~] Movement control center--An operations center [~~that is~~] remote from the transport activity [~~and~~] that maintains position information on the movement of radioactive material, receives reports of attempted attacks or thefts, provides a means for reporting these and other problems to appropriate agencies, and can request and coordinate appropriate aid.

(75) [~~(76)~~] Naturally occurring or accelerator-produced radioactive material (NARM) [~~NARM~~]--Any naturally occurring or accelerator-produced radioactive material except source material or special nuclear material.

(76) [~~(77)~~] Natural radioactivity--Radioactivity of naturally occurring nuclides whose location and chemical and physical form have not been altered by man.

(77) [~~(78)~~] No-later-than arrival time--The date and time that the shipping licensee and receiving licensee have established as the time at which an investigation will be initiated if the shipment has not arrived at the receiving facility. The no-later-than arrival time may not be more than six [~~6~~] hours after the estimated arrival time for shipments of category 2 quantities of radioactive material.

(78) [~~(79)~~] NRC--The United States Nuclear Regulatory Commission or its duly authorized representatives.

(79) [~~(80)~~] Occupational dose--The dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to sources of radiation from licensed/registered and unlicensed/unregistered sources of radiation, whether in the possession of the licensee/registrant or other person. Occupational dose does not include dose received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released as specified in [~~accordance with~~] this chapter, from voluntary participation in medical research programs, or as a member of the public.

(80) [~~(81)~~] Particle accelerator--Any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and designed to discharge the resultant particulate or other associated radiation at energies usually greater than [~~in excess of~~] 1 million electron volts (MeV).

(81) [~~(82)~~] Person--Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, local government, any other state or political subdivision or agency thereof, or any other legal entity, and any legal successor, representative, agent, or agency of the foregoing, other than NRC, and other than federal government agencies licensed or exempted by NRC.

(82) [~~(83)~~] Personnel monitoring equipment (See definition for individual monitoring devices.)

(83) [~~(84)~~] Pharmacist--An individual licensed by the Texas State Board of Pharmacy to compound and dispense drugs, prescriptions, and poisons.

(84) [~~(85)~~] Physician--An individual licensed by the Texas Medical Board to practice medicine under Texas Occupations Code Chapter 155.

(85) Pocket dosimeter--A small ionization detection instrument or electronic personal dosimeter that indicates ionizing radiation exposure directly. An auxiliary charging device may be necessary.

(86) Portable device--A piece of equipment containing licensed radioactive material that is designed by the manufacturer to be hand carried during use.

(87) Positron emission tomography (PET) radionuclide production facility--A facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

(88) Principal activities--Activities authorized by the license that are essential to achieving the purposes [~~purpose(s)~~] for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

(89) Public dose--The dose received by a member of the public from exposure to sources of radiation released by a licensee, or to any other source of radiation under the control of a licensee/registrant. It does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released as specified in [~~accordance with~~] this chapter, or from voluntary participation in medical research programs.

(90) Quality factor (Q)--The modifying factor listed in subsection (m)(1) and (2) [~~(n)(1) and (2)~~] of this section that is used to derive dose equivalent from absorbed dose.

(91) Quarter (calendar quarter)--A period of time equal to one-fourth of the year observed by the licensee, approximately 13 consecutive weeks, providing that the beginning of the first quarter in a

year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

(92) Rad--The special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs per gram (erg/g) or 0.01 J/kg (0.01 Gy).

(93) Radiation--One or more of the following:

(A) gamma and x rays; alpha and beta particles and other atomic or nuclear particles or rays;

(B) emission of radiation from any electronic device to such energy density levels as to reasonably cause bodily harm; or

(C) sonic, ultrasonic, or infrasonic waves from any electronic device or resulting from the operation of an electronic circuit in an electronic device in the energy range to reasonably cause detectable bodily harm.

(94) Radiation area--Any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent more than [~~in excess of~~] 0.005 rem (0.05 mSv) in one hour at 30 cm from the source of radiation or from any surface that the radiation penetrates.

(95) Radiation machine--Any device capable of producing ionizing radiation except those devices with radioactive material as the only source of radiation.

(96) Radiation safety officer (RSO)--An individual who has the [~~a~~] knowledge, [~~of and the~~] authority, and responsibility to apply appropriate radiation protection rules, standards, and practices, who is [~~must be~~] specifically authorized on a radioactive material license, and who is the primary contact with the department [~~agency~~]. Specific training and responsibilities for an RSO are listed in §289.252 of this chapter [~~title~~], §289.253 of this chapter [~~title~~] (relating to Radiation Safety Requirements for Well Logging Service Operations and Tracer Studies), §289.255 of this chapter [~~title~~] (relating to Radiation Safety Requirements and Licensing and Registration Procedures for Industrial Radiography), and §289.256 of this chapter [~~title~~] (relating to Medical and Veterinary Use of Radioactive Material).

(97) Radioactive material--Any material (solid, liquid, or gas) that emits radiation spontaneously.

(98) Radioactive waste--For purposes of this chapter, this term is equivalent to LLRW.

(99) Radioactivity--The disintegration of unstable atomic nuclei with the emission of radiation.

(100) Radiobioassay--See definition for bioassay. [~~(See definition for bioassay.)~~]

(101) Registrant--Any person issued a certificate of registration by the department as specified in [~~agency in accordance with~~] the Act and this chapter.

(102) Regulation--See definition for rule. [~~(See definition for rule.)~~]

(103) Regulations of the United States Department of Transportation (DOT)--The federal requirements in 49 CFR Parts 100 - 189 [~~Title 49, CFR, Parts 100 - 189~~].

(104) Rem--The special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 sievert (Sv)).

(105) Research and development--Research and development is defined as:

(A) theoretical analysis, exploration, or experimentation; or

(B) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes.

(106) Residential location--Any area where a structure or structures are located in which people [~~lodge or~~] live, and the grounds on which these structures are located, including [~~, but not limited to,~~] houses, apartments, condominiums, and garages.

(107) Residual radioactivity--The radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site and previous burials at the site, even if those burials were made as specified in 10 CFR Part 20 [~~in accordance with the provisions of Title 10, CFR, Part 20~~].

(108) Restricted area--An area, access to which is limited by the licensee for the purpose of protecting individuals against undue risks from exposure to sources of radiation. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

(109) Reviewing official--The individual who makes [~~shall make~~] the trustworthiness and reliability determination of an individual to determine whether the individual may have, or continue to have, unescorted access to the category 1 or category 2 quantities of radioactive materials in the possession of [~~that are possessed by~~] the licensee.

(110) Roentgen (R)--The special unit of exposure. One roentgen (R) equals 2.58 x 10^{-4} C/kg of air. (See definition for exposure.)

(111) Rule (as defined in the Texas Government Code Chapter[~~, Chapters~~] 2001 [~~and 2002, as amended~~])--Any agency statement of general applicability that implements, interprets, or prescribes law or policy, or describes the procedure or practice requirements of an agency. The term includes the amendment or repeal of a prior rule and [~~section but~~] does not include a statement regarding [~~statements concerning~~] only the internal management or organization of a state [~~any~~] agency and not affecting private rights or procedures. The word "rule" was formerly referred to as "regulation."

(112) Sabotage--The deliberate damage, with malevolent intent, to a category 1 or category 2 quantity of radioactive material, a device that contains a category 1 or category 2 quantity of radioactive material, or the components of the security system protecting those materials.

(113) Safe haven--A readily recognizable and readily accessible site at which security is present or from which, in the event of an emergency, the transport crew can notify and wait for [~~the~~] local law enforcement authorities.

(114) Sealed source--Any radioactive or byproduct material that is encased in a capsule designed to prevent leakage or escape of the material [~~Radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material~~].

(115) Security zone--Any temporary or permanent area determined and established by the licensee for the physical protection of category 1 or category 2 quantities of radioactive material.

(116) Shallow dose equivalent (H_s) [(H_s)] (that applies to the external exposure of the skin of the whole body or the skin of an extremity)--The dose equivalent at a tissue depth of 0.007 cm (7 mg/cm^2) [(7 mg/cm^2)].

(117) SI--The abbreviation for the International System of Units.

(118) Sievert--The SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).

(119) Site boundary--That line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee.

(120) Source material--Source material is defined as:

(A) uranium or thorium, or any combination thereof, in any physical or chemical form; or

(B) ores that contain by weight 0.05 percent [0.05%] or more of uranium, thorium, or any combination thereof; and

(C) does not include special nuclear material.

(121) Source of radiation--Any radioactive material, or any device or equipment emitting or capable of producing radiation.

(122) Special form radioactive material--Radioactive material satisfying [that satisfies] the following conditions:[.]

(A) [It is] either a single solid piece or [is] contained in a sealed capsule only [that can be] opened [only] by destroying the capsule;

(B) the [The] piece or capsule has at least one dimension not less than 5 millimeters (mm) (0.2 inch); and

(C) [It] satisfies the requirements specified by NRC. A special form encapsulation designed as specified in [accordance with] NRC requirements in effect on June 30, 1983, and constructed before [prior to] July 1, 1985, may continue to be used. A special form encapsulation designed as specified in [accordance with] NRC requirements in effect on March 31, 1996, and constructed before [prior to] April 1, 1998, may continue to be used. A special form encapsulation either designed or constructed after April 1, 1998, must meet the requirements of this definition applicable at the time of its design or construction.

(123) Special nuclear material--Special nuclear material is defined as:

(A) plutonium (Pu), uranium-233 (U-233), uranium enriched in the isotope 233 or in the isotope 235, and any other material that NRC, as specified in [accordance with] the provisions of the Atomic Energy Act of 1954, §51 as amended, determines to be special nuclear material, but does not include source material; or

(B) any material artificially enriched by any of the foregoing, but does not include source material.

(124) Special nuclear material in quantities not sufficient to form a critical mass--Uranium enriched in the isotope 235 in quantities not exceeding 350 grams (g) of contained uranium-235; uranium-233 in quantities not exceeding 200 g; plutonium in quantities not exceeding 200 g; or any combination of them as specified in [accordance with] the following formula.

(A) For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all [of the] kinds of special nuclear material in combination must [shall] not exceed "1" (i.e., unity).

(B) For example, the following quantities in combination would not exceed the limitation and are within the formula.[:] Figure: 25 TAC §289.201(b)(124)(B) (No change.)

(125) Special units--The conventional units historically used by licensees, for example, curie (activity), rad (absorbed dose), and rem (dose equivalent).

(126) Stationary device--A piece of equipment containing licensed radioactive material that is installed in a fixed location.

(127) Survey--An evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or [and/or] presence of sources of radiation. When appropriate, such survey includes [, but is not limited to,] tests, physical examination of location of materials and equipment, measurements of levels of radiation or concentration of radioactive material present, and evaluation of administrative and [and/or] engineered controls.

(128) Telemetric position monitoring system--A data transfer system that captures information by instrumentation or [and/or] measuring devices about the location and status of a transport vehicle or package between the departure and destination locations.

(129) Temporary job site--A location where licensed or registered sources of radiation are used or stored other than the specific use location or locations listed on a license or certificate of registration.

(130) [(129)] Termination--A release by the department [agency] of the obligations and authorizations of the licensee under the terms of the license. It does not relieve a person of duties and responsibilities imposed by law.

(131) [(130)] Test--A method of determining the characteristics or condition of sources of radiation or components thereof.

(132) [(131)] Texas Regulations for Control of Radiation (TRCR)--All sections of 25 Texas Administrative Code (TAC) Chapter 289 [Title 25 TAC, Chapter 289].

(133) [(132)] Total effective dose equivalent (TEDE)--The sum of the effective dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.

(134) [(133)] Total organ dose equivalent (TODE)--The sum of the deep dose equivalent and the committed dose equivalent to the organ receiving the highest dose as described in §289.202(rr)(1)(F) of this chapter [title].

(135) [(134)] Transport index--The dimensionless number (rounded up to the next tenth) placed on the label of a package, to designate the degree of control to be exercised by the carrier during transportation. The transport index is determined as follows:

(A) For non-fissile material packages, the number determined by multiplying the maximum radiation level in millisievert per hour (mSv/hr) at 1 meter (m) (3.3 feet) from the external surface of the package by 100 (equivalent to the maximum radiation level in millirem per hour (mrem/hr) at 1 m (3.3 feet).[; or]

(B) For fissile material packages, the number determined by multiplying the maximum radiation level in mSv/hr at 1 m (3.3 feet) from the external surface of the package by 100 (equivalent to the maximum radiation level in mrem/hr at 1 m (3.3 feet), or, for criticality control purposes, the number obtained as described in 10 CFR §71.59 [Title 10, CFR, §71.59], whichever is larger.

(136) [(135)] Trustworthiness and reliability--Characteristics of an individual considered dependable in judgment, character, and performance, such that unescorted access to category 1 or category 2 quantities of radioactive material by that individual does not constitute

an unreasonable risk to the public health and safety or security. A determination of trustworthiness and reliability for this purpose is based upon the results from a background investigation.

(137) [~~(136)~~] Type A quantity--A quantity of radioactive material, the aggregate radioactivity of which does not exceed A_1 for special form radioactive material or A_2 for normal form radioactive material, where A_1 [~~A_2~~] and A_2 are given in §289.257(ee) of this chapter [~~title~~] (relating to Packaging and Transportation of Radioactive Material) or may be determined by procedures described in §289.257(ee) of this chapter [~~title~~].

(138) [~~(137)~~] Type B quantity--A quantity of radioactive material greater than a type A quantity.

(139) [~~(138)~~] Unescorted access--Solitary access to an aggregated category 1 or category 2 quantity of radioactive material or the devices that contain the material.

(140) [~~(139)~~] Unrefined and unprocessed ore--Ore in its natural form before [~~prior to~~] any processing, such as grinding, roasting or beneficiating, or refining. Processing does not include sieving or encapsulation of ore or preparation of samples for laboratory analysis.

(141) [~~(140)~~] Unrestricted area (uncontrolled area)--An area, or access to, which is neither limited nor controlled by the licensee. For purposes of this chapter, "uncontrolled area" is an equivalent term.

(142) [~~(141)~~] Very high radiation area--An area, accessible to individuals, in which radiation levels from sources of radiation external to the body could result in an individual receiving an absorbed dose more than [~~in excess of~~] 500 rads (5 Gy in one hour at 1 m) [~~meter (m)~~] from a source of radiation or from any surface that the radiation penetrates. At very high doses received at high dose rates, units of absorbed dose, gray and rad, are appropriate, rather than units of dose equivalent, Sv, and rem.

(143) [~~(142)~~] Veterinarian--An individual licensed by the Texas State Board of Veterinary Medical Examiners to practice veterinary medicine under Texas Occupations Code Chapter 801.

(144) [~~(143)~~] Waste--Low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in paragraph (18)(B) - (E) [~~(19)(B) - (E)~~] of this subsection.

(145) [~~(144)~~] Week--Seven consecutive days starting on Sunday.

(146) [~~(145)~~] Whole body--For purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.

(147) [~~(146)~~] Worker--An individual engaged in work under a license or certificate of registration issued by the department [~~agency~~] and controlled by a licensee or registrant[~~,~~] but does not include the licensee or registrant.

(148) [~~(147)~~] Working level (WL)--Any combination of short-lived radon daughters in 1 liter of air that will result in the ultimate emission of 1.3×10^5 MeV of potential alpha particle energy. The short-lived radon daughters are--for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212.

(149) [~~(148)~~] Working level month (WLM)--An exposure to one working level for 170 hours--2,000 working hours per year divided by 12 months per year is approximately equal to 170 hours per month.

(150) [~~(149)~~] Year--The period of time beginning in January used to determine compliance with the provisions of this chapter. The licensee may change the starting date of the year used to determine compliance by the licensee if [~~provided that~~] the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

(c) Exemptions.

(1) General provision. The department [~~agency~~] may, upon application [~~therefore~~] or [~~upon~~] its own initiative, exempt a source of radiation or a kind of use or user from the requirements of this chapter if the department [~~agency~~] determines that the exemption is not prohibited by law and will not result in a significant risk to public health and safety, and the environment. In determining such exemptions, the department considers [~~agency will consider~~]:

(A) state of technology;

(B) economic considerations in relation to benefits to the public health and safety; and

(C) other societal, socioeconomic, or public health and safety considerations.

(2) United States Department of Energy (DOE) contractors and NRC contractors. Any DOE contractor or subcontractor and any NRC contractor or subcontractor of the following categories, operating within Texas, is exempt from this chapter, except [~~with the exception of~~] §289.204 of this subchapter [~~title~~] (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services), to the extent that such contractor or subcontractor under that individual's contract, receives, possesses, uses, transfers, or acquires sources of radiation:

(A) prime contractors performing work for DOE at United States government-owned or controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;

(B) prime contractors of DOE performing research in, or development, manufacture, storage, testing, or transportation of atomic weapons or components of atomic weapons [~~thereof~~];

(C) prime contractors of DOE using or operating nuclear reactors or other nuclear devices in a United States government-owned vehicle or vessel; and

(D) any other prime contractor or subcontractor of DOE or of NRC when Texas [~~the state~~] and NRC jointly determine that:

(i) the exemption of the prime contractor or subcontractor is authorized by law; and

(ii) as specified in [~~accordance with~~] the terms of the contract or subcontract, there is adequate assurance that the work [~~thereunder~~] can be accomplished without undue risk to the public health and safety and the environment.

(d) Records.

(1) Each licensee must [~~shall~~] maintain records showing the receipt, transfer, and disposal of all non-exempt sources of radiation.

(A) Records of receipt, transfer, and disposal of sources of radiation must [~~shall~~] include, as a minimum[~~, the following information~~]:

(i) a unique identification of each source of radiation, including:

(I) manufacturer's name;

(II) isotope;

(III) activity; and

(IV) if available, sealed source serial number;

(ii) the date of receipt, transfer, or disposal of each source of radiation;

(iii) for the licensee transferring the source of radiation, the name of the transferee, the number of the transferee's radioactive material license authorizing possession of the material, and the regulatory agency issuing the license to the transferee; and

(iv) for the licensee receiving the source of radiation, the name of the transferor, the number of the transferor's radioactive material license authorizing possession of the material, and the regulatory agency issuing the license to the transferor.

(B) Records of receipt and[~~,~~] transfer[~~, and disposal~~] of radioactive material must [~~shall~~] be retained [~~maintained~~] by the licensee until disposal of the records is authorized by the department [~~agency~~]. Records of radioactive material disposal must be retained by the licensee until termination of the license.

(2) Additional record requirements and retention periods are specified elsewhere in this chapter.

(3) All records required by this chapter must [~~shall~~] be accurate and factual.

(4) Records are only valid if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated.

(5) Each record required by this chapter must include all pertinent information and be stored in a legible and reproducible format [~~legible~~] throughout the retention period specified by the department [~~agency. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, or specifications, must include all pertinent information such as stamps, initials, and signatures.~~] The licensee must [~~shall~~] maintain adequate safeguards against tampering with and loss of records.

(e) Inspections.

(1) The department [~~agency~~] may enter public or private property at reasonable times to determine whether, in a matter under the department's [~~agency's~~] jurisdiction, there is compliance with the Act, the department's [~~agency's~~] rules, license conditions, and orders issued by the department [~~agency~~].

(2) Each licensee must [~~shall~~] afford the department [~~agency~~], at all reasonable times, opportunity to inspect sources of radiation and the premises and facilities where [~~wherein such~~] sources of radiation are used or stored.

(3) Each licensee must [~~shall~~] make available to the department [~~agency~~] for inspection, upon reasonable notice, records maintained as specified in [~~accordance with~~] this chapter.

(f) Tests.

(1) Each licensee must [~~shall~~] perform, upon instructions from the department [~~agency~~], or must [~~shall~~] permit the department [~~agency~~] to perform, [~~such~~] reasonable tests [~~as~~] the department [~~agency~~] deems appropriate or necessary, including [~~, but not limited to,~~] tests of:

(A) sources of radiation;

(B) facilities where [~~wherein~~] sources of radiation are used or stored;

(C) radiation detection and monitoring instruments; and

(D) other equipment and devices used in connection with utilization or storage of licensed sources of radiation.

(2) Each licensee is required to accept from the department [~~agency~~], samples collected from its facility [~~facility(ies)~~] or from areas that are radioactive resulting from [~~as a result of~~] its licensed activities.

(g) Tests for leakage or [~~and/or~~] contamination of sealed sources.

(1) The licensee possessing [~~in possession of~~] any sealed source must [~~shall~~] assure that:

(A) each sealed source, except as specified in paragraph (2) of this subsection and §289.253(j) [~~§289.253(i)~~] of this chapter [~~title~~], is tested for leakage or contamination and the test results are received before the sealed source is put into use unless the licensee has a certificate from the transferor indicating that the sealed source was tested within six [~~6~~] months before transfer to the licensee;

(B) each sealed source that is not designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed six [~~6~~] months or at alternative intervals approved by the department [~~agency~~], the NRC, or any agreement state after evaluation of information specified in §289.252(v) of this chapter [~~title~~] or equivalent regulations of the NRC or any agreement state;

(C) each sealed source that is designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed three [~~3~~] months or at alternative intervals approved by the department [~~agency~~], the NRC, or any agreement state after evaluation of information specified in §289.252(v) of this chapter [~~title~~], or equivalent regulations of the NRC, or any agreement state;

(D) for each sealed source that is required to be tested for leakage or contamination, at any other time there is reason to suspect that the sealed source might have been damaged or might be leaking, [~~the licensee shall assure that~~] the sealed source is tested for leakage or contamination before further use;

(E) tests for leakage for all sealed sources, except brachytherapy sources manufactured to contain radium, are [~~shall be~~] capable of detecting the presence of 0.005 Ci (185 Bq) of radioactive material on a test sample. Test samples must [~~shall~~] be taken from the sealed source or from the surfaces of the container in which the sealed source is stored or mounted and at the nearest accessible point to the sealed source where contamination might accumulate. For a sealed source contained in a device, test samples are obtained when the source is in the "off" position;

(F) the test for leakage for brachytherapy sources manufactured to contain radium are [~~shall be~~] capable of detecting an absolute leakage rate of 0.001 Ci (37 Bq) of radon-222 in a 24-hour period when the collection efficiency for radon-222 and its daughters has been determined with respect to collection method, volume, and time;

(G) tests for contamination from radium daughters are [~~shall be~~] taken on the interior surface of brachytherapy source storage

containers and are [~~shall be~~] capable of detecting the presence of 0.005 Ci (185 Bq) of a radium daughter that has a half-life greater than four [4] days; and

(H) tests for leakage or contamination are [~~shall be~~] performed using a leak test kit or method approved by the department [~~agency~~], the NRC, or any agreement state.

(2) A licensee need not perform tests for leakage or contamination on the following [~~sealed sources~~]:

(A) sealed sources containing only radioactive material with a half-life of less than 30 days;

(B) sealed sources containing only radioactive material as a gas;

(C) sealed sources containing 100 Ci (3.7 MBq) or less of beta or gamma-emitting material or 10 Ci (370 kBq) or less of alpha or neutron-emitting material;

(D) sealed sources containing only hydrogen-3 (tritium);

(E) seeds of iridium-192 encased in nylon ribbon; and

(F) sealed sources, except teletherapy and brachytherapy sources, that [~~which~~] are stored, not being used, and identified as in storage. However, the [~~The~~] licensee must [~~shall, however,~~] test each [~~such~~] sealed source for leakage or contamination and receive the test results before any use or transfer, unless it has been tested for leakage or contamination in the [~~within~~] six months before the date of use or transfer.

(3) Analysis of tests for leakage or contamination from sealed sources must [~~shall~~] be performed by persons specifically authorized by the department [~~agency~~], the NRC, or any agreement state to perform such services.

(4) Test results must [~~shall~~] be kept in units of microcurie or becquerel and maintained for inspection by the department [~~agency~~].

(5) The following is [~~shall be~~] considered evidence that a sealed source is leaking:

(A) the presence of 0.005 Ci (185 Bq) or more of removable contamination on any test sample;

(B) leakage of 0.001 Ci (37 Bq) of radon-222 per 24 hours for brachytherapy sources manufactured to contain radium; or

(C) the presence of removable contamination resulting from the decay of 0.005 Ci (185 Bq) or more of radium.

(6) The licensee must [~~shall~~] immediately withdraw a leaking sealed source from use and must [~~shall~~] take action to prevent the spread of contamination. Within two years of the determination that a sealed source is leaking, the leaking sealed source must [~~shall~~] be repaired or transferred for disposal as specified in [~~accordance with~~] §289.202 of this subchapter [~~title~~]. The licensee must [~~shall~~] check the equipment associated with the leaking source for radioactive contamination and, if contaminated, have it decontaminated or disposed of as specified in [~~accordance with~~] §289.202 of this subchapter [~~title~~].

(7) Reports of test results for leaking or contaminated sealed sources must [~~shall~~] be made as specified in [~~accordance with~~] §289.202(bbb) of this subchapter [~~title~~].

(h) Additional requirements. The department [~~agency~~] may, by rule, order, or condition of license or general license acknowledgment, impose upon any licensee such requirements in addition to those established in this chapter as it deems appropriate or necessary to minimize danger to public health and safety or property or the environment.

(i) Violations. An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any rule or order issued thereunder. Any person who willfully violates any provision of the Act or any rule or order issued thereunder may be guilty of a misdemeanor and upon conviction, may be punished by fine or imprisonment or both, as provided by law.

(j) Impounding. Sources of radiation are [~~shall be~~] subject to impounding as specified in [~~accordance with~~] §401.068 of the Act and §289.205 of this subchapter [~~title~~] (relating to Hearing and Enforcement Procedures).

(k) Communications.

(1) Except where otherwise specified, all communications and reports concerning this chapter and applications filed under them should be addressed to Radiation Control, Department of State Health Services, P.O. Box 149347, Austin, Texas, 78714-9347. Communications, reports, and applications may be delivered in person to the department's [~~agency's~~] office located at 1100 West 49th Street [~~8407 Wall Street~~], Austin, Texas.

(2) Documents transmitted to the department [~~agency~~] will be deemed submitted on the date of the postmark[~~, facsimile,~~] or other electronic media transmission.

(l) Interpretations. Except as specifically authorized by the department [~~agency~~] in writing, no interpretation of the meaning of this chapter by any officer or employee of the department [~~agency~~] other than a written interpretation by the Office of General Counsel, Department of State Health Services, will be considered binding upon the department [~~agency~~].

(m) [~~(n)~~] Mean quality factors and absorbed dose equivalencies.

(1) As used in this chapter, the quality factors for converting absorbed dose to dose equivalent are shown in the following table:
Figure: 25 TAC §289.201(m)(1)
[~~Figure: 25 TAC §289.201(n)(1)~~]

(2) If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in sievert per hour or rem per hour, as provided in paragraph (1) of this subsection, 1 rem (0.01 Sv) of neutron radiation of unknown energies may, for purposes of this section, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee may use the fluence rate per unit dose equivalent or the appropriate Q value from the following table to convert a measured tissue dose in rad (gray) to dose equivalent in rem (Sv).
Figure: 25 TAC §289.201(m)(2)
[~~Figure: 25 TAC §289.201(n)(2)~~]

~~[(m) Open records.]~~

~~[(1) Subject to the limitations provided in the Texas Public Information Act, Government Code, Chapter 552, all information and data collected, assembled, or maintained by the agency are public records open to inspection and copying during regular office hours.]~~

~~[(2) Any person who submits written information or data to the agency and requests that the information be considered confidential, privileged, or otherwise not available to the public under the Texas Public Information Act, shall justify such request in writing, including statutes and cases where applicable, addressed to the agency.]~~

~~[(A) Documents containing information that is claimed to fall within an exception to the Texas Public Information Act shall be~~

marked to indicate that fact. Markings shall be placed on the document on origination or submission.]

[(i) The words "NOT AN OPEN RECORD" shall be placed conspicuously at the top and bottom of each page containing information claimed to fall within one of the exceptions.]

[(ii) The following wording shall be placed at the bottom of the front cover and title page, or first page of text if there is no front cover or title page:]
[Figure: 25 TAC §289.201(m)(2)(A)(ii)]

[(B) The agency requests, whenever possible, that all information submitted under the claim of an exception to the Texas Public Information Act be extracted from the main body of the application and submitted as a separate annex or appendix to the application.]

[(C) Failure to comply with any of the procedures described in subparagraphs (A) and (B) of this paragraph may result in all information in the agency file being disclosed upon an open records request.]

[(3) The agency will determine whether information falls within one of the exceptions to the Texas Public Information Act. The Office of General Counsel will be queried as to whether or not there has been a previous determination that the information falls within one of the exceptions to the Texas Public Information Act. If there has been no previous determination and the agency believes that the information falls within one of the exceptions, an opinion of the Attorney General will be requested. If the agency agrees in writing to the request, the information shall not be open for public inspection unless the Attorney General's office subsequently determines that it does not fall within an exception.]

[(4) Requests for information.]

[(A) All requests for open records information must be in writing and refer to documents currently in possession of the agency.]

[(B) The agency will ascertain whether the information may be released or whether it falls within an exception to the Texas Public Information Act.]

[(i) The agency may take a reasonable period of time to determine whether information falls within one of the exceptions to the Texas Public Information Act.]

[(ii) If the information is determined to be public, it will be presented for inspection and/or copies of documents will be furnished within a reasonable period of time. A fee will be charged to recover agency costs for copies.]

[(C) Original copies of public records may not be removed from the agency. Under no circumstances shall material be removed from existing records.]

(n) [(o)] Units of activity. For purposes of this chapter, activity is expressed in the special unit of curie (Ci), becquerel (Bq), or its multiples, or disintegrations or transformations per second (dps or tps).

(1) 1 Ci = 3.7 x 10^{10} dps or tps = 3.7 x 10^{10} Bq = 2.22 x 10^{12} disintegrations or transformations per minute (dpm or tpm).

(2) 1 Bq = 1 dps or tps.

§289.202. Standards for Protection Against Radiation from Radioactive Materials.

(a) Purpose.

(1) This section establishes standards for protection against ionizing radiation resulting from activities conducted under [in accordance with] licenses issued by the department [agency].

(2) The requirements in this section are designed to control the receipt, possession, use, and transfer of sources of radiation by any licensee so the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in this section. However, nothing in this section may [shall] be construed as limiting actions that are [may be] necessary to protect health and safety in an emergency.

(b) Scope.

(1) Except as specifically provided in other sections of this chapter, this section applies to persons who receive, possess, use, or transfer sources of radiation, unless otherwise exempted. No person may use, manufacture, produce, transport, transfer, receive, acquire, own, possess, process, or dispose of sources of radiation unless that person has a license or exemption from the department [agency]. The dose limits in this section do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, to exposure from individuals administered radioactive material and released as specified in [accordance with] this chapter, or to voluntary participation in medical research programs. No [However, no] radiation may be deliberately applied to human beings except by or under the supervision of an individual authorized by and licensed as specified in [accordance with] Texas' statutes to engage in the healing arts.

(2) Licensees who are also registered by the department [agency] to receive, possess, use, and transfer radiation machines must [shall] also comply with the requirements of §289.231 of this chapter [title] (relating to General Provisions and Standards for Protection Against Machine-Produced Radiation).

(c) Definitions. The following words and terms when used in this section [shall] have the following meaning[,] unless the context clearly indicates otherwise.

(1) Air-purifying respirator--A respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

(2) Annual limit on intake (ALI)--The derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by Reference Man that would result in a committed effective dose equivalent of 5 rem [rems] (0.05 sievert (Sv)) or a committed dose equivalent of 50 rem [rems] (0.5 Sv) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Columns 1 and 2 of Table I of subsection (ggg)(2) of this section.

(3) Assigned protection factor (APF)--The expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly fitted and trained users. Operationally, the inhaled concentration can be estimated by dividing the ambient airborne concentration by the APF.

(4) Atmosphere-supplying respirator--A respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere and includes supplied-air respirators (SARs) and self-contained breathing apparatus (SCBA) units.

(5) Class--A classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which apply to a range of clearance half-times: for Class D, Days, of less than 10 days; for Class W, Weeks, from 10 to 100 days, and for Class Y, Years, of greater than 100 days. For purposes of this section, lung class and inhalation class are equivalent terms.

(6) Debris--The remains of something destroyed, disintegrated, or decayed. Debris does not include soils, sludges, liquids, gases, naturally occurring radioactive material regulated as specified in [~~accordance with~~] §289.259 of this chapter [~~title~~] (relating to Licensing of Naturally Occurring Radioactive Material (NORM)), or low-level radioactive waste (LLRW) received from other persons.

(7) Declared pregnant woman--A woman who has voluntarily informed the licensee, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman voluntarily withdraws the declaration in writing or is no longer pregnant.

(8) Demand respirator--An atmosphere-supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation.

(9) Derived air concentration (DAC)--The concentration of a given radionuclide in air that, if breathed by Reference Man for a working year of 2,000 hours under conditions of light work, results in an intake of 1 ALI. For purposes of this section, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in Column 3 of Table I of subsection (ggg)(2) of this section.

(10) Derived air concentration-hour (DAC-hour)--The product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee may take 2,000 DAC-hours to represent ALI, equivalent to a committed effective dose equivalent of 5 rem [~~rems~~] (0.05 Sv).

(11) Disposable respirator--A respirator for which maintenance is not intended and that is designed to be discarded after excessive breathing resistance, sorbent exhaustion, physical damage, or end-of-service-life renders it unsuitable for use. Examples of this type of respirator are a disposable half-mask respirator or a disposable escape-only self-contained breathing apparatus.

(12) Dosimetry processor--A person that processes and evaluates personnel monitoring devices [~~in order~~] to determine the radiation dose delivered to the monitoring devices.

(13) Filtering facepiece (dust mask)--A negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium, not equipped with elastomeric sealing surfaces and adjustable straps.

(14) Fit factor--A quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

(15) Fit test--The use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.

(16) Helmet--A rigid respiratory inlet covering that also provides head protection against impact and penetration.

(17) Hood--A respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

(18) Inhalation class (see definition for Class).

(19) Loose-fitting facepiece--A respiratory inlet covering that is designed to form a partial seal with the face.

(20) Lung class (see definition for Class).

(21) Nationally tracked source--A sealed source containing a quantity equal to or greater than category [~~Category~~] 1 or category [~~Category~~] 2 levels of any radioactive material listed in subsection (hhh)(2) of this section. In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded, in a solid form, and which is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the category [~~Category~~] 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the category [~~Category~~] 2 threshold but less than the category [~~Category~~] 1 threshold.

(22) Negative pressure respirator (tight fitting)--A respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

(23) Non-stochastic [~~Nonstochastic~~] effect--A health effect, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a non-stochastic [~~nonstochastic~~] effect. For purposes of this section, deterministic effect is an equivalent term.

(24) Planned special exposure--An infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.

(25) Positive pressure respirator--A respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

(26) Powered air-purifying respirator--An air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

(27) Pressure demand respirator--A positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

(28) Qualitative fit test--A pass/fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

(29) Quantitative fit test--An assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

(30) Quarter--A period of time equal to one-fourth of the year observed by the licensee, approximately 13 consecutive weeks, providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

(31) Reference man--A hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics may be used by researchers and public health employees to standardize results of experiments and to relate biological insult to a common base. A description of Reference Man is contained in the International Commission on Radiological Protection Report, ICRP Publication 23, "Report of the Task Group on Reference Man."

(32) Respiratory protective equipment--An apparatus, such as a respirator, used to reduce an individual's intake of airborne radioactive materials.

(33) Sanitary sewerage--A system of public sewers for carrying off waste water and refuse, but excluding sewage treatment facil-

ities, septic tanks, and leach fields owned or operated by the licensee or registrant.

(34) Self-contained breathing apparatus--An atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

(35) Stochastic effect--A health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects. For purposes of this section probabilistic effect is an equivalent term.

(36) Supplied-air respirator or airline respirator--An atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

(37) Tight-fitting facepiece--A respiratory inlet covering that forms a complete seal with the face.

(38) User seal check (fit check)--An action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, or isoamyl acetate check.

(39) Weighting factor w_T for an organ or tissue (T)--The proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of w_T are:
Figure: 25 TAC §289.202(c)(39) (No change.)

(d) Implementation.

(1) Any existing license condition that is more restrictive than this section remains in force until there is an amendment or renewal of the license that modifies or removes this condition.

(2) If a license condition exempts a licensee from a provision of this section in effect on or before January 1, 1994, it also exempts the licensee from the corresponding provision of this section.

(3) If a license condition cites provisions of this section in effect before [~~prior to~~] January 1, 1994, that do not correspond to any provisions of this section, the license condition remains in force until there is an amendment or renewal of the license that modifies or removes this condition.

(e) Radiation protection programs.

(1) Each licensee must [~~shall~~] develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of this section. See subsection (mm) of this section for recordkeeping requirements relating to these programs. Documentation of the radiation protection program may be incorporated in the licensee's operating, safety, and emergency procedures.

(2) The licensee must [~~shall~~] use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and public doses that are as low as is reasonably achievable (ALARA).

(3) The licensee must [~~shall~~], at intervals not to exceed 12 months, ensure the radiation protection program content and implementation is reviewed. The review must [~~shall~~] include a reevaluation of the assessments made to determine monitoring is not required, as specified in [~~accordance with~~] subsection (q)(1) and (3) of this section in conjunction with the licensee's current operating conditions.

(4) To implement the ALARA requirement in paragraph (2) of this subsection and notwithstanding the requirements in subsection (n) of this section, a constraint on air emissions of radioactive material to the environment, excluding radon-222 and its daughters, must [~~shall~~] be established by licensees such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent (TEDE) more than [~~in excess of~~] 10 millirem [~~millirems~~] (mrem) (0.1 millisievert (mSv)) per year, from these emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee must [~~shall~~] report the exceedance as required in subsection (yy) of this section and promptly take appropriate corrective action to ensure against recurrence.

(5) If monitoring is not required as specified in [~~accordance with~~] subsection (q)(1) and (3) of this section, the licensee must [~~shall~~] document assessments made to determine the requirements of subsection (q)(1) and (3) of this section are not applicable. The licensee must [~~shall~~] maintain the documentation as specified in [~~accordance with~~] subsection (rr)(5) of this section.

(f) Occupational dose limits for adults.

(1) The licensee must [~~shall~~] control the occupational dose to individuals, except for planned special exposures as specified in [~~accordance with~~] subsection (k) of this section, to the following dose limits.

(A) An annual limit that is [~~shall be~~] the lesser [~~more limiting~~] of:

(i) the total effective dose equivalent being equal to 5 rem [~~rems~~] (0.05 Sv); or

(ii) the sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue, other than the lens of the eye, being equal to 50 rem [~~rems~~] (0.5 Sv).

(B) The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities are [~~shall be~~]:

(i) a lens dose equivalent of 15 rem [~~rems~~] (0.15 Sv); and

(ii) a shallow dose equivalent of 50 rem [~~rems~~] (0.5 Sv) to the skin of the whole body or to the skin of any extremity.

(2) Doses received over [~~in excess of~~] the annual limits, including doses received during accidents, emergencies, and planned special exposures, must [~~shall~~] be subtracted from the limits for planned special exposures that the individual may receive during the current year and during the individual's lifetime. See subsection (k)(6)(A) and (B) of this section.

(3) When the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent must [~~shall~~] be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the department [~~agency~~]. The assigned deep dose equivalent must [~~shall~~] be for the part [~~portion~~] of the body receiving the highest exposure. The assigned shallow-dose equivalent must [~~shall~~] be the dose averaged over the contiguous 10 square centimeters (cm^2) [~~(cm^2)~~] of skin receiving the highest exposure.

(4) The deep dose equivalent, lens dose equivalent, and shallow dose equivalent may be assessed from surveys[~~,~~] or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

(5) DAC and ALI [~~Derived air concentration (DAC) and annual limit on intake (ALI)~~] values are specified in Table I of subsection (ggg)(2) of this section and may be used to determine the individ-

ual's dose and to demonstrate compliance with the occupational dose limits. See subsection (rr) of this section.

(6) Notwithstanding the annual dose limits, the licensee must [~~shall~~] limit the soluble uranium intake by an individual to 10 milligrams (mg) in a week, in consideration of chemical toxicity. See footnote 3 of subsection (ggg)(2) of this section.

(7) The licensee must [~~shall~~] reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person. See subsection (j)(4) of this section.

(g) Compliance with requirements for summation of external and internal doses.

(1) If the licensee is required to monitor as specified in [~~accordance with both~~] subsection (q)(1) and (3) of this section, the licensee must [~~shall~~] demonstrate compliance with the dose limits by summing external and internal doses. If the licensee is required to monitor only as specified in [~~accordance with~~] subsection (q)(1) of this section or only as specified in [~~accordance with~~] subsection (q)(3) of this section, then summation is not required to demonstrate compliance with the dose limits. The licensee may demonstrate compliance with the requirements for summation of external and internal doses as specified in [~~accordance with~~] paragraphs (2) - (4) of this subsection. The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.

(2) If the only intake of radionuclides is by inhalation, the TEDE [~~total effective dose equivalent~~] limit is not exceeded if the sum of the deep dose equivalent divided by the TEDE [~~total effective dose equivalent~~] limit, and one of the following, does not exceed unity:

(A) the sum of the fractions of the inhalation ALI for each radionuclide; or

(B) the total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by 2,000; or

(C) the sum of the calculated committed effective dose equivalents to all significantly irradiated organs or tissues (T) calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit. For purposes of this requirement, an organ or tissue is deemed to be significantly irradiated if, for that organ or tissue, the product of the weighting factors, w_T [~~w_T~~], and the committed dose equivalent, $H_{T,50}$ [~~$H_{T,50}$~~], per unit intake is greater than 10 percent [~~10%~~] of the maximum weighted value of $H_{T,50}$ [~~$H_{T,50}$~~], that is, $w_T H_{T,50}$ [~~$w_T H_{T,50}$~~], per unit intake for any organ or tissue.

(3) If the occupationally exposed individual receives an intake of radionuclides by oral ingestion greater than 10 percent [~~10%~~] of the applicable oral ALI, the licensee must [~~shall~~] account for this intake and include it in demonstrating compliance with the limits.

(4) The licensee must [~~shall~~] evaluate and, to the extent practical, account for intakes through wounds or skin absorption. The intake through intact skin has been included in the calculation of DAC for hydrogen-3 and does not need to be evaluated or accounted for as specified in [~~accordance with~~] this paragraph.

(h) Determination of external dose from airborne radioactive material.

(1) Licensees must [~~shall~~], when determining the dose from airborne radioactive material, include the contribution to the deep dose equivalent, eye dose equivalent, and shallow dose equivalent from external exposure to the radioactive cloud. See footnotes 1 and 2 of subsection (ggg)(2) of this section.

(2) Airborne radioactivity measurements and DAC values should [~~shall~~] not be used as the primary means to assess the deep dose equivalent when the airborne radioactive material includes radionuclides other than noble gases or if the cloud of airborne radioactive material is not relatively uniform. The determination of the deep dose equivalent to an individual should [~~shall~~] be based on [~~upon~~] measurements using instruments or individual monitoring devices.

(i) Determination of internal exposure.

(1) For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee must [~~shall~~], when required as specified in [~~accordance with~~] subsection (q) of this section, take suitable and timely measurements of:

(A) concentrations of radioactive materials in air in work areas;

(B) quantities of radionuclides in the body;

(C) quantities of radionuclides excreted from the body; or

(D) combinations of these measurements.

(2) Unless respiratory protective equipment is used, as provided in subsection (x) of this section, or the assessment of intake is based on bioassays, the licensee must [~~shall~~] assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.

(3) When specific information on the physical and biochemical properties of the radionuclides taken into the body or the behavior of the material in an individual is known, the licensee may:

(A) use that information to calculate the committed effective dose equivalent, and, if used, the licensee must [~~shall~~] document that information in the individual's record;

(B) upon prior approval from [~~of~~] the department [~~agency~~], adjust the DAC or ALI values to reflect the actual physical and chemical characteristics of airborne radioactive material, for example, aerosol size distribution or density; and

(C) separately assess the contribution of fractional intakes of Class D, W, or Y compounds of a given radionuclide to the committed effective dose equivalent. See subsection (ggg)(2) of this section.

(4) If the licensee chooses to assess intakes of Class Y material using the measurements given in paragraph (1)(A) or (B) of this subsection, the licensee may delay the recording and reporting of the assessments for periods up to seven months, unless otherwise required by subsections (xx) or (yy) of this section. This delay permits the licensee to make additional measurements basic to the assessments.

(5) If the identity and concentration of each radionuclide in a mixture are known, the fraction of the DAC applicable to the mixture for use in calculating DAC-hours must [~~shall~~] be either:

(A) the sum of the ratios of the concentration to the appropriate DAC value, that is, D, W, or Y, from subsection (ggg)(2) of this section for each radionuclide in the mixture; or

(B) the ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture.

(6) If the identity of each radionuclide in a mixture is known, but the concentration of one or more of the radionuclides in the mixture is unknown [~~not known~~], the DAC for the mixture must [~~shall~~] be the most restrictive DAC of any radionuclide in the mixture.

(7) When a mixture of radionuclides in air exists, a licensee may disregard certain radionuclides in the mixture if:

(A) the licensee uses the total activity of the mixture in demonstrating compliance with the dose limits in subsection (f) of this section and in complying with the monitoring requirements in subsection (q)(3) of this section;

(B) the concentration of any radionuclide disregarded is less than 10 percent [~~10%~~] of its DAC; and

(C) the sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed 30 percent [~~30%~~].

(8) When determining the committed effective dose equivalent, the following information may be considered.

(A) To [~~In order to~~] calculate the committed effective dose equivalent, the licensee may assume that the inhalation of 1 ALI, or an exposure of 2,000 DAC-hours, results in a committed effective dose equivalent of 5 rem [~~rems~~] (0.05 Sv) for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent.

(B) For an ALI and the associated DAC determined by the non-stochastic [~~nonstochastic~~] organ dose limit of 50 rem [~~rems~~] (0.5 Sv), the intake of radionuclides that would result in a committed effective dose equivalent of 5 rem [~~rems~~] (0.05 Sv), that is, the stochastic ALI, is listed in parentheses in Table I of subsection (ggg)(2) of this section. The licensee may, as a simplifying assumption, use the stochastic ALI to determine committed effective dose equivalent. However, if the licensee uses the stochastic ALI, the licensee must [~~shall also~~] demonstrate that the limit in subsection (f)(1)(A)(ii) of this section is met.

(j) Determination of occupational dose for the current year.

(1) For each individual who is likely to receive, in a year, an occupational dose requiring monitoring as specified in [~~accordance with~~] subsection (q) of this section, the licensee must [~~shall~~] determine the occupational radiation dose received during the current year.

(2) In complying with the requirements of paragraph (1) of this subsection, a licensee may:

(A) accept, as a record of the occupational dose that the individual received during the current year, RC Form 202-2 from previous [~~prior~~] or other current employers, or other clear and legible records [~~record~~], of all information required on that form and indicating any periods of time for which data are not available; or

(B) accept, as a record of the occupational dose that the individual received during the current year, a written, signed statement from the individual, or from the individual's previous [~~prior~~] or other current employer [~~employer(s)~~] for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual received during the current year; or

(C) obtain reports of the individual's dose equivalent from previous [~~prior~~] or other current employers [~~employer(s)~~] for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee, by telephone, [~~facsimile,~~] letter, or other electronic media transmission. The licensee must [~~shall~~] request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

(3) The licensee must [~~shall~~] record the exposure data for the current year, as required by paragraph (1) of this subsection, on RC Form 202-3, or other clear and legible record, of all the information required on that form.

(4) If the licensee is unable to obtain a complete record of an individual's current occupational dose while employed by any other licensee, the licensee must [~~shall~~] assume in establishing administrative controls as specified in [~~accordance with~~] subsection (f)(7) of this section for the current year, [~~that~~] the allowable dose limit for the individual is reduced by 1.25 rem [~~rems~~] (12.5 mSv) for each quarter; or 416 mrem (4.16 mSv) for each month for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure.

(5) If an individual has incomplete (e.g., a lost or damaged personnel monitoring device) current occupational dose data for the current year and that individual is employed solely by the licensee during the current year, the licensee must [~~shall~~]:

(A) assume [~~that~~] the allowable dose limit for the individual is reduced by 1.25 rem [~~rems~~] (12.5 mSv) for each quarter;

(B) assume [~~that~~] the allowable dose limit for the individual is reduced by 416 mrem (4.16 mSv) for each month; or

(C) assess an occupational dose for the individual during the period of missing data using surveys, radiation measurements, or other comparable data for the purpose of demonstrating compliance with the occupational dose limits.

(6) Administrative controls established as specified in [~~accordance with~~] paragraph (4) of this subsection must [~~shall~~] be documented and maintained for inspection by the department [~~agency~~]. Occupational dose assessments made as specified in [~~accordance with~~] paragraph (5) of this subsection and records of data used to make the assessment must [~~shall~~] be maintained for inspection by the department [~~agency~~]. The licensee must [~~shall~~] retain the records as specified in [~~accordance with~~] subsection (rr) of this section.

(k) Planned special exposures. A licensee may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in subsection (f) of this section, if [~~provided that~~] each of the following conditions is satisfied.

(1) The licensee authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the doses estimated to result from the planned special exposure are unavailable or impractical.

(2) The licensee and employer, if the employer is not the licensee, specifically authorizes the planned special exposure, in writing, before the exposure occurs.

(3) Before a planned special exposure, the licensee ensures that each individual involved is:

(A) informed of the purpose of the planned operation;

(B) informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and

(C) instructed in the measures to be taken to keep the dose ALARA considering other risks that may be present.

(4) Before [~~Prior to~~] permitting an individual to participate in a planned special exposure, the licensee must [~~shall~~] determine:

(A) the internal and external doses from all previous planned special exposures;

(B) all doses over [~~in excess of~~] the limits, including doses received during accidents and emergencies, received during the lifetime of the individual; and

(C) all lifetime cumulative occupational radiation doses.

(5) In complying with the requirements of paragraph (4)(C) of this subsection, a licensee may:

(A) accept, as the record of lifetime cumulative radiation dose, an up-to-date RC Form 202-2 or equivalent, signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee; and

(B) obtain reports of the individual's dose equivalent from previous employers [~~prior employer(s)~~] for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee, by telephone, [~~facsimile,~~] letter, or other electronic media transmission. The licensee must [~~shall~~] request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

(6) Subject to subsection (f)(2) of this section, the licensee must [~~shall~~] not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses over [~~in excess of~~] the limits to exceed:

(A) the numerical values of any of the dose limits in subsection (f)(1) of this section in any year; and

(B) five times the annual dose limits in subsection (f)(1) of this section during the individual's lifetime.

(7) The licensee maintains records of the conduct of a planned special exposure as specified in [~~accordance with~~] subsection (qq) of this section and submits a written report to the department as specified in [~~agency in accordance with~~] subsection (zz) of this section.

(8) The licensee records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within 30 days of [~~from~~] the date of the planned special exposure. The dose from planned special exposures are [~~shall~~] not [~~be~~] considered in controlling future occupational dose of the individual as specified in [~~accordance with~~] subsection (f)(1) of this section but must [~~shall~~] be included in evaluations required by paragraphs (4) and (6) of this subsection.

(9) The licensee must [~~shall~~] record the exposure history, as required by paragraph (4) of this subsection, on RC Form 202-2, or other clear and legible record, of all the information required on that form. The form or record must [~~shall~~] show each period in which the individual received occupational exposure to radiation or radioactive material and must [~~shall~~] be signed by the individual who received the exposure. For each period for which the licensee obtains reports, the licensee must [~~shall~~] use the dose shown in the report in preparing RC Form 202-2, or equivalent.

(l) Occupational dose limits for minors. The annual occupational dose limits for minors are 10 percent [~~10%~~] of the annual occupational dose limits specified for adult workers in subsection (f) of this section.

(m) Dose equivalent to an embryo/fetus.

(1) If a woman declares her pregnancy, the licensee must [~~shall~~] ensure that the dose equivalent to an embryo/fetus during the entire pregnancy, due to occupational exposure [~~of a declared pregnant woman~~], does not exceed 0.5 rem (5 mSv). If a woman chooses not to declare pregnancy, the occupational dose limits specified in subsection (f)(1) of this section are applicable to the woman. See subsection (rr) of this section for recordkeeping requirements.

(2) The licensee must [~~shall~~] make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman [~~so as~~] to satisfy the limit in paragraph (1) of this subsection. The National Council on Radiation Protection and Measurements (NCRP) recommended in NCRP Report No. 91 "Recommendations on Limits for Exposure to Ionizing Radiation" (June 1, 1987), that no more than 0.05 rem (0.5 mSv) to the embryo/fetus be received in any one month.

(3) The dose equivalent to an embryo/fetus is [~~shall be~~] taken as:

(A) the dose equivalent to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman; and

(B) the dose equivalent that is most representative of the dose equivalent to the embryo/fetus from external radiation, that is, in the mother's lower torso region.

(i) If multiple measurements have not been made, assignment of the highest deep dose equivalent for the declared pregnant woman is [~~shall be~~] the dose equivalent to the embryo/fetus.

(ii) If multiple measurements have been made, assignment of the deep dose equivalent for the declared pregnant woman from the individual monitoring device that is most representative of the dose equivalent to the embryo/fetus is [~~shall be~~] the dose equivalent to the embryo/fetus. Assignment of the highest deep dose equivalent for the declared pregnant woman to the embryo/fetus is not required unless that dose equivalent is also the most representative deep dose equivalent for the region of the embryo/fetus.

(4) If by the time the woman declares pregnancy to the licensee, the dose equivalent to the embryo/fetus has exceeded 0.45 rem (4.5 mSv), the licensee will be [~~shall be~~] deemed compliant [~~to be in compliance~~] with paragraph (1) of this subsection, if the additional dose equivalent to the embryo/fetus does not exceed 0.05 rem (0.5 mSv) during the remainder of the pregnancy.

(n) Dose limits for individual members of the public.

(1) Each licensee must [~~shall~~] conduct operations and ensure [~~so that~~]:

(A) the TEDE [~~The total effective dose equivalent~~] to individual members of the public from the licensed and [~~and/or~~] registered operation does not exceed 0.1 rem (1 mSv) in a year, exclusive of the dose contribution from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released as specified in [~~accordance with~~] §289.256 of this chapter [~~title~~] (relating to Medical and Veterinary Use of Radioactive Material), from voluntary participation in medical research programs, and from the licensee's disposal of radioactive material into sanitary sewerage as specified in [~~accordance with~~] subsection (gg) of this section; and

(B) the dose in any unrestricted area from licensed and [~~and/or~~] registered external sources, exclusive of the dose contributions from patients administered radioactive material and released as specified in [~~accordance with~~] §289.256 of this chapter [~~title~~], does not exceed 0.002 rem (0.02 mSv) in any one hour.

(2) If the licensee permits members of the public to have access to restricted areas, the limits for members of the public continue to apply to those individuals.

(3) A licensee or an applicant for a license may apply for prior department [~~agency~~] authorization to operate up to an annual dose

limit for an individual member of the public of 0.5 rem (5 mSv). This application must [~~shall~~] include [~~the following information~~]:

(A) a demonstration of the need for and the expected duration of operations over [~~in excess of~~] the limit in paragraph (1) of this subsection;

(B) the licensee's program to assess and control dose within the 0.5 rem (5 mSv) annual limit; and

(C) the procedures [~~to be followed~~] to maintain the dose ALARA.

(4) In addition to the requirements of this section, a licensee subject to the provisions of the United States Environmental Protection Agency's (EPA) generally applicable environmental radiation standards in 40 Code of Federal Regulations (CFR)[~~,~~] §190, must also [~~shall~~] comply with those requirements.

(5) The department [~~agency~~] may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee may release in effluents [~~in order~~] to restrict the collective dose.

(6) Notwithstanding paragraph (1)(A) of this subsection, a licensee may permit visitors to an individual who cannot be released, as specified in [~~accordance with~~] §289.256 of this chapter [~~title~~], to receive a radiation dose greater than 0.1 rem (1 mSv) if:

(A) the radiation dose received does not exceed 0.5 rem (5 mSv); and

(B) the authorized user, as defined in §289.256 of this chapter [~~title~~], has determined before the visit that it is appropriate.

(o) Compliance with dose limits for individual members of the public.

(1) The licensee must [~~shall~~] make, or cause to be made, surveys of radiation levels in unrestricted areas and radioactive materials in effluents released to unrestricted areas to demonstrate compliance with the dose limits for individual members of the public as required in subsection (n) of this section.

(2) A licensee must [~~shall~~] show compliance with the annual dose limit in subsection (n) of this section by:

(A) demonstrating by measurement or calculation that the TEDE [~~total effective dose equivalent~~] to the individual likely to receive the highest dose from the licensed or registered operation, does not exceed the annual dose limit; or

(B) demonstrating that:

(i) the annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table II of subsection (ggg)(2) of this section; and

(ii) if an individual were continuously present in an unrestricted area, the dose from external sources of radiation would not exceed 0.002 rem (0.02 mSv) in an hour and 0.05 rem (0.5 mSv) in a year.

(3) Upon approval from the department [~~agency~~], the licensee may adjust the effluent concentration values in Table II, of subsection (ggg)(2) of this section, for members of the public, to consider [~~take into account~~] the actual physical and chemical characteristics of the effluents, such as, aerosol size distribution, solubility, density, radioactive decay equilibrium, and chemical form.

(p) General surveys and monitoring.

(1) Each licensee must [~~shall~~] make, or cause to be made, surveys of areas, including the subsurface that:

(A) are necessary for the licensee to comply with this chapter; and

(B) are necessary under the circumstances to evaluate:

(i) the magnitude and extent of radiation levels;

(ii) concentrations or quantities of residual radioactivity; and

(iii) the potential radiological hazards of the radiation levels and residual radioactivity detected.

(2) In addition to subsection (nn) of this section, records from surveys describing the location and amount of subsurface residual radioactivity identified at the site must [~~shall~~] be kept with records important for decommissioning, and such records must [~~shall~~] be maintained and retained as specified in [~~accordance with~~] §289.252(gg) of this chapter [~~title~~] (relating to Licensing of Radioactive Material).

(3) The licensee must [~~shall~~] ensure that instruments and equipment used for quantitative radiation measurements, for example, dose rate and effluent monitoring, are operable and calibrated:

(A) by a person licensed or registered by the department [~~agency~~], the United States Nuclear Regulatory Commission (NRC), or any agreement state to perform such service;

(B) at intervals not to exceed 12 months unless a different time interval is specified in another section of this chapter;

(C) after each instrument or equipment repair;

(D) for the types of radiation used and at energies appropriate for use; and

(E) at an accuracy within 20 percent [~~20%~~] of the true radiation level.

(4) All individual monitoring devices requiring processing to determine the radiation dose, except for [~~direct and indirect reading pocket dosimeters, electronic personal dosimeters, and~~] those individual monitoring devices used to measure the dose to any extremity, [~~that require processing to determine the radiation dose~~] and that are used by licensees to comply with subsection (f) of this section, with other applicable provisions of this chapter, or with conditions specified in a license, must [~~shall~~] be processed and evaluated by a dosimetry processor:

(A) holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

(B) approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

(5) All individual monitoring devices must [~~shall~~] be appropriate for the environment in which they are used.

(q) Conditions requiring individual monitoring of external and internal occupational dose. Each licensee must [~~shall~~] monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of this section. As a minimum:

(1) each licensee must [~~shall~~] monitor occupational exposure to radiation and must [~~shall~~] supply and require the use of individual monitoring devices by:

(A) adults likely to receive, in one year from sources of radiation external to the body, a dose more than 10 percent [~~in excess of 10%~~] of the limits in subsection (f)(1) of this section;

(B) minors likely to receive, in one year from sources of radiation external to the body, a deep dose equivalent more than [~~in excess of~~] 0.1 rem (1 mSv), a lens dose equivalent more than [~~in excess of~~] 0.15 rem (1.5 mSv), or a shallow dose equivalent to the skin or to the extremities more than [~~in excess of~~] 0.5 rem (5 mSv);

(C) declared pregnant women likely to receive, during the entire pregnancy, from sources of radiation external to the body, a deep dose equivalent more than [~~in excess of~~] 0.1 rem (1 mSv); and

(D) individuals entering a high or very high radiation area;

(2) notwithstanding paragraph (1)(C) of this subsection, a licensee is exempt from supplying individual monitoring devices to healthcare personnel who may enter a high radiation area while providing patient care if:

(A) the personnel are not likely to receive, in one year from sources external to the body, a dose more than 10 percent [~~in excess of 10%~~] of the limits in subsection (f)(1) of this section; and

(B) the licensee complies with the requirements of subsection (e)(2) of this section; and

(3) each licensee must [~~shall~~] monitor, to determine compliance with subsection (i) of this section, the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

(A) adults likely to receive, in one year, an intake more than 10 percent [~~in excess of 10%~~] of the applicable ALI in Columns 1 and 2 of Table I of subsection (ggg)(2) of this section;

(B) minors likely to receive, in one year, a committed effective dose equivalent more than [~~in excess of~~] 0.1 rem (1 mSv); and

(C) declared pregnant women likely to receive, during the entire pregnancy, a committed effective dose equivalent more than [~~in excess of~~] 0.1 rem (1 mSv).

(r) Location and use of individual monitoring devices.

(1) Each licensee must [~~shall~~] ensure that individuals who are required to monitor occupational doses as specified in [~~accordance with~~] subsection (q)(1) [~~(q)(1)~~] of this section wear and use individual monitoring devices as follows.

(A) An individual monitoring device used for monitoring the dose to the whole body is [~~shall be~~] worn at the unshielded location of the whole body likely to receive the highest exposure. When a protective apron is worn, the location of the individual monitoring device is typically at the neck (collar).

(B) If an additional individual monitoring device is used for monitoring the dose to an embryo/fetus of a declared pregnant woman, as specified in [~~accordance with~~] subsection (m)(1) of this section, it is [~~shall be~~] located at the waist under any protective apron being worn by the woman.

(C) An individual monitoring device used for monitoring the lens dose equivalent, to demonstrate compliance with subsection (f)(1)(B)(i) of this section, is [~~shall be~~] located at the neck (collar) or at a location closer to the eye, outside any protective apron being worn by the monitored individual.

(D) An individual monitoring device used for monitoring the dose to the skin of the extremities, to demonstrate compliance with subsection (f)(1)(B)(ii) of this section, is [~~shall be~~] worn on the skin of the extremity likely to receive the highest exposure. Each individual monitoring device, to the extent practicable, is [~~shall be~~] oriented to measure the highest dose to the skin of the extremity being monitored.

(E) An individual monitoring device is [~~shall be~~] assigned to and worn by only one individual.

(F) An individual monitoring device that requires processing is [~~shall be~~] worn for the period of time authorized by the dosimetry processor [~~processor's certificate of registration~~] or for no longer than three months, whichever is earlier [~~more restrictive~~].

(G) All individual monitoring devices are processed or evaluated at least quarterly or promptly after replacement, whichever is more frequent.

(2) Each licensee must [~~shall~~] ensure that individual monitoring devices are returned to the dosimetry processor for proper processing, as applicable.

(3) Each licensee must [~~shall~~] ensure that adequate precautions are taken to prevent a deceptive exposure of an individual monitoring device.

(s) Control of access to high radiation areas.

(1) The licensee must [~~shall~~] ensure that each entrance or access point to a high radiation area has one or more of the following features:

(A) a control device that, upon entry into the area, causes the level of radiation to be reduced below the [~~that~~] level at which an individual might receive a deep dose equivalent of 0.1 rem (1 mSv) in one hour at 30 centimeters (cm), from the source of radiation, from any surface that the radiation penetrates;

(B) a control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or

(C) entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

(2) In place of the controls required by paragraph (1) of this subsection for a high radiation area, the licensee may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

(3) The licensee may apply to the department [~~agency~~] for approval of alternative methods for controlling access to high radiation areas.

(4) The licensee must [~~shall~~] establish [~~the~~] controls required by paragraphs (1) and (3) of this subsection in a way that does not prevent individuals from leaving a high radiation area.

(5) The licensee is not required to control each entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled as specified in [~~accordance with~~] the regulations of the United States Department of Transportation (DOT) if [~~provided that~~]:

(A) the packages do not remain in the area longer than three days; and

(B) the dose rate at 1 meter (m) from the external surface of any package does not exceed 0.01 rem (0.1 mSv) per hour.

(6) The licensee is not required to control entrance or access to rooms or other areas in hospitals solely because of the presence of patients containing radioactive material, if [~~provided that~~] there are personnel in attendance who are taking the necessary precautions to prevent the exposure of individuals to sources of radiation over [~~in excess of~~] the established limits in this section and who [~~to~~] operate within the ALARA provisions of the licensee's radiation protection program.

(t) Control of access to very high radiation areas. In addition to the requirements in subsection (s) of this section, the licensee must [~~shall~~] institute measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas where [~~in which~~] radiation levels could be encountered at 500 rads (5 gray (Gy) [~~grays~~]) or more in one hour at 1 m from a source of radiation or any surface through which the radiation penetrates at this level.

(u) Control of access to very high radiation areas for irradiators.

(1) This subsection applies to licensees with sources of radiation in non-self-shielded irradiators. This subsection does not apply to sources of radiation that are used in teletherapy, [~~in~~] industrial radiography, or [~~in~~] completely self-shielded irradiators where [~~in which~~] the source of radiation is both stored and operated within the same shielding radiation barrier and, in the designed configuration of the irradiator, is always physically inaccessible to any individual and cannot create high levels of radiation in an area that is accessible to any individual.

(2) Each area in which there may exist radiation levels more than [~~in excess of~~] 500 rads (5 Gy [~~grays~~]) in one hour at 1 m from a source of radiation that is used to irradiate materials must [~~shall~~] meet the following requirements.

(A) Each entrance or access point is [~~shall be~~] equipped with entry control devices that:

(i) function automatically to prevent any individual from inadvertently entering a very high radiation area;

(ii) permit deliberate entry into the area only after a control device is actuated that causes the radiation level within the area, from the source of radiation, to be reduced below that at which it would be possible for an individual to receive a deep dose equivalent more than [~~in excess of~~] 0.1 rem (1 mSv) in one hour; and

(iii) prevent operation of the source of radiation if it would produce radiation levels in the area that could result in a deep dose equivalent to an individual more than [~~in excess of~~] 0.1 rem (1 mSv) in one hour.

(B) Additional control devices are [~~shall be~~] provided so that, upon failure of the entry control devices to function as required by subparagraph (A) of this paragraph:

(i) the radiation level within the area, from the source of radiation, is reduced below that at which it would be possible for an individual to receive a deep dose equivalent more than [~~in excess of~~] 0.1 rem (1 mSv) in one hour; and

(ii) conspicuous visible and audible alarm signals are generated to make an individual attempting to enter the area aware of the hazard and at least one other authorized individual, who is physically present, familiar with the activity, and prepared to render or summon assistance, aware of the failure of the entry control devices.

(C) The licensee provides [~~shall provide~~] control devices so that, upon failure or removal of physical radiation barriers other than the sealed source's shielded storage container:

(i) the radiation level from the source of radiation is reduced below that at which it would be possible for an individual to receive a deep dose equivalent more than [~~in excess of~~] 0.1 rem (1 mSv) in one hour; and

(ii) conspicuous visible and audible alarm signals are generated to make potentially affected individuals aware of the hazard and the licensee or at least one other individual, who is familiar with the activity and prepared to render or summon assistance, is aware of the failure or removal of the physical barrier.

(D) When the shield for stored sealed sources is a liquid, the licensee provides [~~shall provide~~] means to monitor the integrity of the shield and to signal, automatically, loss of adequate shielding.

(E) Physical radiation barriers that comprise permanent structural components, such as walls, that have no credible probability of failure or removal in ordinary circumstances, are not required to comply with [~~need not meet the requirements of~~] subparagraphs (C) and (D) of this paragraph.

(F) Each area is [~~shall be~~] equipped with devices that [~~will~~] automatically generate conspicuous visible and audible alarm signals to alert personnel in the area before the source of radiation can be put into operation and in time for any individual in the area to operate a clearly identified control device, [~~which must be~~] installed in the area that [~~and which~~] can prevent the source of radiation from being put into operation.

(G) Each area is [~~shall be~~] controlled by use of [~~such~~] administrative procedures and [~~such~~] devices [~~as are~~] necessary to ensure that the area is cleared of personnel before [~~prior to~~] each use of the source of radiation.

(H) Each area is [~~shall be~~] checked by a radiation measurement to ensure that, before [~~prior to~~] the first individual's entry into the area after any use of the source of radiation, the radiation level from the source of radiation in the area is below that at which it would be possible for an individual to receive a deep dose equivalent more than [~~in excess of~~] 0.1 rem (1 mSv) in one hour.

(I) The entry control devices required in subparagraph (A) of this paragraph are [~~shall be~~] tested for proper functioning. See subsection (uu) of this section for recordkeeping requirements.

(i) Testing must [~~shall~~] be conducted before [~~prior to~~] initial operation of [~~with~~] the source of radiation on any day[~~,~~] unless operations were continued uninterrupted from the previous day.

(ii) Testing must [~~shall~~] be conducted before [~~prior to~~] resumption of operation of the source of radiation after any unintentional interruption.

(iii) The licensee must [~~shall~~] submit and adhere to a schedule for periodic tests of the entry control and warning systems.

(J) The licensee does [~~shall~~] not conduct operations, other than those necessary to place the source of radiation in safe condition or to effect repairs on controls, unless control devices are functioning properly.

(K) Entry and exit portals [~~that are~~] used to transport [~~in transporting~~] materials to and from the irradiation area, and [~~that are~~] not intended for use by individuals, are [~~shall be~~] controlled by such devices and administrative procedures as [~~are~~] necessary to physically protect and warn against inadvertent entry by any individual through these portals. Exit portals for irradiated materials are [~~shall be~~] equipped to automatically detect and signal the presence of any loose radioactive material that is carried toward such an exit to prevent [~~and~~

~~automatically to prevent~~] loose radioactive material from being carried out of the area.

(3) Licensees or applicants for licenses for sources of radiation under [~~within the purview of~~] paragraph (2) of this subsection [~~that will be~~] used in a variety of positions or in locations, such as open fields or forests, making [~~which make~~] it impracticable to comply with certain requirements of paragraph (2) of this subsection, such as those for the automatic control of radiation levels, may apply to the department [~~agency~~] for approval of alternative safety measures. Alternative safety measures must [~~shall~~] provide personnel protection at least equivalent to those specified in paragraph (2) of this subsection. At least one of the alternative measures must [~~shall~~] include an entry-preventing interlock control based on a measurement of the radiation that ensures the absence of high radiation levels before an individual enters an [~~can gain access to the~~] area where [~~such~~] sources of radiation are used.

(4) The entry control devices required by paragraphs (2) and (3) of this subsection must [~~shall~~] be established so [~~in such a way that~~] no individual is [~~will be~~] prevented from leaving the area.

(v) Use of process or other engineering controls. The licensee must [~~shall~~] use, to the extent practicable, process or other engineering controls, such as containment, decontamination, or ventilation, to control the concentrations of radioactive material in air.

(w) Use of other controls.

(1) When it is not practicable to apply process or other engineering controls to ensure [~~control the~~] concentrations of radioactive material in air [~~to~~] values are below those that define an airborne radioactivity area, the licensee must [~~shall~~], consistent with maintaining the TEDE [~~total effective dose equivalent~~] ALARA, increase monitoring and limit intakes by one or more of the following means:

(A) control of access;

(B) limitation of exposure times;

(C) use of respiratory protection equipment; or

(D) other controls.

(2) If the licensee performs an ALARA analysis to determine whether respirators should be used, the licensee may consider safety factors other than radiological factors. The licensee must [~~shall also~~] consider the impact of respirator use on workers' industrial health and safety.

(x) Use of individual respiratory protection equipment.

(1) If the licensee uses respiratory protection equipment to limit intakes of radioactive material as specified in [~~accordance with~~] subsection (w) of this section, the licensee must: [~~shall do the following.~~]

(A) [~~Except as provided in subparagraph (B) of this paragraph, the licensee shall~~] use only respiratory protection equipment that is tested and certified by the National Institute for Occupational Safety and Health (NIOSH), except as provided in subparagraph (B) of this paragraph.

(B) [~~If the licensee wishes to use equipment that has not been tested or certified by the NIOSH, or for which there is no schedule for testing or certification, the licensee shall~~] submit an application to the department [~~agency~~] for authorized use of [~~that~~] equipment, including a demonstration by testing, or a demonstration on the basis of test information, that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use, if the licensee wishes to use equipment that has not been tested or certified by the NIOSH, or for which there is no schedule for testing or certification.

(C) [~~The licensee shall~~] implement and maintain a respiratory protection program that includes:

(i) air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate doses;

(ii) surveys and bioassays, as appropriate, to evaluate actual intakes;

(iii) testing of respirators for operability (user seal check for face sealing devices and functional check for others) immediately before [~~prior to~~] each use;

(iv) written procedures regarding the following:

(I) monitoring, including air sampling and bioassays;

(II) supervision and training of respirator users;

(III) fit testing;

(IV) respirator selection;

(V) breathing air quality;

(VI) inventory and control;

(VII) storage, issuance, maintenance, repair, testing, and quality assurance of respiratory protection equipment;

(VIII) recordkeeping; and

(IX) limitations on periods of respirator use and relief from respirator use;

(v) determination by a physician before [~~prior to~~] initial fitting of a face-sealing [~~face sealing~~] respirator and the first field use of non-face-sealing [~~non-face sealing~~] respirators, and either, every 12 months thereafter or periodically at a frequency determined by a physician, [~~that~~] the individual user is medically fit to use the respiratory protection equipment; and

(vi) fit testing, with fit factor >10 times the APF for negative pressure devices, and a fit factor ≥500 [~~> 500~~] for any positive pressure, continuous flow, and pressure-demand devices, before the first field use of tight fitting, face-sealing respirators and periodically thereafter at a frequency not to exceed one [~~1~~] year. Fit testing must [~~shall~~] be performed with the facepiece operating in the negative pressure mode.

(D) [~~The licensee shall~~] advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require [~~such~~] relief.

(E) [~~The licensee shall~~] use respiratory protection equipment within the equipment manufacturer's expressed limitations for type and mode of use and [~~shall~~] provide for vision correction, adequate communication, low-temperature work environment, and the concurrent use of other safety or radiological protection equipment. The licensee must [~~shall~~] use equipment so that it does not [~~in such a way as not to~~] interfere with the proper operation of the respirator.

(F) ensure standby [~~Standby~~] rescue persons are positioned to render aid [~~required~~] whenever one-piece atmosphere-supplying suits, or any combination of supplied air respiratory protection device and personnel protective equipment are used from which an unaided individual may have difficulty extricating himself or

herself. The standby persons must [~~shall~~] be equipped with respiratory protection devices or other apparatus appropriate for the potential hazards. The standby rescue persons must [~~shall~~] observe or otherwise maintain continuous communication with the workers (visual, voice, signal line, telephone, radio, or other suitable means), and be immediately available to assist them in case of a failure of the air supply or for any other reason that requires relief from distress. A sufficient number of standby rescue persons must be immediately available to assist all users of this type of equipment and [~~to~~] provide effective emergency rescue, if needed.

(G) ensure atmosphere-supplying [~~Atmosphere-supplying~~] respirators are [~~shall be~~] supplied with respirable air of grade D quality, or better, as defined by the Compressed Gas Association in publication G-7.1, "Commodity Specification for Air," 1997 and included in the regulations of the Occupational Safety and Health Administration (29 CFR §1910.134(i)(1)(ii)(A) - (E)) [~~(Title 29, CFR, §1910.134(i)(1)(ii)(A) through (E)~~]. Grade D quality air criteria include:

(i) oxygen content (volume/volume) of 19.5 - 23.5 percent [~~19.5-23.5%~~];

(ii) hydrocarbon (condensed) content of 5 mg per cubic meter of air or less;

(iii) carbon monoxide (CO) content of 10 parts per million (ppm) or less;

(iv) carbon dioxide content of 1,000 ppm or less; and

(v) lack of noticeable odor.

(H) [~~The licensee shall~~] ensure [~~that~~] no objects, materials, or substances, such as facial hair, or any conditions interfering [~~that interfere~~] with the facepiece [~~face-facepiece~~] seal or valve function, and that are under the control of the respirator wearer, are present between the skin of the wearer's face and the sealing surface of a tight-fitting respirator facepiece.

(I) when [~~In~~] estimating the dose to individuals from intake of airborne radioactive materials, initially assume the concentration of radioactive material in the air, [~~that is~~] inhaled when respirators are worn, is [~~initially assumed to be~~] the ambient concentration in air without respiratory protection, divided by the assigned protection factor. If the dose is later found to be greater than the estimated dose, the corrected value must [~~shall~~] be used. If the dose is later found to be less than the estimated dose, the corrected value may be used.

(2) The department [~~agency~~] may impose restrictions in addition to those in paragraph (1) of this subsection, subsection (w) of this section, and subsection (ggg)(1) of this section, [~~in order~~] to:

(A) ensure that the respiratory protection program of the licensee is adequate to limit doses to individuals from intakes of airborne radioactive materials consistent with maintaining TEDE [~~total effective dose equivalent~~] ALARA; and

(B) limit the extent to which a licensee may use respiratory protection equipment instead of process or other engineering controls.

(3) The licensee must [~~shall~~] obtain authorization from the department [~~agency~~] before assigning respiratory protection factors exceeding [~~in excess of~~] those specified in subsection (ggg)(1) of this section. The department [~~agency~~] may authorize a licensee to use higher protection factors on receipt of an application that:

(A) describes the situation for which a need exists for higher protection factors; and

(B) demonstrates that the respiratory protection equipment provides [~~these~~] higher protection factors under the proposed conditions of use.

(y) Security and control of licensed sources of radiation.

(1) The licensee must [~~shall~~] secure radioactive material from unauthorized removal or access.

(2) The licensee must [~~shall~~] maintain constant surveillance, using devices or [~~and/or~~] administrative procedures to prevent unauthorized access to use of radioactive material [~~that is~~] in an unrestricted area and [~~that is~~] not in storage.

(3) Each portable gauge licensee must [~~shall~~] use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

(4) Utilization records must [~~shall~~] be maintained for portable and mobile devices containing [~~which contain~~] radioactive material[~~, and which are~~] transported from a licensed site temporarily for use by the licensee and then returned to the licensed site of origin. The information required by subparagraphs (A) - (D) of this paragraph must [~~shall~~] be recorded when a device is removed from the licensed site. The information in subparagraph (E) of this paragraph must [~~shall~~] be recorded when a device is returned to the licensed site:

(A) the manufacturer, model, and serial number of the device;

(B) the names [~~name~~] of personnel [~~the individual(s)~~] transporting and using the device;

(C) the locations [~~location(s)~~] where each device is used;

(D) the date each device is removed from storage; and

(E) the date each device is returned to storage.

(5) Utilization records must [~~shall~~] be maintained at the licensed site where the devices are stored for inspection by the department as specified in [~~agency in accordance with~~] subsection (ggg)(5) of this section.

(z) Caution signs.

(1) Unless otherwise authorized by the department [~~agency~~], the standard radiation symbol prescribed must [~~shall~~] use the colors magenta, or purple, or black on yellow background. The standard radiation symbol prescribed is the three-bladed design as follows:

Figure: 25 TAC §289.202(z)(1) (No change.)

(A) the cross-hatched area of the symbol is [~~to be~~] magenta, or purple, or black; and

(B) the background of the symbol is [~~to be~~] yellow.

(2) Notwithstanding the requirements of paragraph (1) of this subsection, licensees are authorized to label sources, source holders, or device components containing sources of radiation that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.

(aa) Posting requirements.

(1) The licensee must [~~shall~~] post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA."

(2) The licensee must [~~shall~~] post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA."

(3) The licensee must [~~shall~~] post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words "GRAVE DANGER, VERY HIGH RADIATION AREA." If the very high radiation area involves medical treatment of patients, the licensee may omit the word "GRAVE" from the sign or signs.

(4) The licensee must [~~shall~~] post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, AIRBORNE RADIOACTIVITY AREA" or "DANGER, AIRBORNE RADIOACTIVITY AREA."

(5) The licensee must [~~shall~~] post each area or room where [~~in which~~] there is used or stored amounts [~~an amount~~] of licensed material exceeding 10 times the quantity of such material specified in subsection (ggg)(3) of this section, with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)."

(bb) Exceptions to posting requirements.

(1) A licensee is not required to post caution signs in areas or rooms containing sources of radiation for periods of less than eight [8] hours, if each of the following conditions are [~~is~~] met:

(A) the sources of radiation are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to sources of radiation over [~~in excess of~~] the limits established in this section; and

(B) the area or room is subject to the licensee's control.

(2) Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs as specified in [~~accordance with~~] subsection (aa) of this section if [~~provided that~~] the patient could be released from licensee control as specified in [~~accordance with~~] this chapter.

(3) A room or area is not required to be posted with a caution sign because of the presence of a sealed source if [~~source(s) provided~~] the radiation level at 30 cm from the surface of the sealed source container [~~container(s)~~] or housing [~~housing(s)~~] does not exceed 0.005 rem (0.05 mSv) per hour.

(4) Rooms in medical facilities [~~that are~~] used for teletherapy are exempt from the requirement to post caution signs as specified in [~~accordance with~~] subsection (aa) of this section if [~~provided~~] the following conditions are met.

(A) Access to the room is controlled as specified in [~~accordance with~~] this chapter; and

(B) Personnel in attendance take necessary precautions to prevent the inadvertent exposure of workers, other patients, and members of the public to radiation over [~~in excess of~~] the limits established in this section.

(cc) Labeling containers.

(1) The licensee must [~~shall~~] ensure that each container of licensed material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL." The label must [~~shall~~] also provide information, such as the radionuclides present, an estimate of the quantity of radioactivity, the date [~~for which~~] the activity is estimated, radiation levels, kinds of materials, and mass enrichment, to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

(2) Each licensee must [~~shall~~], before [~~prior to~~] removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

(dd) Exemptions to labeling requirements. A licensee is not required to label:

(1) containers holding licensed material in quantities less than the quantities listed in subsection (ggg)(3) of this section;

(2) containers holding licensed material in concentrations less than those specified in Table III of subsection (ggg)(2) of this section;

(3) containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals over [~~in excess of~~] the limits established by this section;

(4) containers when they are in transport and packaged and labeled as specified in [~~accordance with~~] the rules of the DOT (labeling of packages containing radioactive materials is required by the DOT if the amount and type of radioactive material exceeds the limits for an excepted quantity or article as defined and limited by DOT regulations 49 CFR §173.403(m) [~~Title 49, CFR, §§173.403(m)~~] and (w) and §173.424 [~~173.424~~]);

(5) containers that are accessible only to individuals authorized to handle or use them, or to work in the vicinity of the containers, if the contents are identified to these individuals by a readily available written record. Examples of containers of this type are containers in locations such as water-filled canals, storage vaults, or hot cells. The record must [~~shall~~] be retained while [~~as long as~~] the containers are in use for the purpose indicated on the record; or

(6) installed manufacturing or process equipment, such as piping and tanks.

(ee) Procedures for receiving and opening packages.

(1) Each licensee who expects to receive a package containing quantities of radioactive material more than [~~in excess of~~] a Type A quantity, as defined in §289.201(b) of this subchapter [~~title~~] (relating to General Provisions for Radioactive Material) and specified in §289.257(ee) of this chapter [~~title~~] (relating to Packaging and Transportation of Radioactive Material), must [~~shall~~] make arrangements to receive:

(A) the package when the carrier offers it for delivery; or

(B) the notification of the arrival of the package at the carrier's terminal and to take possession of the package expeditiously.

(2) Each licensee must [~~shall~~]:

(A) monitor the external surfaces of a labeled package, labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in DOT regulations 49 CFR §§172.403 [~~Title 49, CFR, §§172.403~~] and 172.436 - 172.440 [~~172.436-440~~], for radioactive contamination unless the package contains only radioactive material in the form of gas or in special form as defined in §289.201(b) of this subchapter [~~title~~];

(B) monitor the external surfaces of a labeled package, labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in DOT regulations 49 CFR §§172.403 [~~Title 49, CFR, §§172.403~~] and 172.436 - 172.440 [~~172.436 - 440~~], for radiation levels, unless the package contains quantities of radioactive material

[~~that are~~] less than or equal to the Type A quantity, as defined in §289.201(b) of this subchapter [~~title~~] and specified in §289.257(ee) of this chapter [~~title~~]; and

(C) monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.

(3) The licensee must [~~shall~~] perform the monitoring required by paragraph (2) of this subsection as soon as practicable after receipt of the package, but not later than three hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours. If a package is received after working hours, the package must [~~shall~~] be monitored no later than three hours from the beginning of the next working day. If the licensee discovers there is evidence of degradation of package integrity, such as a package that is crushed, wet, or damaged, the package must [~~shall~~] be surveyed immediately.

(4) The licensee must [~~shall~~] immediately notify the final delivery carrier and, by telephone[~~, facsimile,~~] or other electronic media transmission, the department [~~agency~~] when removable radioactive surface contamination or external radiation levels exceed the limits established in subparagraphs (A) and (B) of this paragraph.

(A) Limits for removable radioactive surface contamination levels.

(i) The level of removable radioactive contamination on the external surfaces of each package offered for shipment must [~~shall~~] be ALARA. The level of removable radioactive contamination may be determined by wiping an area of 300 square centimeters (cm^2) [~~(cm^2)~~] of the surface concerned with an absorbent material, using moderate pressure, and measuring the activity on the wiping material. Sufficient measurements must [~~shall~~] be taken in the most appropriate locations to yield a representative assessment of the removable contamination levels. Except as provided in clause (iii) of this subparagraph, the amount of radioactivity measured on any single wiping material, when averaged over the surface wiped must [~~, shall~~] not be more than [~~exceed~~] the limits given in clause (ii) of this subparagraph at any time during transport. If other methods are used, the detection efficiency of the method used must [~~shall~~] be considered [~~taken into account~~] and [~~in no case may~~] the removable contamination on the external surfaces of the package must not be more than [~~exceed~~] 10 times the limits listed in clause (ii) of this subparagraph.

(ii) Removable external radioactive contamination wipe limits are as follows.

Figure: 25 TAC §289.202(ee)(4)(A)(ii)

[~~Figure: 25 TAC §289.202(ee)(4)(A)(ii)~~]

(iii) In the case of packages transported as exclusive use shipments by rail or highway only, the removable radioactive contamination at any time during transport must not exceed 10 times the levels prescribed in clause (ii) of this subparagraph. The levels at the beginning of transport must not exceed the levels in clause (ii) of this subparagraph.

(B) Limits for external radiation levels.

(i) External radiation levels around the package and around the vehicle, if applicable, must not be more than [~~will not exceed~~] 200 millirem [~~millirems~~] per hour (mrem/hr) (2 millisieverts per hour (mSv/hr)) at any point on the external surface of the package at any time during transportation. The transport index must [~~shall~~] not be more than [~~exceed~~] 10.

(ii) For a package transported in exclusive use by rail, highway, or water, radiation levels external to the package may exceed the limits specified in clause (i) of this subparagraph but must [~~shall~~] not be more than [~~exceed~~] any of the following:

(I) 200 mrem/hr (2 mSv/hr) on the accessible external surface of the package unless the following conditions are met, in which case the limit is 1,000 mrem/hr (10 mSv/hr):

(-a-) the shipment is made in a closed transport vehicle;

(-b-) provisions are made to secure the package so that its position within the vehicle remains fixed during transportation; and

(-c-) there are no loading or unloading operations between the beginning and end of the transportation;

(II) 200 mrem/hr (2 mSv/hr) at any point on the outer surface of the vehicle, including the upper and lower surfaces, or, in the case of a flat-bed style vehicle, with a personnel barrier, at any point on the vertical planes projected from the outer edges of the vehicle, on the upper surface of the load (or enclosure, if used), and on the lower external surface of the vehicle (a flat-bed style vehicle with a personnel barrier must [~~shall~~] have radiation levels determined at vertical planes. If no personnel barrier, the package cannot exceed 200 mrem/hr (2 mSv/hr) at the surface.);

(III) 10 mrem/hr (0.1 mSv/hr) at any point 2 m from the vertical planes represented by the outer lateral surfaces of the vehicle, or, in the case of a flat-bed style vehicle, at any point 2 m from the vertical planes projected from the outer edges of the vehicle; and

(IV) 2 mrem/hr (0.02 mSv/hr) in any normally occupied positions of the vehicle, except that this provision does not apply to private motor carriers when persons occupying these positions are provided with special health supervision, personnel radiation exposure monitoring devices, and training as specified in [~~accordance with~~] §289.203(c) of this subchapter [~~title~~] (relating to Notices, Instructions, and Reports to Workers; Inspections).

(5) Each licensee must [~~shall~~]:

(A) establish, maintain, and retain written procedures for safely opening packages in which radioactive material is received; and

(B) ensure that the procedures are followed and that due consideration is given to special instructions for the type of package being opened.

(6) Licensees transferring special form sources in vehicles owned or operated by the licensee to and from a work site are exempt from the contamination monitoring requirements of paragraph (2) of this subsection, but are not exempt from the monitoring requirement in paragraph (2) of this subsection for measuring radiation levels ensuring [~~that ensures that~~] the source is still properly lodged in its shield.

(ff) General requirements for waste management.

(1) Unless otherwise exempted, a licensee may [~~shall~~] discharge, treat, or decay licensed material or transfer waste for disposal only:

(A) by transfer to an authorized recipient as provided in subsection (jj) of this section, §289.252 of this chapter [~~title~~], §289.257 of this chapter [~~title~~], §289.259 of this chapter [~~title~~], or to the United States Department of Energy (DOE);

(B) by decay in storage with prior approval from the department [~~agency~~], except as authorized in §289.256(ee) of this chapter [~~title~~];

(C) by release in effluents within the limits in subsection (n) of this section as specified in [accordance with] the applicable requirements of the Texas Commission on Environmental Quality (TCEQ) or the Railroad Commission of Texas [(RRC)];

(D) as authorized in [in accordance with] paragraph (2) of this subsection, and subsections (gg), (hh), and (fff) of this section; [or]

(E) by transfer of residual radiopharmaceutical waste for decay in storage only to persons who manufactured, compounded, and supplied the radiopharmaceutical and who otherwise meet the requirements for exemption under 30 Texas Administrative Code (TAC) §336.1209 (relating to Exemptions) [Title 30, Texas Administrative Code (TAC), §336.1209]; or[.]

(F) by procedures reviewed and authorized by the department following approval of an application that includes:

(i) a description of the waste-containing licensed material to be disposed, including the physical and chemical properties important to risk evaluation, and the proposed manner and conditions of waste disposal;

(ii) an analysis and evaluation of pertinent information on the nature of the environment;

(iii) the nature and location of other potentially affected licensed and unlicensed facilities; and

(iv) analyses and procedures to ensure doses are maintained ALARA and within the dose limits in this chapter.

(2) Upon [agency] approval from the department, emission control dust and other material from electric arc furnaces or foundries contaminated because [as a result] of inadvertent melting of cesium-137 or americium-241 sources may be transferred for disposal to a hazardous waste disposal facility authorized by TCEQ or its successor, another state's regulatory agency with jurisdiction to regulate hazardous waste as classified under Subtitle C of the Resource Conservation and Recovery Act (RCRA), or the EPA. The material may be transferred for disposal without regard to its radioactivity if the following conditions are met.

(A) Contaminated material described in paragraph (2) of this subsection, whether packaged or unpackaged (i.e., bulk), must be treated through stabilization to comply with all waste treatment requirements of the appropriate state or federal regulatory agency as listed in this paragraph. The treatment operations must be undertaken by either of the following:

(i) the owner/operator of the electric arc furnace or foundry licensed to possess, treat, or transfer cesium-137 or americium-241 contaminated incident-related material; or

(ii) a service contractor licensed by the department [agency], NRC, or an agreement state to possess, treat, or transfer cesium-137 or americium-241 contaminated incident-related material.

(B) The emission control dust and other incident-related materials have been stored (if applicable) and transferred as specified in [accordance with] operating and emergency procedures approved by the department [agency].

(C) The total cesium-137 or americium-241 activity contained in emission control dust and other incident-related materials to be transferred to a hazardous waste disposal facility has been specifically approved by NRC or the appropriate agreement state or states [state(s)] and does not exceed the total activity associated with the inadvertent melting incident.

(D) The hazardous waste disposal facility operator is [has been] notified, in writing, of the impending transfer of the incident-related materials and has agreed, in writing, to receive and dispose of the packaged or unpackaged materials. Copies of the notification and agreement must [shall] be submitted to the department [agency].

(E) The licensee, as listed in subparagraph (A)(i) or (ii) of this paragraph, notifies the NRC or agreement state or states where [state(s) in which] the transferor and transferee are located, in writing, of the impending transfer, at least 30 days before the transfer.

(F) The packaged stabilized material has been packaged for transportation and disposal in non-bulk steel packaging as defined in DOT regulations at 49 CFR §173.213 [Title 49, CFR, §173.213].

(G) The emission control dust and other incident-related materials that have been stabilized and packaged as described in subparagraph (F) of this paragraph [shall] contain pretreatment average concentrations of cesium-137 that do not exceed 130 picocuries per gram (pCi/g) [pCi/g] of material, above background, or pretreatment average concentrations of americium-241 that do not exceed 3 pCi/g of material, above background.

(H) The dose rate at 3.28 feet (1 m) from the surface of any package containing stabilized waste does [shall] not exceed 20 microrem (rem) [rem] per hour or 0.20 microsieverts (Sv) [Sv] per hour, above background.

(I) The unpackaged stabilized material contains [shall contain] pretreatment average concentrations of cesium-137 that do not exceed 100 pCi/g of material, above background, or pretreatment average concentrations of americium-241 that do not exceed 3 pCi/g of material, above background.

(J) The licensee transferring the cesium-137 or americium-241 contaminated incident-related material must [shall] consult with the department [agency], [the] TCEQ or its successor, another state's regulatory agency with jurisdiction to regulate hazardous waste as classified under RCRA, or the EPA and other authorized parties, including state and local governments, and obtain all necessary approvals, in addition to those of the NRC or [and/or] any agreement state, for the transfers described in paragraph (2) of this subsection.

(K) Nothing in this subsection [shall be or] is intended to be construed as a waiver of any RCRA permit condition or term, of any state or local statute or regulation, or of any [federal] RCRA regulation.

(L) The total incident-related cesium-137 activity described in paragraph (2) of this subsection received by a facility over its operating life, is [shall] not more than [exceed] 1 curie (Ci) [Ci] (37 gigabequerels (GBq)). The total incident-related americium-241 activity described in paragraph (2) of this subsection received by a facility over its operating life, is not more than [shall not exceed] 30 millicuries (mCi) [mCi] (1.11 GBq). The department maintains [agency will maintain] a record of the total incident-related cesium-137 or americium-241 activity shipped by a person licensed by the department [agency]. Upon consultation with [the] TCEQ, the department determines [agency will determine] if the total incident-related activity received by a hazardous waste disposal facility over its operating life has reached 1 Ci (37 GBq) of cesium-137 or 30 mCi (1.11 GBq) of americium-241. The department does not [agency will not] approve shipments of cesium-137 or americium-241 contaminated incident-related material that will cause this limit to be exceeded.

(3) Radioactive waste exempted by TCEQ for disposal in a hazardous waste disposal facility holding [that holds] a TCEQ permit

issued under Subtitle C of the RCRA may be transferred for disposal as authorized by TCEQ.

(4) A person must [~~shall~~] be specifically licensed to receive waste containing licensed material from other persons for:

(A) treatment before [~~prior to~~] disposal;

(B) treatment by incineration;

(C) decay in storage;

(D) disposal at an authorized land disposal facility; or

(E) storage until transferred to a storage or disposal facility authorized to receive the waste.

(5) Byproduct material as defined in §289.201(b)(18)(C) - (E) [~~§289.201(b)(19)(C) - (E)~~] of this subchapter [~~title~~] may be disposed of as specified in 10 CFR Part 61 [~~in accordance with Title 10, CFR, Part 61~~], even though it is not defined as low-level [~~low level~~] radioactive waste. Any [~~Therefore, any~~] byproduct material being disposed of at a facility, or transferred for ultimate disposal at a facility licensed under 10 CFR Part 61 [~~Title 10, CFR, Part 61~~], must [~~shall~~] meet the requirements of this chapter.

(6) A licensee may dispose of byproduct material, as defined in §289.201(b)(18)(C) - (E) [~~§289.201(b)(19)(C) - (E)~~] of this subchapter [~~title~~], at a disposal facility authorized to dispose of such material [~~in accordance~~] with any federal [~~Federal~~] or state [~~State~~] solid or hazardous waste law.

(7) Any licensee shipping byproduct material as defined in §289.201(b)(18)(C) - (E) [~~§289.201(b)(19)(C) - (E)~~] of this subchapter [~~title~~] intended for ultimate disposal at a land disposal facility licensed under 10 CFR Part 61 must [~~Title 10, CFR, Part 61, shall~~] document the information required on the NRC's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee as specified in [~~accordance with~~] §289.257(gg) of this chapter [~~title~~].

(gg) Discharge by release into sanitary sewerage.

(1) A licensee may discharge licensed material into sanitary sewerage if each of the following conditions is satisfied:

(A) the material is readily soluble, or is readily dispersible biological material, in water;

(B) the quantity of licensed radioactive material that the licensee releases into the sewer in one month divided by the average monthly volume of water released into the sewer by the licensee is not more than [~~does not exceed~~] the concentration listed in Table III of subsection (ggg)(2) of this section; and

(C) if more than one radionuclide is released, the following additional conditions must also be satisfied:

(i) the fraction of the limit in Table III of subsection (ggg)(2) of this section represented by discharges into sanitary sewerage determined by dividing the actual monthly average concentration of each radionuclide released by the licensee into the sewer by the concentration of that radionuclide listed in Table III of subsection (ggg)(2) of this section; and

(ii) the sum of the fractions for each radionuclide required by clause (i) of this subparagraph is not more than [~~does not exceed~~] unity; and

(D) the total quantity of licensed radioactive material that the licensee releases into the sanitary sewerage in a year is not more than [~~does not exceed~~] 5 Ci [~~curies (Ci)~~] (185 GBq) of hydrogen-3, 1 Ci (37 GBq) of carbon-14, and 1 Ci (37 GBq) of all other radioactive materials combined.

(2) Excreta from individuals undergoing medical diagnosis or therapy with radioactive material are not subject to the limitations contained in paragraph (1) of this subsection.

(hh) Treatment by incineration. A licensee may treat licensed material by incineration only in the form and concentration specified in subsection (fff)(1) of this section or as authorized by the department [~~agency~~].

(ii) Discharge by release into septic tanks. Licensees must not [~~No licensee shall~~] discharge radioactive material into a septic tank system except as specifically approved by the department [~~agency~~].

(jj) Transfer for disposal and manifests.

(1) The control of transfers of LLRW intended for disposal at a licensed low-level radioactive waste disposal facility, the establishment of a manifest tracking system, and additional requirements concerning transfers and recordkeeping for those wastes are found in §289.257(ff) of this chapter [~~title~~].

(2) Each person involved in the transfer of waste for disposal, including the waste generator, waste collector, and waste processor, must [~~shall~~] comply with the requirements specified in §289.257(ff) of this chapter [~~title~~].

(kk) Compliance with environmental and health protection regulations. Nothing in subsections (ff), (gg), (hh), or (jj) of this section relieves the licensee from complying with other applicable federal, state, and local regulations governing any other toxic or hazardous properties of materials that may be disposed of as specified in [~~accordance with~~] subsections (ff), (gg), (hh), or (jj) of this section.

(ll) General provisions for records.

(1) Each licensee must [~~shall~~] use the International System of Units (SI) units becquerel, gray, sievert, and coulomb per kilogram, or the special units curie, rad, rem, and roentgen, including multiples and subdivisions, and must [~~shall~~] clearly indicate the units of all quantities on records required by this section. Disintegrations per minute may be indicated on records of surveys performed to determine compliance with subsections (ee)(4) and (ggg)(6) of this section. To ensure compatibility with international transportation standards, all limits in this section are given in terms of dual units: The SI units followed or preceded by United States (U.S.) standard or customary units. The U.S. customary units are not exact equivalents, but are rounded to a convenient value, providing a functionally equivalent unit. For the purpose of this section, either unit may be used.

(2) Notwithstanding the requirements of paragraph (1) of this subsection, when recording information on shipment manifests, as required in §289.257 of this chapter [~~title~~], information must be recorded in SI units or in SI and units as specified in paragraph (1) of this subsection.

(3) The licensee must [~~shall~~] make a clear distinction among the quantities entered on the records required by this section, such as, total effective dose equivalent, total organ dose equivalent, shallow dose equivalent, lens dose equivalent, deep dose equivalent, or committed effective dose equivalent.

(4) Records required as specified in [~~accordance with~~] §289.201(d) of this subchapter [~~title~~], and subsections (mm) - (oo) and (ss) - (uu) of this section, must [~~shall~~] include the date and the identification of personnel [~~individual(s)~~] making the record, and, as applicable, a unique identification of survey instruments [~~instrument(s)~~] used, and an exact description of the location of

the survey. Records of receipt, transfer, and disposal of sources of radiation must [~~shall~~] uniquely identify the source of radiation.

(5) Copies of records required as specified in [~~accordance with~~] §289.201(d) of this subchapter [~~title~~], and subsections (mm) - (uu) of this section, and by license condition that are relevant to operations at an additional authorized use/storage site must [~~shall~~] be maintained at that site in addition to the main site specified on a license.

(mm) Records of radiation protection programs.

(1) Each licensee must [~~shall~~] maintain records of the radiation protection program, including:

(A) the provisions of the program; and

(B) audits and other reviews of program content and implementation.

(2) The licensee must [~~shall~~] make, maintain, and retain the records required by paragraphs (1)(A) and (1)(B) of this subsection for inspection by the department as specified in [~~agency in accordance with~~] subsection (ggg)(5) of this section.

(nn) Records of surveys.

(1) Each licensee must [~~shall~~] make, maintain, and retain records documenting the results of surveys and calibrations required by subsections (p) and (ee)(2) of this section and include a unique identification of survey instruments [~~instrument(s)~~]. The licensee must [~~shall~~] maintain these records for inspection by the department as specified in [~~agency in accordance with~~] subsection (ggg)(5) of this section.

(2) Record of the calibration must [~~shall~~] include:

(A) the manufacturer's name, model, and serial number of each calibrated source or [~~and/or~~] device;

(B) the complete date of the calibration; and

(C) the name of the individual recording the information.

(3) The licensee must [~~shall~~] make, maintain, and retain each of the following records for inspection by the department as specified in [~~agency in accordance with~~] subsection (ggg)(5) of this section:

(A) the results of surveys to determine the dose from external sources of radiation used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents; [~~and~~]

(B) the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose; [~~and~~]

(C) the results of air sampling, surveys, and bioassays required as specified in [~~accordance with~~] subsection (x)(1)(C)(i) and (ii) of this section; and

(D) the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

(oo) Records of tests for leakage or contamination of sealed sources. Records of tests for leakage or contamination of sealed sources required by §289.201(g) of this subchapter [~~title~~] must [~~shall~~] be kept in units of becquerel or microcurie and maintained and retained for inspection by the department as specified in [~~agency in accordance with~~] subsection (ggg)(5) of this section.

(pp) Records of lifetime cumulative occupational radiation dose. The licensee must [~~shall~~] make, maintain, and retain the records of lifetime cumulative occupational radiation dose as specified in subsection (k) of this section on RC Form 202-2, or equivalent, and the records used in preparing RC Form 202-2, or equivalent, for inspection by the department as specified in [~~agency in accordance with~~] subsection (ggg)(5) of this section.

(qq) Records of planned special exposures.

(1) For each use of the provisions of subsection (k) of this section for planned special exposures, the licensee must [~~shall~~] maintain records that describe:

(A) the exceptional circumstances requiring the use of a planned special exposure;

(B) the name of the management official who authorized the planned special exposure and a copy of the signed authorization;

(C) what actions were necessary;

(D) why the actions were necessary;

(E) what precautions were taken to assure that doses were maintained ALARA;

(F) what individual and collective doses were expected to result; and

(G) the doses actually received in the planned special exposure.

(2) The licensee must [~~shall~~] retain the records until the department [~~agency~~] terminates each pertinent license requiring these records.

(rr) Records of individual monitoring results.

(1) Each licensee must [~~shall~~] maintain records of doses received by all individuals for whom monitoring was required as specified in [~~accordance with~~] subsection (q) of this section, and records of doses received during planned special exposures, accidents, and emergency conditions. Assessments of dose equivalent and records made using units in effect before January 1, 1994, need not be changed. These records must [~~shall~~] include, when applicable:

(A) the deep dose equivalent to the whole body, lens dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities;

(B) the estimated intake of radionuclides. See [~~, see~~] subsection (g) of this section;

(C) the committed effective dose equivalent assigned to the intake of radionuclides;

(D) the specific information used to calculate the committed effective dose equivalent as specified in [~~accordance with~~] subsection (i)(1) and (3) of this section and when required by subsection (q)(1) of this section;

(E) the TEDE [~~total effective dose equivalent~~] when required by subsection (g) of this section;

(F) the total of the deep dose equivalent and the committed dose to the organ receiving the highest total dose; and

(G) the data used to make occupational dose assessments as specified in [~~accordance with~~] subsection (j)(5) of this section.

(2) The licensee must [~~shall~~] make entries of the records specified in paragraph (1) of this subsection at intervals not more than one [~~to exceed 1~~] year and not later than [~~by~~] April 30 of the following year.

(3) The licensee must [~~shall~~] maintain the records specified in paragraph (1) of this subsection on RC Form 202-3, as specified in [~~accordance with~~] the instructions for RC Form 202-3, or in clear and legible records containing all the information required by RC Form 202-3.

(4) The licensee must [~~shall~~] maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy, including the estimated date of conception, must [~~shall~~] also be kept on file, but may be maintained separately from the dose records.

(5) The licensee must [~~shall~~] retain each required form or record until the department [~~agency~~] terminates each pertinent license requiring the record. The licensee must [~~shall~~] retain records used in preparing RC Form 202-3 or equivalent for three years after the record is made.

(ss) Records of dose to individual members of the public.

(1) Each licensee must [~~shall~~] maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public. See subsection (n) of this section.

(2) The licensee must [~~shall~~] retain the records required by paragraph (1) of this subsection until the department [~~agency~~] terminates each pertinent license requiring the record.

(tt) Records of discharge, treatment, or transfer for disposal.

(1) Each licensee must [~~shall~~] maintain records of the discharge or treatment of licensed materials made as specified in [~~accordance with~~] subsection (gg) and (hh) of this section and of transfers for disposal made as specified in [~~accordance with~~] subsection (jj) of this section and §289.257 of this chapter [~~title~~].

(2) The licensee must [~~shall~~] retain the records required by paragraph (1) of this subsection until the department [~~agency~~] terminates each pertinent license requiring the record.

(uu) Records of testing entry control devices for very high radiation areas.

(1) Each licensee must [~~shall~~] maintain records of tests made as specified in [~~accordance with~~] subsection (u)(2)(I) of this section on entry control devices for very high radiation areas. These records must include the date, time, and results of each such test of function.

(2) The licensee must [~~shall~~] retain the records required by paragraph (1) of this subsection for three years after the record is made.

(vv) Form of records. Each record required by this chapter must include all pertinent information and [~~shall~~] be stored in a legible and reproducible format [~~legible~~] throughout the specified retention period. [~~The record shall be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period or the record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, shall include all pertinent information, such as stamps, initials, and signatures.~~] The licensee must [~~shall~~] maintain adequate safeguards against tampering with and loss of records.

(ww) Reports of stolen, lost, or missing licensed sources of radiation.

(1) Each licensee must [~~shall~~] report to the department [~~agency~~] by telephone as follows:

(A) immediately after its occurrence becomes known to the licensee, stolen, lost, or missing licensed radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in subsection (ggg)(3) of this section, if [~~under such circumstances that~~] it appears to the licensee [~~that~~] an exposure could result to individuals in unrestricted areas; or

(B) within 30 days after the licensee knows [~~its occurrence becomes known to the licensee,~~] lost, stolen, or missing licensed radioactive material in an aggregate quantity greater than 10 times the quantity specified in subsection (ggg)(3) of this section [~~that~~] is still missing.

(2) Each licensee required to make a report as specified in [~~accordance with~~] paragraph (1) of this subsection must [~~shall~~], within 30 days after making the telephone report, make a written report to the department, including [~~agency setting forth the following information~~]:

(A) a description of the licensed source of radiation involved, including, for radioactive material, the kind, quantity, chemical and physical form, source or [~~and/or~~] device manufacturer, model number, and serial number;

(B) a description of the circumstances under which the loss or theft occurred;

(C) a statement of disposition, or probable disposition, of the licensed source of radiation involved;

(D) exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible TEDE [~~total effective dose equivalent~~] to persons in unrestricted areas;

(E) actions [~~that have been~~] taken, or to [~~will~~] be taken, to recover the source of radiation; and

(F) procedures or measures adopted [~~that have been~~], or to be [~~will be,~~] adopted, ensuring [~~to ensure~~] against a recurrence of the loss or theft of licensed sources of radiation.

(3) Subsequent to filing the written report, the licensee must [~~shall~~] also report additional substantive information on the loss or theft within 30 days after the licensee learns of such information.

(4) The licensee must [~~shall~~] prepare any report filed with the department as specified in [~~agency in accordance with~~] this subsection so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

(xx) Notification of incidents.

(1) Notwithstanding other requirements for notification, each licensee must [~~shall~~] immediately report each event involving a source of radiation possessed by the licensee that may have caused or threatens to cause:

(A) an individual, except a patient administered radiation for purposes of medical diagnosis or therapy, to receive:

(i) a TEDE [~~total effective dose equivalent~~] of 25 rem [~~rems~~] (0.25 Sv) or more;

(ii) a lens dose equivalent of 75 rem [~~rems~~] (0.75 Sv) or more; or

(iii) a shallow dose equivalent to the skin or extremities or a total organ dose equivalent of 250 rads (2.5 Gy [~~grays~~]) or more; or

(B) the release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the occupational ALI. This provision does not apply to locations where personnel are

not normally stationed during routine operations, such as hot-cells or process enclosures.

(2) Each licensee must [~~shall~~], within 24 hours of discovery of the event, report to the department [~~agency~~] each event involving loss of control of a licensed source of radiation possessed by the licensee that may have caused, or threatens to cause:

(A) an individual to receive, in a period of 24 hours:

(i) a TEDE [~~total effective dose equivalent~~] exceeding 5 rem [~~rems~~] (0.05 Sv);

(ii) a lens dose equivalent exceeding 15 rem [~~rems~~] (0.15 Sv); or

(iii) a shallow dose equivalent to the skin or extremities or a total organ dose equivalent exceeding 50 rem [~~rems~~] (0.5 Sv); or

(B) the release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake more than [~~in excess of~~] one occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

(3) Licensees must [~~shall~~] make the initial notification reports required by paragraphs (1) and (2) of this subsection by telephone to the department [~~agency~~] and must [~~shall~~] confirm the initial notification report within 24 hours by [~~facsimile or~~] other electronic media transmission to the department [~~agency~~].

(4) The licensee must [~~shall~~] prepare each report filed with the department as specified in [~~agency in accordance with~~] this section so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.

(5) The provisions of this section do not apply to doses that result from planned special exposures, provided such doses are within the limits for planned special exposures and are reported as specified in [~~accordance with~~] subsection (zz) of this section.

(6) Each licensee must [~~shall~~] notify the department [~~agency~~] as soon as possible, but not later than four hours after the discovery, of an event that prevents immediate protective actions necessary to avoid exposures to radioactive materials that could exceed regulatory limits, or releases of radioactive materials that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.).

(7) Each licensee must [~~shall~~] notify the department [~~agency~~] within 24 hours after the discovery of any of the following events involving radioactive material:

(A) an unplanned contamination event [~~that~~]:

(i) requiring [~~requires~~] access to the contaminated area[~~, by workers or the public,~~] to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;

(ii) involving [~~involves~~] a quantity of material greater than five times the lowest annual limit on intake specified in subsection (ggg)(2) of this section for the material; and

(iii) restricting [~~has~~] access to the area [~~restricted~~] for a reason other than to allow isotopes with a half-life of less than 24 hours to decay before [~~prior to~~] decontamination;

(B) an event in which equipment is disabled or fails to function as designed when:

(i) the equipment is required by rule or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;

(ii) the equipment is required to be available and operable when it is disabled or fails to function; and

(iii) no redundant equipment is available and operable to perform the required safety function;

(C) an event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body; or

(D) an unplanned fire or explosion damaging any radioactive material or any device, container, or equipment containing radioactive material when:

(i) the quantity of material involved is greater than five times the lowest annual limit on intake specified in subsection (ggg)(2) of this section for the material; and

(ii) the damage affects the integrity of the radioactive material or its container.

(8) Preparation and submission of reports. Reports made by licensees in response to the requirements of paragraphs (6) and (7) of this subsection must [~~shall~~] be made as follows.

(A) Licensees must [~~shall~~] make reports required by paragraphs (6) and (7) of this subsection by telephone to the department [~~agency~~]. To the extent that the information is available at the time of notification, the information provided in these reports must [~~shall~~] include:

(i) the caller's name and call back telephone number;

(ii) a description of the event, including date and time;

(iii) the exact location of the event;

(iv) the isotopes, quantities, and chemical and physical form of the radioactive material involved;

(v) any personnel radiation exposure data available; and

(vi) the source or [~~and/or~~] device manufacturer, model, and serial number.

(B) Each licensee who makes a report required by paragraphs (6) and (7) of this subsection must [~~shall~~] submit to the department [~~agency~~] a written follow-up report within 30 days of the initial report. Written reports prepared as specified in [~~accordance with~~] other requirements of this chapter may be submitted to fulfill this requirement if the reports contain all [~~of the~~] necessary information and the appropriate distribution is made. The reports must include [~~the following~~]:

(i) a description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;

(ii) the exact location of the event;

(iii) the isotopes, quantities, chemical and physical form of the radioactive material involved, and the source or [~~and/or~~] device manufacturer, model number, and serial number;

(iv) date and time of the event;

(v) corrective actions taken or planned and the results of any evaluations or assessments; and

(vi) the extent of exposure of individuals to radioactive materials without identification of individuals by name.

(yy) Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the limits.

(1) In addition to the notification required by subsection (xx) of this section, each licensee must [~~shall~~] submit a written report within 30 days after becoming aware [~~learning~~] of [~~any of the following occurrences~~]:

(A) incidents for which notification is required by subsection (xx) of this section;

(B) doses exceeding [~~in excess of any of the following~~]:

(i) the occupational dose limits for adults in subsection (f) of this section;

(ii) the occupational dose limits for a minor in subsection (l) of this section;

(iii) the limits for an embryo/fetus of a declared pregnant woman in subsection (m) of this section;

(iv) the limits for an individual member of the public in subsection (n) of this section;

(v) any applicable limit in the license; or

(vi) the ALARA constraints for air emissions as required by subsection (e)(4) of this section;

(C) levels of radiation or concentrations of radioactive material in:

(i) a restricted area exceeding [~~in excess of~~] applicable limits in the license; or

(ii) an unrestricted area more than [~~in excess of~~] 10 times the applicable limit set forth in this section or in the license, whether or not involving exposure of any individual over [~~in excess of~~] the limits in subsection (n) of this section; or

(D) for licensees subject to the provisions of the EPA's generally applicable environmental radiation standards in 40 CFR §190 [~~Title 40, CFR, §190~~], levels of radiation or releases of radioactive material exceeding [~~in excess of~~] those standards, or of license conditions related to those requirements.

(2) Each report required by paragraph (1) of this subsection must [~~shall~~] describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

(A) estimates of each individual's dose;

(B) the levels of radiation, dose limit exceeded, concentrations of radioactive material involved, and the source or [~~and/or~~] device manufacturer, model number, and serial number;

(C) the cause of the elevated exposures, dose rates, or concentrations; and

(D) corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, ALARA constraints, generally applicable environmental standards, and associated license conditions.

(3) Each report filed as specified in [~~accordance with~~] paragraph (1) of this subsection must [~~shall~~] include for each individual exposed: the name, identification number, and date of birth. With respect to the limit for the embryo/fetus in subsection (m) of this section, the identifiers should be those of the declared pregnant woman. The report must [~~shall~~] be prepared so that this information is stated in a separate and detachable portion of the report.

(4) All licensees who make reports as specified in [~~accordance with~~] paragraph (1) of this subsection must [~~shall~~] submit the report in writing to the department [~~agency~~].

(zz) Reports of planned special exposures. The licensee must [~~shall~~] submit a written report to the department [~~agency~~] within 30 days following any planned special exposure conducted as specified in [~~accordance with~~] subsection (k) of this section, informing the department [~~agency that~~] a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by subsection (qq) of this section.

(aaa) Notifications and reports to individuals.

(1) Requirements for notification and reports to individuals of exposure to sources of radiation are specified in §289.203 of this subchapter [~~title~~].

(2) When a licensee is required as specified in [~~accordance with~~] subsection (yy) or (zz) of this section to report to the department [~~agency~~] any exposure of an identified occupationally exposed individual, or an identified member of the public, to sources of radiation, the licensee must [~~shall~~] also notify the individual and provide a copy of the report submitted to the department [~~agency,~~] to the individual. Such notice must [~~shall~~] be transmitted [~~at a time~~] not later than the transmittal to the department [~~agency,~~] and must [~~shall~~] comply with the provisions of §289.203(d)(1) of this subchapter [~~title~~].

(bbb) Reports of leaking or contaminated sealed sources. The licensee must [~~shall~~] immediately notify the department [~~agency~~] if the test for leakage or contamination required as specified in [~~accordance with~~] §289.201(g) of this subchapter [~~title~~] indicates a sealed source is leaking or contaminated. A written report of a leaking or contaminated source must [~~shall~~] be submitted to the department [~~agency~~] within five [~~5~~] days. The report must [~~shall~~] include the equipment involved, including the device manufacturer, model and serial number; the test results; the date of the test; model and serial number,[~~;~~] if assigned, of the leaking source; [~~,~~] the radionuclide and its estimated activity; and the corrective action taken.

(ccc) Vacating premises.

(1) Each licensee or person possessing non-exempt sources of radiation must notify the department, in writing, at least [~~shall, no less than~~] 30 days before vacating and relinquishing possession or control of premises[~~, notify the agency, in writing, of the intent to vacate~~].

(2) The licensee or person possessing non-exempt radioactive material must [~~shall~~] decommission the premises to a degree consistent with subsequent use as an unrestricted area and as specified in [~~accordance with~~] the requirements of subsection (ddd) of this section.

(ddd) Radiological requirements for license termination.

(1) General provisions and scope.

(A) The requirements in this section apply to the decommissioning of facilities licensed as specified in [~~accordance with~~] §289.252 of this chapter [~~title~~], §289.253 of this chapter [~~title~~] (relating to Radiation Safety Requirements for Well Logging Service Operations and Tracer Studies), §289.255 of this chapter [~~title~~] (relating to Radiation Safety Requirements and Licensing and Registration Procedures for Industrial Radiography), §289.258 of this chapter [~~title~~] (relating to Licensing and Radiation Safety Requirements for Irradiators), and §289.259 of this chapter [~~title~~] (relating to Licensing of Naturally Occurring Radioactive Material (NORM)).

(B) The requirements in this section do not apply to [~~the following~~]:

(i) sites that have been decommissioned before [~~prior to~~] October 1, 2000, as specified in [~~accordance with~~] requirements identified in this section and in §289.252 of this chapter [~~title~~]; or

(ii) sites that have previously submitted and received approval on a decommissioning plan before [~~by~~] October 1, 2000.

(C) After a site has been decommissioned and the license terminated as specified in [~~accordance with~~] the requirements in this [~~the~~] subsection, the department requires [~~agency will require~~] additional cleanup when [~~if~~] it determines that the requirements of this [~~the~~] subsection were not met and residual radioactivity remaining at the site could result in significant threat to public health and safety.

(D) When calculating TEDE to the average member of the critical group, the licensee must [~~shall~~] determine the peak annual TEDE dose expected within the first 1,000 years after decommissioning.

(2) Radiological requirements for unrestricted use. A site will be considered acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a TEDE to an average member of the critical group that is not more than [~~does not exceed~~] 25 mrem (0.25 mSv) per year, including [~~that~~] from groundwater sources of drinking water, and the residual radioactivity has been reduced to levels that are ALARA. Determination of ALARA [~~the~~] levels must [~~that are ALARA shall~~] take into [~~account~~] consideration [~~of~~] any detriments, such as deaths from transportation accidents, that could [~~expected to potentially~~] result from decontamination and waste disposal.

(3) Criteria for license termination under restricted conditions. A site will be considered acceptable for license termination under restricted conditions if:

(A) the licensee demonstrates [~~can demonstrate that~~] further reductions in residual radioactivity necessary to comply with the requirements of paragraph (2) of this subsection would result in net public or environmental harm or were not being made because the residual levels associated with restricted conditions are ALARA. Determination of ALARA [~~the~~] levels must [~~which are ALARA shall~~] take into [~~account~~] consideration [~~of~~] any detriments, such as traffic accidents, expected to potentially result from decontamination and waste disposal;

(B) the licensee has made provisions for legally enforceable institutional controls providing [~~that provide~~] reasonable assurance [~~that~~] the TEDE from residual radioactivity distinguishable from background to the average member of the critical group is not more than [~~will not exceed~~] 25 mrem (0.25 mSv) per year;

(C) the licensee has provided sufficient financial assurance enabling [~~to enable~~] an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site. Acceptable financial assurance mechanisms include [~~are~~]:

(i) funds placed into a trust segregated from the licensee's assets and outside the licensee's administrative control, and in which the adequacy of the trust funds is [~~to be~~] assessed based on an assumed annual 1 percent [~~1%~~] real rate of return on investment;

(ii) a statement of intent in the case of federal, state, or local government licensees, as described in §289.252(gg) of this chapter [~~title~~]; or

(iii) when a governmental entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity.

(D) the licensee has submitted a decommissioning plan or License Termination Plan (LTP) to the department [~~agency~~] indicating the licensee's intent to decommission as specified in [~~accordance with~~] §289.252(y) of this chapter [~~title~~], and specifying that the licensee intends to decommission by restricting use of the site. The licensee must [~~shall~~] document in the LTP or decommissioning plan how the input [~~advice~~] of individuals and institutions in the community who may be affected by the decommissioning has been sought and incorporated, as appropriate, following analysis of that input [~~advice~~].

(i) Licensees proposing to decommission by restricting use of the site must [~~shall~~] seek input [~~advice~~] from [~~such~~] affected parties regarding the following [~~matters~~] concerning the proposed decommissioning:

(I) whether provisions for institutional controls proposed by the licensee;

(-a-) [~~will~~] provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 25 mrem (0.25 mSv) TEDE per year;

(-b-) are [~~will be~~] enforceable; and

(-c-) do [~~will~~] not impose undue burdens on the local community or other affected parties; and

(II) whether the licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site.

(ii) In seeking input [~~advice~~] on the issues identified in clause (i) of this subparagraph, the licensee must [~~shall~~] provide for:

(I) participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;

(II) an opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

(III) a publicly available summary of the results of all [~~such~~] discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues; and

(E) residual radioactivity at the site has been reduced so that, if the institutional controls were no longer in effect, there is reasonable assurance [~~that~~] the TEDE from residual radioactivity distinguishable from background to the average member of the critical group is ALARA and would not exceed either:

(i) 100 mrem (1 mSv) per year; or

(ii) 500 mrem (5 mSv) per year provided the licensee:

(I) demonstrates that further reductions in residual radioactivity necessary to comply with the 1 mSv per year (100 mrem per year) [~~100 mrem/y (1 mSv/y)~~] value of clause (i) of this subparagraph are not technically achievable, are [~~would be~~] prohibitively expensive, or [~~would~~] result in net public or environmental harm;

(II) makes provisions for durable institutional controls; and

(III) provides sufficient financial assurance to enable a responsible government entity or independent third party,

including a governmental custodian of a site, [both] to carry out periodic rechecks of the site no less frequently than every five [5] years to assure that the institutional controls remain in place as necessary to meet the criteria of paragraph (2) of this subsection, and to assume and carry out responsibilities for any necessary control and maintenance of those controls. Acceptable financial assurance mechanisms are those in subparagraph (C) of this paragraph.

(4) Alternate requirements for license termination.

(A) The department [agency] may terminate a license using alternate requirements greater than the dose requirements specified in paragraph (2) of this subsection if the licensee [does the following]:

(i) provides assurance that public health and safety would continue to be protected, and [that] it is unlikely [that] the dose from all man-made sources combined, other than medical, would be more than the 1 mSv per year (100 mrem per year) limit specified in subsection (o) of this section, by submitting an analysis of possible sources of exposure;

(ii) reduces doses to ALARA levels, taking into consideration any detriments such as traffic accidents that could [expected to potentially] result from decontamination and waste disposal;

(iii) submits [has submitted] a decommissioning plan to the department [agency] indicating the licensee's intent to decommission as specified in [accordance with] the requirements in §289.252(y) of this chapter [title], and specifying that the licensee proposes to decommission by use of alternate requirements. The licensee must [shall] document in the decommissioning plan how the input [advice] of individuals and institutions in the community who may be affected by the decommissioning has been sought and addressed, as appropriate, following analysis of that input [advice]. In seeking input [such advice], the licensee must [shall] provide for [the following]:

(I) participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;

(II) an opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

(III) a publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues; and

(iv) has provided sufficient financial assurance in the form of a trust fund to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site.

(B) The use of alternate requirements to terminate a license requires the approval of the department [agency] after consideration of the department's [agency's] recommendations addressing [that will address] any comments provided by the EPA and any public comments submitted as specified in [accordance with] paragraph (5) of this subsection.

(5) Public notification and public participation. Upon receipt of a decommissioning plan from the licensee, or a proposal from the licensee for release of a site pursuant to paragraphs (3) and (4) of this subsection, or whenever the department [agency] deems such notice to be in the public interest, the department [agency will do the following]:

(A) notifies and solicits [notify and solicit] comments from [the following]:

(i) local and state governments in the vicinity of the site and any Indian Nation or other indigenous people having [that have] treaty or statutory rights that could be affected by the decommissioning; and

(ii) the EPA, for cases where the licensee proposes to release a site as specified in [accordance with] paragraph (4) of this subsection; and

(B) publishes [publish] a notice in the *Texas Register* and a forum, such as local newspapers, letters to state or local organizations, or other appropriate forum, that is readily accessible to individuals in the vicinity of the site, and solicit comments from affected parties.

(6) Minimization of contamination.

(A) Applicants for licenses, other than renewals, after October 1, 2000, must [shall] describe in the application how facility design and procedures for operation [will] minimize, to the extent practical, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practical, the generation of LLRW.

(B) Licensees must conduct operations [shall], to the extent practical, [conduct operations] to minimize the introduction of residual radioactivity into the site, including the subsurface, as specified in [accordance with] the existing radiation protection requirements and radiological criteria for license termination in this subsection.

(eee) Limits for contamination of soil, surfaces of facilities and equipment, and vegetation.

(1) Licensees must not [No licensee shall] possess, receive, use, or transfer radioactive material in [such] a manner causing [as to cause] contamination of surfaces of facilities or equipment in unrestricted areas to the extent that the contamination is more than [exceeds] the limits specified in subsection (ggg)(6) of this section.

(2) Licensees must not [No licensee shall] possess, receive, use, or transfer radioactive material in [such] a manner causing [as to cause] contamination of soil in unrestricted areas, to the extent that the contamination is more than [exceeds], on a dry weight basis, the concentration limits specified in:

(A) subsection (ddd) of this section; or

(B) the effluent concentrations in Table II, Column 2 of subsection (ggg)(2)(F) of this section, with the units changed from microcuries per milliliter to microcuries per gram, for radionuclides not specified in paragraph (4) of this subsection.

(3) Where combinations of radionuclides are involved, the sum of the ratios between the concentrations present and the limits specified in paragraph (2) of this subsection must [shall] not exceed one.

(4) Notwithstanding the limits specified in paragraph (2) of this subsection, licensees must not [no licensee shall] cause the concentration of radium-226 or radium-228 in soil in unrestricted areas, averaged over any 100 square meters (m^2) [(m^2)], to exceed the background level by more than:

(A) 5 pCi/g [picocuries per gram (pCi/g)] (0.185 becquerel per gram (Bq/g)), averaged over the first 15 cm of soil below the surface; and

(B) 15 pCi/g (0.555 Bq/g), averaged over 15 cm thick layers of soil more than 15 cm below the surface.

(5) Licensees must not [~~No licensee shall~~] possess, receive, use, or transfer radioactive material in [~~such~~] a manner causing [~~as to cause~~] contamination of vegetation in unrestricted areas to be more than [~~exceed~~] 5 pCi/g (0.185 Bq/g), based on dry weight, for radium-226 or radium-228.

(6) Notwithstanding the limits specified in paragraph (2) of this subsection, licensees must not [~~no licensee shall~~] cause the concentration of natural uranium with no daughters present, based on dry weight and averaged over any 100 m^2 of area, to exceed the following limits:

(A) 30 pCi/g (1.11 Bq/g), averaged over the top 15 cm of soil below the surface; and

(B) 150 pCi/g (5.55 Bq/g), average concentration at depths greater than 15 cm [~~centimeters~~] below the surface so that no individual member of the public will receive an effective dose equivalent more than [~~in excess of~~] 100 mrem (1 mSv) per year.

(fff) Exemption of specific wastes.

(1) A licensee may discard the following licensed material without regard to its radioactivity:

(A) 0.05 microcurie (Ci) (1.85 kilobecquerels (kBq)), or less, of hydrogen-3 or carbon-14 [~~, carbon-14, or iodine-125~~] per gram of medium used for liquid scintillation counting [~~or in vitro clinical or in vitro laboratory testing~~]; and

(B) 0.05 Ci (1.85 kBq), or less, of hydrogen-3 or carbon-14 [~~, carbon-14, or iodine-125,~~] per gram of animal tissue[~~,~~] averaged over the weight of the entire animal.

(2) A licensee must [~~shall~~] not discard tissue as specified in [~~accordance with~~] paragraph (1)(B) of this subsection in a manner permitting [~~that would permit~~] its use either as food for humans or as animal feed.

(3) The licensee must [~~shall~~] maintain records as specified in [~~accordance with~~] subsection (tt) of this section.

(4) Any licensee may, upon [~~agency~~] approval from the department of procedures required in paragraph (6) of this subsection, discard licensed material included in subsection (ggg)(7) of this section, if [~~provided that~~] it does not exceed the concentration and total curie limits contained therein, in a Type I municipal solid waste site as defined in the Municipal Solid Waste Regulations of the authorized regulatory agency (30 TAC Chapter 330 (relating to Municipal Solid Waste [~~Title 30, Texas Administrative Code, Chapter 330~~]), unless such licensed material also contains hazardous waste, as defined in §361.003(12) of the Solid Waste Disposal Act, Texas Health and Safety Code[~~,~~] Chapter 361. Any licensed material included in subsection (ggg)(7) of this section and which is a hazardous waste as defined in the Solid Waste Disposal Act, may be discarded at a facility authorized to manage hazardous waste by the authorized regulatory agency.

(5) Each licensee discarding [~~who discards~~] material described in paragraphs (1) or (4) of this subsection must [~~shall~~]:

(A) make surveys adequate to assure that the limits of paragraphs (1) or (4) of this subsection are not exceeded; and

(B) remove or otherwise obliterate or obscure all labels, tags, or other markings that would indicate that the material or its contents is radioactive.

(6) Before [~~Prior to~~] authorizations as specified in [~~accordance with~~] paragraph (4) of this subsection, a licensee must [~~shall~~] submit procedures to the department [~~agency~~] for:

(A) the physical delivery of the material to the disposal site;

(B) surveys to be performed for compliance with paragraph (5)(A) of this subsection;

(C) maintaining secure packaging during transportation to the site; and

(D) maintaining records of any discards made under paragraph (4) of this subsection.

(7) Nothing in this section relieves the licensee of maintaining records showing the receipt, transfer, and discard of such radioactive material as specified in §289.201(d) of this subchapter [~~title~~].

(8) Nothing in this section relieves the licensee from complying with other applicable federal, state, and local regulations governing any other toxic or hazardous property of these materials.

(9) Licensed material discarded under this section is exempt from the requirements of §289.252(ff) of this chapter [~~title~~].

(ggg) Appendices.

(1) Assigned protection factors for respirators. The following table contains assigned protection factors for respirators[a] [~~respirators[a]~~]:
Figure: 25 TAC §289.202(ggg)(1)
[~~Figure: 25 TAC §289.202(ggg)(1)~~]

(2) ALI and DAC [~~Annual limits on intake (ALI) and derived air concentrations (DAC)~~] of radionuclides for occupational exposure; effluent concentrations; concentrations for release to sanitary sewerage.

(A) Introduction.

(i) For each radionuclide, Table I of subparagraph (F) of this paragraph indicates the chemical form [~~that is~~] to be used for selecting the appropriate ALI or DAC value. The ALIs and DACs for inhalation are given for an aerosol with an activity median aerodynamic diameter (AMAD) of 1 micron, and for three classes (D, W, Y) of radioactive material, which refer to their retention (approximately days, weeks, or years) in the pulmonary region of the lung. This classification applies to a range of clearance half-times for D if less than 10 days, for W from 10 to 100 days, and for Y greater than 100 days. Table II of subparagraph (F) of this paragraph provides concentration limits for airborne and liquid effluents released to the general environment. Table III of subparagraph (F) of this paragraph provides concentration limits for discharges to sanitary sewerage.

(ii) The values in Tables I, II, and III of subparagraph (F) of this paragraph are presented in the computer "E" notation. In this notation a value of 6E-02 represents a value of 6×10^{-2} or 0.06, 6E+2 represents 6×10^{2} or 600, and 6E+0 represents 6×10^{0} or 6.

(B) Occupational values.

(i) Note that the columns in Table I of subparagraph (F) of this paragraph captioned "Oral Ingestion ALI," "Inhalation ALI," and "DAC," are applicable to occupational exposure to radioactive material.

(ii) The ALIs in subparagraph (F) of this paragraph are the annual intakes of given radionuclide by Reference Man [~~"Reference Man"~~] that would result in either a committed effective dose equivalent of 5 rem [~~rems~~] (0.05 Sv), stochastic ALI, or a committed dose equivalent of 50 rem [~~rems~~] (0.5 Sv) to an organ or tissue, non-stochastic ALI. The stochastic ALIs were derived to result in a risk, due to irradiation of organs and tissues, comparable to the risk associated with deep dose equivalent to the whole body of 5 rem

[~~rems~~] (0.05 Sv). The derivation includes multiplying the committed dose equivalent to an organ or tissue by a weighting factor, w_T [~~w_T~~]. This weighting factor is the proportion of the risk of stochastic effects resulting from irradiation of the organ or tissue, T, to the total risk of stochastic effects when the whole body is irradiated uniformly. The values of w are listed under the definition of "weighting factor" in subsection (c) of this section. The non-stochastic ALIs were derived to avoid non-stochastic effects, such as prompt damage to tissue or reduction in organ function.

(iii) A value of $w_T = 0.06$ is applicable to each of the five organs or tissues in the "remainder" category receiving the highest dose equivalents, and the dose equivalents of all other remaining tissues may be disregarded. These [~~the following~~] portions of the gastrointestinal (GI) [~~GI~~] tract are treated as four separate organs:[~~;~~] stomach, small intestine, upper large intestine, and lower large intestine[~~, are to be treated as four separate organs~~].

(iv) The dose equivalents for an extremity, skin, and lens of the eye are not considered in computing the committed effective dose equivalent, but are subject to limits that must [~~shall~~] be met separately.

(v) When an ALI is defined by the stochastic dose limit, this value alone is given. When an ALI is determined by the non-stochastic dose limit to an organ, the organ or tissue to which the limit applies is shown, and the ALI for the stochastic limit is shown in parentheses. Abbreviated organ or tissue designations are used as follows:

(I) LLI wall = lower large intestine wall;

(II) St. wall = stomach wall;

(III) Blad wall = bladder wall; and

(IV) Bone surf = bone surface.

(vi) The use of the ALIs listed first, the more limiting of the stochastic and non-stochastic ALIs, will ensure non-stochastic effects are avoided and risk of stochastic effects is limited to an acceptably low value. If, in a particular situation involving a radionuclide for which the non-stochastic ALI is limiting, use of that non-stochastic ALI is considered unduly conservative, the licensee may use the stochastic ALI to determine the committed effective dose equivalent. The licensee must also ensure the 50 rem (0.5 Sv) dose equivalent limit for any organ or tissue is not exceeded by the sum of the external deep dose equivalent plus the internal committed dose equivalent to that organ, not the effective dose. For the case where there is no external dose contribution, this is demonstrated if the sum of the fractions of the non-stochastic ALIs (ALI_w) contributing to the committed dose equivalent to the organ receiving the highest dose does not exceed unity, that is, Σ(intake in Ci of each radionuclide/ALI_w) < 1.0. If there is an external deep dose equivalent contribution (H_d), then this sum must be less than 1 - (H_d/50), instead of < 1.0.
[~~Figure: 25 TAC §289.202(ggg)(2)(B)(vi)~~]

~~*[(vii)* The dose equivalents for an extremity, skin, and lens of the eye are not considered in computing the committed effective dose equivalent, but are subject to limits that must be met separately.]~~

(vii) [~~(viii)~~] The DAC values are derived limits intended to control chronic occupational exposures. The relationship between the DAC and the ALI is given by:
Figure: 25 TAC §289.202(ggg)(2)(B)(vii)
[~~Figure: 25 TAC §289.202(ggg)(2)(B)(viii)~~]

(viii) [~~(ix)~~] The DAC values relate to one of two modes of exposure: either external submersion or the internal committed dose equivalents resulting from inhalation of radioactive materials. DACs based upon submersion are for immersion in a semi-infinite cloud of uniform concentration and apply to each radionuclide separately.

(ix) [~~(x)~~] The ALI and DAC values include contributions to exposure by the single radionuclide named and any in-growth of daughter radionuclides produced in the body by decay of the parent. Intakes [~~However, intakes~~] that include both the parent and daughter radionuclides are [~~should be~~] treated by the general method appropriate for mixtures.

(x) [~~(xi)~~] The values of ALI and DAC do not apply directly when the individual both ingests and inhales a radionuclide, when the individual is exposed to a mixture of radionuclides by either inhalation or ingestion or both, or when the individual is exposed to both internal and external irradiation. See subsection (g) of this section. When an individual is exposed to radioactive materials falling [~~which fall~~] under several of the translocation classifications of the same radionuclide, such as, Class D, [~~Class~~] W, or [~~Class~~] Y, the exposure may be evaluated as if it were a mixture of different radionuclides.

(xi) [~~(xii)~~] It should be noted that the classification of a compound as Class D, W, or Y is based on the chemical form of the compound and does not consider [~~take into account~~] the radiological half-life of different radionuclides. For this reason, values are given for Class D, W, and Y compounds, even for very short-lived radionuclides.

(C) Effluent concentrations.

(i) The columns in Table II of subparagraph (F) of this paragraph captioned "Effluents," "Air," and "Water" are applicable to the assessment and control of dose to the public, particularly in the implementation of the provisions of subsection (o) of this section. The concentration values given in Columns 1 and 2 of Table II of subparagraph (F) of this paragraph are equivalent to the radionuclide concentrations that [~~which~~], if inhaled or ingested continuously over the course of a year, would produce a TEDE [~~total effective dose equivalent~~] of 0.05 rem (0.5 mSv).

(ii) Consideration of non-stochastic limits has not been included in deriving the air and water effluent concentration limits because non-stochastic effects are presumed not to occur at or below the dose levels established for individual members of the public. For radionuclides, where the non-stochastic limit was governing in deriving the occupational DAC, the stochastic ALI was used in deriving the corresponding airborne effluent limit in Table II of subparagraph (F) of this paragraph. For this reason, the DAC and airborne effluent limits are not always proportional as they were in the previous radiation protection standards.

(iii) The air concentration values listed in Column I of Table II of subparagraph (F) of this paragraph were derived by one of two methods. For those radionuclides for which the stochastic limit is governing, the occupational stochastic inhalation ALI was divided by 2.4 x 10^9 [~~10^9~~], relating the inhalation ALI to the DAC, as explained in subparagraph (B)(viii) of this paragraph, and then divided by a factor of 300. The factor of 300 includes the following components:

(I) a factor of 50 to relate the 5 rem [~~rems~~] (0.05 Sv) annual occupational dose limit to the 0.1 rem limit for members of the public;

(II) a factor of 3 to adjust for the difference in exposure time and the inhalation rate for a worker and [~~that for~~] members of the public; and

(III) a factor of 2 to adjust the occupational values, derived for adults, so that they are applicable to other age groups.

(iv) For those radionuclides for which submersion, that is external dose, is limiting, the occupational DAC in Column 3 of Table I of subparagraph (F) of this paragraph was divided by 219. The factor of 219 is composed of a factor of 50, as described in clause (iii) of this subparagraph, and a factor of 4.38 relating occupational exposure for 2,000 hours per year to full-time exposure (8,760 hours per year). Note that an additional factor of two [~~2~~] for age considerations is not warranted in the submersion case.

(v) The water concentrations were derived by taking the most restrictive occupational stochastic oral ingestion ALI and dividing by 7.3 x 10^7 [~~7.3 x 10^2~~]. The factor of 7.3 x 10^7milliliters (mL) [~~(ml)~~] includes the following components:

(I) the factors of 50 and two [~~2~~] described in clause (iii) of this subparagraph; and

(II) a factor of 7.3 x 10^5mL [~~ml~~] which is the annual water intake of Reference Man. [~~"Reference Man."~~]

(vi) Note 2 of subparagraph (F) of this paragraph provides groupings of radionuclides that are applicable to unknown mixtures of radionuclides. These groupings, including occupational inhalation ALIs and DACs, air and water effluent concentrations, and releases to sewer, require demonstrating that the most limiting radionuclides in successive classes are absent. The limit for the unknown mixture is defined when the presence of one of the listed radionuclides cannot be definitively [~~definitely~~] excluded as being present either from knowledge of the radionuclide composition of the source or from actual measurements.

(D) Releases to sewers. The monthly average concentrations for release to sanitary sewerage are applicable to the provisions in subsection (gg) of this section. The concentration values were derived by taking the most restrictive occupational stochastic oral ingestion ALI and dividing by 7.3 x 10^6mL [~~ml~~]. The factor of 7.3 x 10^6ml is composed of a factor of 7.3 x 10^5mL [~~ml~~], the annual water intake by Reference Man, [~~"Reference Man,"~~] and a factor of 10, such that the concentrations, if the sewage released by the licensee is [~~were~~] the only source of water ingested by a Reference Man [~~"Reference Man"~~] during a year, results [~~would result~~] in a committed effective dose equivalent of 0.5 rem.

(E) List of elements.
Figure: 25 TAC §289.202(ggg)(2)(E) (No change.)

(F) Tables--Values for annual limits. The following tables contain values for ALI [~~annual limits on intake (ALI)~~] and DAC [~~derived air concentrations (DAC)~~] of radionuclides for occupational exposure,[~~;~~] effluent concentrations, and[~~;~~] concentrations for release to sanitary sewerage:
Figure: 25 TAC §289.202(ggg)(2)(F)
[~~Figure: 25 TAC §289.202(ggg)(2)(F)~~]

(3) Quantities of licensed material requiring labeling. The following tables contain quantities of licensed material requiring labeling:
Figure: 25 TAC §289.202(ggg)(3) (No change.)

(4) Classification and characteristics of LLRW [~~low-level radioactive waste (LLRW)~~].

(A) Classification of radioactive waste for land disposal.

(i) Considerations. Determination of the classification of LLRW involves two considerations. First, consideration must be given to the concentration of long-lived radionuclides (and their shorter-lived precursors) whose potential hazard persists [~~will persist~~] long after such precautions as institutional controls, improved waste form, and deeper disposal have ceased to be effective. These precautions delay the time when long-lived radionuclides could cause exposures. In addition, the magnitude of the potential dose is limited by the concentration and availability of the radionuclide at the time of exposure. Second, consideration must be given to the concentration of shorter-lived radionuclides for which requirements on institutional controls, waste form, and disposal methods are effective.

(ii) Classes of waste.

(I) Class A waste is waste that is usually segregated from other waste classes at the disposal site. The physical form and characteristics of Class A waste must meet the minimum requirements set forth in subparagraph (B)(i) of this paragraph. If Class A waste also meets the stability requirements set forth in subparagraph (B)(ii) of this paragraph, it is not necessary to segregate the waste for disposal.

(II) Class B waste is waste that must meet more rigorous requirements on waste form to ensure stability after disposal. The physical form and characteristics of Class B waste must meet both the minimum and stability requirements set forth in subparagraph (B) of this paragraph.

(III) Class C waste is waste that not only must meet more rigorous requirements on waste form to ensure stability but also requires additional measures at the disposal facility to protect against inadvertent intrusion. The physical form and characteristics of Class C waste must meet both the minimum and stability requirements set forth in subparagraph (B) of this paragraph.

(iii) Classification determined by long-lived radionuclides. If the radioactive waste contains only radionuclides listed in subclause (V) of this clause, classification must [~~shall~~] be determined as follows.

(I) If the concentration does not exceed 0.1 times the value in subclause (V) of this clause, the waste is Class A.

(II) If the concentration exceeds 0.1 times the value in Table I, but does not exceed the value in subclause (V) of this clause, the waste is Class C.

(III) If the concentration exceeds the value in subclause (V) of this clause, the waste is not generally acceptable for land disposal.

(IV) For wastes containing mixtures of radionuclides listed in subclause (V) of this clause, the total concentration must [~~shall~~] be determined by the sum of fractions rule described in clause (vii) of this subparagraph.

(V) Classification table for long-lived radionuclides.
Figure: 25 TAC §289.202(ggg)(4)(A)(iii)(V) (No change.)

(iv) Classification determined by short-lived radionuclides. If the waste does not contain any of the radionuclides listed in clause (iii)(V) of this subparagraph, classification must [~~shall~~] be determined based on the concentrations shown in subclause (VI) of this clause. As [~~However, as~~] specified in clause (vi) of this subparagraph, if radioactive waste does not contain any nuclides listed in either clause (iii)(V) of this subparagraph or subclause (VI) of this clause, it is Class A.

(I) If the concentration does not exceed the value in Column 1 of subclause (VI) of this clause, the waste is Class A.

(II) If the concentration exceeds the value in Column 1 of subclause (VI) of this clause but does not exceed the value in Column 2 of subclause (VI) of this clause, the waste is Class B.

(III) If the concentration exceeds the value in Column 2 of subclause (VI) of this clause but does not exceed the value in Column 3 of subclause (VI) of this clause, the waste is Class C.

(IV) If the concentration exceeds the value in Column 3 of subclause (VI) of this clause, the waste is not generally acceptable for near-surface disposal.

(V) For wastes containing mixtures of the radionuclides listed in subclause (VI) of this clause, the total concentration must [~~shall~~] be determined by the sum of fractions rule described in clause (vii) of this subparagraph.

(VI) Classification table for short-lived radionuclides.

Figure: 25 TAC §289.202(ggg)(4)(A)(iv)(VI) (No change.)

(v) Classification determined by both long and short-lived radionuclides. If the radioactive waste contains a mixture of radionuclides, some of which are listed in clause (iii)(V) of this subparagraph and some of which are listed in clause (iv)(VI) of this subparagraph, classification must [~~shall~~] be determined as follows.

(I) If the concentration of a radionuclide listed in clause (iii)(V) of this subparagraph is less than 0.1 times the value listed in clause (iii)(V) of this subparagraph, the class must [~~shall~~] be that determined by the concentration of radionuclides listed in clause (iv)(VI) of this subparagraph.

(II) If the concentration of a radionuclide listed in clause (iii)(V) of this subparagraph exceeds 0.1 times the value listed in clause (iii)(V) of this subparagraph, but does not exceed the value listed in clause (iii)(V) of this subparagraph, the waste is [~~shall be~~] Class C, provided the concentration of radionuclides listed in clause (iv)(VI) of this subparagraph does not exceed the value shown in Column 3 of clause (iv)(VI) of this subparagraph.

(vi) Classification of wastes with radionuclides other than those listed in clauses (iii)(V) and (iv)(VI) of this subparagraph. If the waste does not contain any radionuclides listed in either clause [~~clauses~~] (iii)(V) or [~~and~~] (iv)(VI) of this subparagraph, it is Class A.

(vii) The sum of the fractions rule for mixtures of radionuclides. When [~~For~~] determining classification for waste containing [~~that contains~~] a mixture of radionuclides, it is necessary to determine the sum of fractions by dividing each radionuclide's concentration by the appropriate limit and adding the resulting values. The appropriate limits must [~~shall~~] all be taken from the same column of the same table. The sum of the fractions for the column must [~~shall~~] be less than 1.0 if the waste class is to be determined by that column. Example: A waste contains strontium-90 (Sr-90) [~~Sr-90~~] in a concentration of 50 curies per cubic meter (Ci/m^3(1.85 terabecquerels per cubic meter (TBq/m^3) [~~(TBq/m^3)~~]) and cesium-137 (Cs-137) [~~Cs-137~~] in a concentration of 22 Ci/m^3(814 gigabecquerels per cubic meter (GBq/m^3) [~~(GBq/m^3)~~]). Since the concentrations both exceed the values in Column 1 of clause (iv)(VI) of this subparagraph, they must [~~shall~~] be compared to Column 2 values. For Sr-90 fraction, 50/150 = 0.33, for Cs-137 fraction, 22/44 = 0.5; the sum of the fractions = 0.83. Since the sum is less than 1.0, the waste is Class B.

(viii) Determination of concentrations in wastes. The concentration of a radionuclide may be determined by indirect methods such as use of scaling factors, which relate the inferred concentration of one radionuclide to another that is measured, or radionuclide material accountability, if there is reasonable assurance [~~that~~] the indirect methods can be correlated with actual measurements. The concentration of a radionuclide may be averaged over the volume of the waste, or weight of the waste if the units are expressed as nanocurie (becquerel) per gram.

(B) Radioactive waste characteristics.

(i) The following are minimum requirements for all classes of waste and are intended to facilitate handling and provide health and safety protections [~~protection of health and safety~~] of personnel at the disposal site.

(I) Wastes must [~~shall~~] be packaged in conformance with the conditions of the license issued to the site operator where [~~to which~~] the waste will be shipped. Where the conditions of the site license are more restrictive than the provisions of this section, the site license conditions [~~shall~~] govern.

(II) Wastes must [~~shall~~] not be packaged for disposal in cardboard or fiberboard boxes.

(III) Liquid waste must [~~shall~~] be packaged in sufficient absorbent material to absorb twice the volume of the liquid.

(IV) Solid waste containing liquid must [~~shall~~] contain as little free-standing and non-corrosive liquid as is reasonably achievable. The liquid must not [~~, but in no case shall the liquid~~] exceed 1 percent [~~1.0%~~] of the volume.

(V) Waste must [~~shall~~] not be readily capable of detonation or of explosive decomposition or reaction at normal pressures and temperatures, or of explosive reaction with water.

(VI) Waste must [~~shall~~] not contain, or be capable of generating, quantities of toxic gases, vapors, or fumes harmful to persons transporting, handling, or disposing of the waste. This does not apply to radioactive gaseous waste packaged as specified in [~~accordance with~~] subclause (VIII) of this clause.

(VII) Waste must not be pyrophoric. Pyrophoric materials contained in wastes must [~~shall~~] be treated, prepared, and packaged to be nonflammable.

(VIII) Wastes in a gaseous form must [~~shall~~] be packaged at an absolute pressure that does not exceed 1.5 atmospheres at 20 degrees Celsius. Total activity must [~~shall~~] not exceed 100 Ci (3.7 TBq [~~terabecquerels (TBq)~~]) per container.

(IX) Wastes containing hazardous, biological, pathogenic, or infectious material must [~~shall~~] be treated to reduce, to the maximum extent practicable, the potential hazard from the non-radiological materials.

(ii) The following requirements are intended to provide stability of the waste. Stability is intended to ensure that the waste does not degrade and affect overall stability of the site through slumping, collapse, or other failure of the disposal unit and thereby lead to water infiltration. Stability is also a factor in limiting exposure to an inadvertent intruder[~~,~~] since it provides a recognizable and non-dispersible [~~nondispersible~~] waste.

(I) Waste must [~~shall~~] have structural stability. A structurally stable waste form [~~will~~] generally maintains [~~maintain~~] its physical dimensions and its form[~~,~~] under the expected disposal conditions such as weight of overburden and compaction equipment, the presence of moisture, [~~and~~] microbial activity, and internal factors such as radiation effects and chemical changes. Structural stability can be provided by the waste form itself, processing the waste to a stable form, or placing the waste in a disposal container or structure that provides stability after disposal.

(II) Notwithstanding the provisions in clause (i)(III) and (IV) of this subparagraph, liquid wastes, or wastes contain-

ing liquid, must [~~shall~~] be converted into a form that contains as little free-standing and non-corrosive liquid as is reasonably achievable. The liquid must not[~~, but in no case shall the liquid~~] exceed 1 percent [~~1.0%~~] of the volume of the waste when the waste is in a disposal container designed to ensure stability, or 0.5 percent [~~0.5%~~] of the volume of the waste for waste processed to a stable form.

(III) Void spaces within the waste and between the waste and its package must [~~shall~~] be reduced to the extent practicable.

(C) Labeling. Each package of waste must [~~shall~~] be clearly labeled to identify whether it is Class A, Class B, or Class C waste, as specified in [~~accordance with~~] subparagraph (A) of this paragraph.

(5) Time requirements for record keeping.
Figure: 25 TAC §289.202(ggg)(5)
[~~Figure: 25 TAC §289.202(ggg)(5)~~]

(6) Acceptable surface contamination levels (per 100 cm^2).
Figure: 25 TAC §289.202(ggg)(6)
[~~Figure: 25 TAC §289.202(ggg)(6)~~]

(7) Concentration and activity limits of nuclides for disposal in a Type I municipal solid waste site or a hazardous waste facility (for use in subsection (fff) of this section). The following table contains concentration and activity limits of nuclides for disposal in a Type I municipal solid waste site or a hazardous waste facility.
Figure: 25 TAC §289.202(ggg)(7) (No change.)

(8) Cumulative occupational exposure form. RC Form 202-2, found in the attached graphic, Figure: 25 TAC §289.202(ggg)(8), or other equivalent clear and legible record of all the required information [~~required on that form~~], must be used to document cumulative occupational exposure history:
Figure: 25 TAC §289.202(ggg)(8) (No change.)

(9) Occupational exposure form. RC Form 202-3, found in the attached graphic, Figure: 25 TAC §289.202(ggg)(9), or other equivalent clear and legible record of all the required information [~~required on that form~~], must be used to document occupational exposure record for a monitoring period:
Figure: 25 TAC §289.202(ggg)(9) (No change.)

(hhh) Requirements for nationally tracked sources.

(1) Reports of transactions involving nationally tracked sources. Each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source must [~~shall~~] complete and submit to NRC a National Source Tracking Transaction Report as specified in the following subparagraphs for each type of transaction.

(A) Each licensee who manufactures a nationally tracked source must [~~shall~~] complete and submit to NRC a National Source Tracking Transaction Report. The report must [~~shall~~] include [~~the following information~~]:

(i) the name, address, and license number of the reporting licensee;

(ii) the name of the individual preparing the report;

(iii) the manufacturer, model, and serial number of the source;

(iv) the radioactive material in the source;

(v) the initial source strength in curies (becquerels) [~~becquerels (curies)~~] at the time of manufacture; and

(vi) the manufacture date of the source.

(B) Each licensee that transfers a nationally tracked source to another person must [~~shall~~] complete and submit to NRC a National Source Tracking Transaction Report. A source transfer transaction does not include transfers to a temporary domestic job site. Domestic transactions in which the nationally tracked source remains in the possession of the licensee do not require a report to the National Source Tracking System. The report must [~~shall~~] include [~~the following information~~]:

(i) the name, address, and license number of the reporting licensee;

(ii) the name of the individual preparing the report;

(iii) the name and license number of the recipient facility and the shipping address;

(iv) the manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(v) the radioactive material in the source;

(vi) the initial or current source strength in curies (becquerels) [~~becquerels (curies)~~];

(vii) the date for which the source strength is reported;

(viii) the shipping date;

(ix) the estimated arrival date; and

(x) for nationally tracked sources transferred as waste under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification [~~of the container with the nationally tracked source~~].

(C) Each licensee that receives a nationally tracked source must [~~shall~~] complete and submit to NRC a National Source Tracking Transaction Report. The report must [~~shall~~] include [~~the following information~~]:

(i) the name, address, and license number of the reporting licensee;

(ii) the name of the individual preparing the report;

(iii) the name, address, and license number of the person that provided the source;

(iv) the manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(v) the radioactive material in the source;

(vi) the initial or current source strength in curies (becquerels) [~~becquerels (curies)~~];

(vii) the date for which the source strength is reported;

(viii) the date of receipt; and

(ix) for material received under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification [~~with the nationally tracked source~~].

(D) Each licensee that disassembles a nationally tracked source must [~~shall~~] complete and submit to NRC a National Source Tracking Transaction Report. The report must [~~shall~~] include [~~the following information~~]:

(i) the name, address, and license number of the reporting licensee;

(ii) the name of the individual preparing the report;

(iii) the manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(iv) the radioactive material in the source;

(v) the initial or current source strength in curies (becquerels) [~~becquerels~~ ~~(curies)~~];

(vi) the date for which the source strength is reported; and

(vii) the disassemble date of the source.

(E) Each licensee disposing [~~who disposes of~~] a nationally tracked source must [~~shall~~] complete and submit to NRC a National Source Tracking Transaction Report. The report must [~~shall~~] include [~~the following information~~]:

(i) the name, address, and license number of the reporting licensee;

(ii) the name of the individual preparing the report;

(iii) the waste manifest number;

(iv) the container identification [~~with the nationally tracked source~~];

(v) the date of disposal; and

(vi) the method of disposal.

(F) The reports discussed in subparagraphs (A) - (E) of this paragraph must [~~shall~~] be submitted to NRC by the close of the next business day after the transaction. A single report may be submitted for multiple sources and transactions. The reports must [~~shall~~] be submitted to the National Source Tracking System by using the following:

(i) the on-line National Source Tracking System;

(ii) electronically, using a computer-readable format;

(iii) by other electronic media transmission [~~facsimile~~];

(iv) by mail to the address on the National Source Tracking Transaction Report Form (NRC Form 748); or

(v) by telephone with follow-up by other electronic media transmission [~~facsimile~~] or mail.

(G) Each licensee must [~~shall~~] correct any error in previously filed reports or file a new report for any missed transaction within five [~~5~~] business days of the discovery of the error or missed transaction. Such errors may be detected by a variety of methods such as administrative reviews or by physical inventories required by regulation. In addition, each licensee must [~~shall~~] reconcile the inventory of nationally tracked sources possessed by the licensee against that licensee's data in the National Source Tracking System. The reconciliation must [~~shall~~] be conducted during the month of January [~~in~~] each year. The reconciliation process must [~~shall~~] include resolving any discrepancies between the National Source Tracking System and the actual inventory by filing the reports identified by subparagraphs (A) - (E) of this paragraph. By January 31 of each year, each licensee must [~~shall~~] submit to the National Source Tracking System confirmation [~~that~~] the data in the National Source Tracking System is correct.

[~~(H) Each licensee that possesses Category 1 or Category 2 nationally tracked sources listed in paragraph (2) of this subsection shall report its initial inventory of Category 1 or Category 2 nationally tracked sources to the National Source Tracking System by January 31, 2009. The information may be submitted to NRC by using any of the methods identified by subparagraph (F)(i) - (iv) of this paragraph. The initial inventory report shall include the following information:~~]

[~~*(i)* the name, address, and license number of the reporting licensee;~~]

[~~*(ii)* the name of the individual preparing the report;~~]

[~~*(iii)* the manufacturer, model, and serial number of each nationally tracked source or, if not available, other information to uniquely identify the source;~~]

[~~*(iv)* the radioactive material in the sealed source;~~]

[~~*(v)* the initial or current source strength in becquerels (curies); and~~]

[~~*(vi)* the date for which the source strength is reported.~~]

(2) Nationally tracked source thresholds. The TBq [~~Terabecquerel (TBq)~~] values are the regulatory standards. The Ci [~~curie (Ci)~~] values specified are obtained by converting from the TBq value. The Ci [~~curie~~] values are provided for practical usefulness only and are rounded after conversion.
Figure: 25 TAC §289.202(hhh)(2) (No change.)

(3) Serialization of nationally tracked sources. Each licensee who manufactures a nationally tracked source after February 6, 2007 must [~~, shall~~] assign a unique serial number to each nationally tracked source. Serial numbers must [~~shall~~] be composed only of alpha-numeric characters.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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Department of State Health Services
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SUBCHAPTER F. LICENSE REGULATIONS

25 TAC §§289.253, 289.255 - 289.258

STATUTORY AUTHORITY

The amendments are authorized by Texas Health and Safety Code Chapter 401 (the Texas Radiation Control Act), which provides for DSHS radiation control rules and regulatory program to be compatible with federal standards and regulation; §401.051, which provides the required authority to adopt rules and guidelines relating to the control of sources of radiation; §401.052, which provides authority for rules providing for transportation and routing of radioactive material and waste in Texas; §401.103, which provides authority for licensing and registration for transportation of sources of radiation; §401.104 which provides for rulemaking authority for general or specific licensing of radioac-

tive material and devices or equipment using radioactive material; §401.224, which provides rulemaking authority relating to the packaging of radioactive waste; Chapter 401, Subchapter J, which authorizes enforcement of the Act; Texas Government Code §531.0055; and Texas Health and Safety Code §1001.075, which authorizes the Executive Commissioner of HHSC to adopt rules and policies for the operation and provision of health and human services by DSHS and for the administration of Texas Health and Safety Code Chapter 1001. The amendments also implement Texas Health and Safety Code Chapters 401 and 1001, and Texas Government Code Chapter 531.

§289.253. Radiation Safety Requirements for Well Logging Service Operations and Tracer Studies.

(a) Purpose. This section establishes radiation safety requirements for persons using sources of radiation for well logging service operations, including radioactive markers, mineral exploration, and tracer studies.

(b) Scope.

(1) This section applies to all persons who use sources of radiation for well logging service operations, radioactive markers, mineral exploration, and tracer studies.

(2) In addition to the requirements of this section, persons are subject to the requirements of:

(A) §289.201 of this chapter (relating to General Provisions for Radioactive Material);

(B) §289.202 of this chapter (relating to Standards for Protection Against Radiation from Radioactive Materials);

(C) §289.203 of this chapter (relating to Notices, Instructions, and Reports to Workers; Inspections);

(D) §289.204 of this chapter (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services);

(E) §289.205 of this chapter (relating to Hearing and Enforcement Procedures);

(F) §289.226 of this chapter (relating to Registration of Radiation Machine Use and Services);

(G) §289.229 of this chapter (relating to Radiation Safety Requirements for Accelerators, Therapeutic Radiation Machines, Simulators, and Electronic Brachytherapy Devices);

(H) §289.231 of this chapter (relating to General Provisions and Standards for Protection Against Machine-Produced Radiation);

(I) §289.252 of this subchapter (relating to Licensing of Radioactive Material); and

(J) §289.257 of this subchapter (relating to Packaging and Transportation of Radioactive Material).

[~~(b) Scope. This section applies to all persons who use sources of radiation for well logging service operations, radioactive markers, mineral exploration, and tracer studies. In addition to the requirements of this section, persons are subject to the requirements of §289.201 of this title (relating to General Provisions for Radioactive Material), §289.202 of this title (relating to Standards for Protection Against Radiation from Radioactive Materials), §289.203 of this title (relating to Notices, Instructions, and Reports to Workers; Inspections), §289.204 of this title (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services), §289.205 of this title (relating to Hearing and Enforcement Procedures), §289.226 of this title (relating to Registration of Radiation Machine Use and Services), §289.229 of this title (relating to Radiation Safety Requirements for Accelerators, Therapeutic Radiation Machines, Simulators, and Electronic Brachytherapy Devices), §289.231 of this title (relating to General Provisions and Standards for Protection Against Machine-Produced Radiation), §289.252 of this title (relating to Licensing of Radioactive Material), and §289.257 of this title (relating to Packaging and Transportation of Radioactive Material).~~]

(c) Definitions. The following words and terms when used in this section [~~shall~~] have the following meaning unless the context clearly indicates otherwise.

(1) Energy compensation source (ECS)--A small, sealed source with an activity not exceeding 100 microcuries (Ci) (3.7 megabecquerel (MBq)), used within a logging tool or other tool component, to provide a reference standard to maintain the tool's calibration when in use.

(2) Field station (additional authorized use/storage location)--A facility where sources of radiation may be stored or used and from which equipment is dispatched to temporary job sites.

(3) Injection tool--A device used for subsurface or downhole controlled injection of radioactive tracer material.

(4) Logging assistant (equipment operator)--Any individual who, under the personal supervision of a logging supervisor, handles sealed sources or tracers that are not in logging tools or shipping containers or who performs surveys required by subsection (bb) of this section.

(5) Logging supervisor (field engineer)--The individual who provides personal supervision of the use of sources of radiation at temporary job sites.

(6) Logging tool--A device used subsurface to perform well logging.

(7) Mineral logging--Any logging performed for the purpose of mineral exploration other than oil or gas.

(8) Personal supervision--Guidance and instruction by the supervisor, who is physically present at the job site and in such proximity that visual contact can be maintained and immediate assistance given as required.

(9) Radiation safety officer--An individual named by the licensee or registrant and listed on the license or certificate of registration having [~~who has a~~] knowledge of, responsibility for, and authority to enforce appropriate radiation protection rules, standards, and practices on behalf of the licensee or [~~and/or~~] registrant, and who meets the requirements of subsection (s) of this section.

(10) Radioactive marker--Radioactive material placed subsurface or upon a structure intended for subsurface use for the purpose of depth determination or direction orientation.

(11) Residential location--Any area where a structure or structures are located, in which people [~~lodge or~~] live [~~are located~~], and the grounds on which these structures are located, including [~~, but not limited to,~~] houses, apartments, condominiums, and garages.

(12) Screenout--A situation in which radioactive tracer material is reversed out of an oil or gas well (well returns).

(13) Service company--Any contracted or subcontracted company that is present at the temporary job site[~~,~~] specifically, a [~~that~~] company whose equipment is connected to [~~which the~~] licensee's equipment [~~is connected~~] and [~~that is~~] exposed to radioactive material.

(14) Source holder--A housing or assembly into which a radioactive source is placed for the purpose of facilitating the handling and use of the source.

(15) Storage container--A container used to secure and store radioactive sources [~~designed to provide radiation safety and security when sources of radiation are being stored~~].

(16) Temporary job site--A location where well logging or tracer studies are performed other than the specific locations [~~location(s)~~] listed on a license or certificate of registration.

(17) Tracer study--The release of a substance tagged with radioactive material for the purpose of tracing the movement or position of the tagged substance in the wellbore, at the wellhead, or adjacent formation.

(18) Transport container--A container that meets the requirements of the United States Department of Transportation (DOT) and is designed to provide radiation safety and security when sources of radiation are being transported.

(19) Tritium neutron generator target source--A tritium source used within a neutron generator tube to produce neutrons for use in well logging applications.

(20) Uranium sinker bar--A weight containing depleted uranium used to aid in the descent of a logging tool down toward the bottom of a wellbore.

(21) Wellbore--A drilled hole in which wireline service operations are performed.

(22) Well logging--All operations involving the lowering and raising of measuring devices or logging tools (that may or may not contain sources of radiation) into wellbores or cavities for the purpose of obtaining information about the well or [~~and/or~~] adjacent formations.

(23) Wireline--An armored steel cable, containing one or more electrical conductors, used to lower and raise logging tools in the wellbore.

(24) Wireline service operation--Any mechanical or electronic service that is performed in the wellbore using devices that are lowered into the well on a wireline for purposes of evaluation.

(d) Specific licenses for well logging.

(1) The applicant must [~~shall~~] satisfy the general requirements specified in this subsection and in §289.252(e) of this subchapter [~~title~~].

(2) The applicant must [~~shall~~] develop a program for training logging supervisors and logging assistants and submit to the department [~~agency~~] a description of this program which specifies [~~the~~]:

(A) initial training;

(B) on-the-job training;

(C) annual safety reviews provided by the licensee;

(D) how [~~means~~] the applicant will [~~use to~~] demonstrate the logging supervisor's knowledge and understanding of and ability to comply with the department's [~~agency's~~] regulations and licensing requirements and the applicant's operating and emergency procedures; and

(E) how [~~means~~] the applicant will [~~use to~~] demonstrate the logging assistant's knowledge and understanding of and ability to comply with the applicant's operating and emergency procedures.

(3) The applicant must [~~shall~~] submit to the department [~~agency~~] written operating and emergency procedures as described in subsection (ee)(4) of this section.

(4) The applicant must [~~shall~~] establish and submit to the department [~~agency~~] its program for annual inspections of the job performance of each logging supervisor to ensure [~~that~~] the department's [~~agency's~~] regulations, license requirements, and the applicant's operating and emergency procedures are followed. Inspection records must be retained for three [~~3~~] years after each annual internal inspection.

(5) The applicant must [~~shall~~] submit a description of its overall organizational structure as it applies to the radiation safety responsibilities in well logging, including specified delegations of authority and responsibility.

(6) If an applicant wants to perform leak testing of sealed sources, the applicant must [~~shall~~] identify the manufacturers and the model numbers of the leak test kits [~~to be~~] used. If the applicant wants to analyze its own wipe samples, the applicant must [~~shall~~] establish procedures to follow [~~be followed~~] and submit a description of these procedures to the department [~~agency~~]. The description must include the:

(A) instruments [~~to be~~] used;

(B) methods of performing the analysis; and

(C) pertinent experience of the person who will analyze the wipe samples.

(e) Prohibitions.

(1) Licensees must not [~~No licensee shall~~] perform well logging service operations with a sealed source [~~source(s)~~] in any well or wellbore unless, before [~~prior to~~] commencement of the operation, the licensee has a written agreement with the well operator, well owner, drilling contractor, or land owner, that specifies who will be responsible for ensuring [~~the following requirements are met~~]:

(A) a reasonable effort at recovery will be made in the event a sealed source is lost or lodged downhole;

(B) a person does [~~shall~~] not attempt to recover a sealed source in a manner that, in the licensee's opinion, could result in a source rupture;

(C) if [~~in the event~~] the environment, any equipment, or personnel are contaminated with radioactive material, decontamination to levels specified in §289.202(f), (n), and (eee) of this chapter are [~~title shall be~~] performed; and

(D) the requirements of subsection (dd)(4) of this section are [~~shall be~~] met if [~~in the event~~] a decision is made to abandon the sealed source downhole.

(2) Licensees must not [~~No licensee shall~~] perform tracer study operations with a substance tagged with radioactive material in any well or wellbore unless, before [~~prior to~~] commencement of the operation, the licensee has a written agreement with the well operator, well owner, drilling contractor, or land owner, and the service company to which the licensee's equipment is connected, as applicable, specifying [~~that specifies~~] who is [~~will be~~] responsible for ensuring [~~the following requirements are met~~]:

(A) in the event the service company's personnel or equipment are contaminated with radioactive material, they will [~~shall~~] be decontaminated as specified in [~~accordance with~~] §289.202(n) or (ddd) of this chapter [~~title~~] before release from the job site or release for unrestricted use, respectively;

(B) in the event the well head or job site is contaminated with radioactive material, it will [~~shall~~] be decontaminated as specified in [~~accordance with~~] §289.202(ddd) of this chapter [~~title~~]; and

(C) in the event radioactive material is [~~to be~~] reversed from the well or the well screens out, the licensee will [~~shall~~] have established procedures and equipment or facilities to [~~do the following~~]:

(i) reverse material into a preconstructed steel or lined pit that is specifically established in the event of a screen out; or

(ii) reverse material into a suitable transport container or containers [~~container(s)~~] in the event of a screen out.

(3) The licensee must [~~shall~~] maintain, as specified in [~~accordance with~~] subsection (ee)(5) of this section, a copy of the written agreement specified in paragraph (1) or (2) of this subsection.

(f) Limits on levels of radiation. Sources of radiation must [~~shall~~] be used, stored, and transported in such a manner that the requirements of §289.202 of this chapter [~~title~~], §289.231 of this chapter [~~title~~], and §289.257 of this subchapter [~~title~~], as applicable, are met.

(g) Storage precautions.

(1) Each source of radiation, except accelerators, must [~~shall~~] be provided with a storage or [~~and/or~~] transport container. Each container must [~~shall~~] have a lock (or tamper seal for calibration sources) to prevent unauthorized removal of, or exposure to, the source of radiation.

(2) Each area or room in which sources of radiation are stored must [~~shall~~] be posted as specified in [~~accordance with~~] §289.202(aa)(5) or §289.231(x) of this chapter [~~title~~], as applicable.

(3) Sources of radiation, except accelerators, must [~~shall~~] be stored downhole or in a bunker [~~in order~~] to minimize the danger from explosion or [~~and/or~~] fire.

(4) Sources of radiation may not be stored in residential locations unless specifically authorized by the department. [~~This section does not apply to storage of radioactive material in a vehicle in transit for use at temporary job sites, if the licensee complies with subsection (bb)(2) of this section.~~]

(5) Sources of radiation in storage must [~~shall~~] be secured to prevent tampering[~~,~~] or removal by unauthorized individuals.

(h) Transport precautions. Transport containers must [~~shall~~] be locked and physically secured to the transporting vehicle to prevent shifting during transport, accidental loss, tampering, or unauthorized removal.

(i) Radiation survey instruments.

(1) The licensee or registrant must [~~shall~~] maintain a sufficient number of calibrated and operable radiation survey instruments capable of detecting beta and gamma radiation at each location where sources of radiation are stored or used to make physical radiation surveys, as required by this section and by §289.202(p) or §289.231(s)[~~,~~] of this chapter [~~title~~], as applicable. Instrumentation must [~~shall~~] be capable of measuring 0.1 milliroentgen per hour (mR/hr) (1 microsievert per hour (Sv/hr)) through at least 50 mR/hr (500 Sv/hr). (Instrumentation capable of measuring 0.1 mR/hr (1 Sv/hr) through 50 mR/hr (500 Sv/hr) may not be sufficient to determine compliance with DOT requirements.)

(2) A licensee using tracer material must [~~shall~~] have available at each additional authorized use/storage location and temporary job site, additional calibrated and operable radiation survey instruments sensitive enough to detect the radioactive surface contamination limits specified in §289.202(eee) of this chapter [~~title~~].

(3) Each radiation survey instrument required under paragraph (1) of this subsection must [~~capable of detecting beta and gamma radiation shall~~] be calibrated:

(A) by a person specifically licensed or registered by the department [~~agency~~], another agreement state, or the United States Nuclear Regulatory Commission (NRC) to perform such service;

(B) at intervals not to exceed six months and after each survey instrument repair;

(C) for the types of radiation used and at energies appropriate for use; and

(D) at an accuracy within plus or minus 20 percent [~~±20%~~] of the true radiation level at each calibration point.

(4) The licensee or registrant must [~~shall~~] maintain calibration records as specified in [~~accordance with~~] subsection (ee)(5) of this section.

(j) Leak testing of sealed sources.

(1) Testing and record keeping. Sealed sources must [~~shall~~] be tested for leakage and contamination as specified in [~~accordance with~~] this section and §289.201(g) of this chapter [~~title~~]. The licensee must [~~shall~~] maintain records of leak tests as specified in [~~accordance with~~] subsection (ee)(5) of this section.

(2) Each energy compensation source that is not exempt from testing as specified in [~~accordance with~~] §289.201(g)(2) of this chapter must [~~title shall~~] be tested at intervals not to exceed three years. In the absence of a certificate from a transferor that a test has been made within the three years before the transfer, the energy compensation source must [~~may~~] not be used until tested as specified in [~~accordance with~~] §289.201(g) of this chapter [~~title~~].

(3) If a sealed source is found to be leaking as specified in [~~accordance with~~] §289.201(g) of this chapter [~~title~~], the licensee must [~~shall~~] check the equipment associated with the leaking source for radioactive contamination and, if contaminated, have it decontaminated or disposed of by persons specifically authorized by the department [~~agency~~], the NRC, or an agreement state, to perform such services.

(k) Quarterly inventory. Each licensee or registrant must [~~shall~~] conduct a physical inventory to account for all sources of radiation received or possessed at intervals not to exceed three months. The licensee or registrant must [~~shall~~] make and maintain records of inventories as specified in [~~accordance with~~] subsection (ee)(5) of this section and must [~~shall~~] include [~~the following~~]:

(1) the quantities and kinds of sources of radiation;

(2) the location where sources of radiation are assigned;

(3) the [~~a~~] unique identification of each source of radiation;

(4) the date of the inventory; and

(5) the name of the individual conducting the inventory.

(l) Utilization records. For each source of radiation, utilization [~~Utilization~~] records must [~~shall~~] be maintained by each licensee or registrant as specified in [~~accordance with~~] subsection (ee)(5) of this section and must [~~shall~~] include [~~the following information for each source of radiation~~]:

(1) identification of each source of radiation, including [~~to include~~]:

(A) the make and model number or [~~and/or~~] serial number (or if absent, a description) of each sealed source used; or

(B) the radionuclide and activity of tracer materials and radioactive markers used at a particular well site and the disposition of any unused tracer materials.

(2) the identity of the logging supervisor or individual who is responsible for receiving sources of radiation, to whom assigned; and

(3) the locations where used and dates of use.

(m) Design and performance criteria for sealed sources used in well logging operations.

(1) Each sealed source used in well logging applications must [~~shall~~] meet the following minimum criteria.

(A) The sealed source is of doubly encapsulated construction.

(B) The sealed source contains radioactive material with a chemical/physical form as insoluble and non-dispersible [~~nondispersible~~] as practicable.

(C) The sealed source meets one of the following requirements:

(i) for a sealed source manufactured on or before July 14, 1989, the requirements from the United States of America Standards Institute (USASI) N5.10-1968, "Classification of Sealed Radioactive Sources," or the requirements in clause (ii) or (iii) of this subparagraph;

(ii) for a sealed source manufactured after July 14, 1989, the oil-well logging requirements from the American National Standards Institute/Health Physics Society (ANSI/HPS) N43.6-1997, "Sealed Radioactive Sources-Classification;" or

(iii) for a sealed source manufactured after July 14, 1989, the sealed source's prototype has been tested and found to maintain its integrity after each of the following tests:

(I) Temperature. The test source must [~~shall~~] be held at negative 40 [~~-40~~] degrees Celsius for 20 minutes, 600 degrees Celsius for one hour, and then be subjected to a thermal shock test with a temperature drop from 600 degrees Celsius to 20 degrees Celsius within 15 seconds.

(II) Impact. A 5 kilogram (kg) steel hammer, 2.5 centimeters (cm) in diameter, must [~~shall~~] be dropped from a height of 1 meter (m) onto the test source.

(III) Vibration. The test source must [~~shall~~] be subjected to a vibration from 25 Hertz (Hz) to 500 Hz with a peak amplitude of five times the acceleration of gravity for 30 minutes.

(IV) Puncture. A 1 gram (g) [~~(gm)~~] hammer and pin, 0.3 cm pin diameter, must [~~shall~~] be dropped from a height of 1 m onto the test source.

(V) Pressure. The test source must [~~shall~~] be subjected to an external pressure of 24,600 pounds per square inch absolute (1.695×10^7 pascals) [~~(1.695 x 107 pascals)~~] without leakage.

(2) The requirements in paragraph (1) of this subsection do not apply to sealed sources containing [~~that contain~~] radioactive material in gaseous form.

(3) The requirements in this subsection do not apply to energy compensation sources.

(n) Labeling.

(1) Each source, source holder, or logging tool containing radioactive material in other than an exempt quantity must[~~, shall~~] bear a durable, legible, and clearly visible marking or label, including [~~that has~~], as a minimum, the standard radiation caution symbol with no color requirement, and the wording DANGER (or CAUTION), RADIOACTIVE--DO NOT HANDLE, NOTIFY CIVIL AUTHORITIES (OR NAME OF COMPANY).

(2) The labeling specified in paragraph (1) of this subsection must [~~shall~~] be on the smallest component, source, source holder, or logging tool that is transported as a separate piece of equipment.

(3) Each transport container must [~~shall~~] have permanently attached [~~to it~~] a durable, legible, and clearly visible label having [~~that has~~], as a minimum, the standard radiation caution symbol and the wording DANGER (or CAUTION), RADIOACTIVE, NOTIFY CIVIL AUTHORITIES (OR NAME OF COMPANY).

(4) Each transport container must [~~shall~~] have attached [~~to it~~] a durable, legible, and clearly visible label having [~~label(s) that has~~], at [~~as~~] a minimum, the licensee's name, address, and telephone number, the radionuclide, its activity, and assay date.

(o) Inspection and maintenance.

(1) Each licensee or registrant must [~~shall~~] conduct, at intervals not to exceed six months, a program of visual inspection and maintenance of source holders (or sealed source, if there is no source holder), logging tools, source handling tools, storage containers, transport containers, and injection tools to assure proper labeling and physical condition. The inspection program may be performed concurrently with routine leak testing of sealed sources. Records of inspection and maintenance must [~~shall~~] be made and maintained by the licensee or registrant as specified in [~~accordance with~~] subsection (ee)(5) of this section.

(2) If any inspection conducted as specified in [~~accordance with~~] paragraph (1) of this subsection reveals damage to labeling or components critical to radiation safety, the device must [~~shall~~] be removed from service at the time the damage is discovered and until repairs have been made.

(3) Any operation, such as drilling, cutting, or chiseling on a source holder containing a sealed source, must [~~shall~~] be performed on the source holder only by persons specifically licensed to do so by the department [~~agency~~], another agreement state, or the NRC. The provisions of this paragraph do not apply to logging tool recovery (fishing) operations conducted as specified in [~~accordance with~~] the provisions of subsection (dd)(4) of this section.

(4) The repair, opening, or modification of any sealed source must [~~shall~~] be performed only by persons specifically licensed to do so by the department [~~agency~~], another agreement [~~or licensing~~] state, or the NRC.

(p) Training requirements.

(1) Licensees or registrants must not [~~No licensee or registrant shall~~] permit any individual to act as a logging supervisor until such individual has [~~met the following requirements~~]:

(A) [~~successfully~~] completed [~~an agency-accepted course or~~] a course [~~recognized by another agreement state, or the NRC,~~] including at least 24 hours of formal training in the subjects outlined in subsection (ee)(1) of this section;

(B) received copies of and instruction in [~~the following~~]:

(i) the requirements contained in this section and the applicable subsections of §§289.201, 289.202, 289.203, and 289.231 of this chapter [~~title~~] or their equivalent;

(ii) the conditions of the appropriate license or certificate of registration; and

(iii) the licensee's or registrant's operating, safety, and emergency procedures;

(C) demonstrated understanding of the requirements in subparagraphs (A) and (B) of this paragraph by successfully completing a written examination administered by the licensee or registrant;

(D) completed two months of on-the-job training under the supervision of a logging supervisor; and

(E) demonstrated, through a field evaluation, competence in the use of sources of radiation, related handling tools, and the type of radiation survey instruments that will be used in the job assignment.

(2) Licensees or registrants must not [~~No licensee or registrant shall~~] permit any individual to act as a logging assistant until such individual has [~~met the following requirements~~]:

(A) received copies of and instruction in the applicable subsections of §§289.201, 289.202, 289.203, and 289.231 of this chapter [~~title~~] or their equivalent, and the licensee's or registrant's operating, safety, and emergency procedures;

(B) demonstrated understanding of the requirements in subparagraph (A) of this paragraph by successfully completing a written examination administered by the licensee or registrant; and

(C) demonstrated competence to use, under the personal supervision of the logging supervisor, the sources of radiation, related handling tools, and radiation survey instruments [~~that will be~~] used in the job assignment.

(3) The licensee or registrant must [~~shall~~] provide an annual radiation safety review for logging supervisors and logging assistants.

(4) Each licensee or registrant must [~~shall~~] maintain records documenting [~~that document that~~] the requirements of paragraphs (1) - (3) of this subsection are met. Such records must [~~shall~~] be maintained as specified in [~~accordance with~~] subsection (ee)(5) of this section.

(q) Operating, safety, and emergency procedures. The licensee or registrant must [~~shall~~] maintain written operating, safety, and emergency procedures that include descriptions of and directions in at least the items listed in subsection (ee)(4) of this section.

(r) Personnel monitoring.

(1) In addition to the requirements of §289.202(p)(4) and (q) of this chapter [~~title~~] or §289.231(n) and (s)(3) of this chapter [~~title~~], as applicable, no licensee or registrant may [~~shall~~] permit any individual to act as a logging supervisor or logging assistant unless that individual wears an individual monitoring device [~~that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor,~~] at all times during well logging service operations or [~~and/or~~] tracer studies utilizing sources of radiation. Each individual monitoring device must [~~shall~~] be assigned to and worn by only one individual. Film badges must [~~shall~~] be replaced at least monthly. Other individual monitoring devices requiring replacement must [~~shall~~] be replaced at least quarterly. After replacement, each individual monitoring device requiring processing must [~~shall~~] be returned to the supplier for processing within 14 calendar days or as soon as practicable. All individual monitoring devices must be evaluated at least quarterly or promptly after replacement, whichever is more frequent. Circumstances preventing meeting these time limits must be documented, and those records must be available for review by the department. [~~In circumstances that make it impossible to return each individual monitoring device to the supplier for processing within 14 calendar days, such circumstances shall be documented and available for review by the agency.~~]

(2) When necessary [~~in order~~] to aid in determining the extent of an individual's intake [~~exposure to concentrations~~] of radioactive material, the department [~~agency~~] may require a licensee or registrant to make available to the individual, appropriate bioassay services and to furnish a copy of the reports of such services to the department [~~agency~~].

(3) Personnel monitoring records must [~~shall~~] be maintained by the licensee or registrant as specified in [~~accordance with~~] subsection (ee)(5) of this section.

(s) Radiation safety officer.

(1) A radiation safety officer (RSO) must [~~shall~~] be designated for every license and certificate of registration issued by the department [~~agency~~].

(2) The RSO's documented qualifications must [~~shall~~] include:

(A) possession of a high school diploma or a certificate of high school equivalency based on the General Education Development (GED) test;

(B) completion of the training and testing requirements of subsection (o)(1) of this section; and

(C) two years of experience as a logging supervisor, including [~~to include~~] knowledge of well logging service operations and tracer studies.

(3) The duties of the RSO include [~~, but are not limited to, the following~~]:

(A) establishing and overseeing operating, safety, [~~and~~] emergency, and as low as reasonably achievable (ALARA) procedures, and reviewing [~~to review~~] them regularly to ensure [~~that~~] the procedures are current and conform with this chapter;

(B) overseeing and approving all phases of the training program for well logging service operations and [~~and/or~~] tracer studies personnel so that appropriate and effective radiation protection practices are taught;

(C) ensuring [~~that~~] required radiation surveys and leak tests are performed and documented as specified in [~~accordance with~~] this chapter, including any corrective measures when levels of radiation exceed established limits;

(D) ensuring [~~that~~] personnel monitoring is used properly by occupationally exposed [~~occupationally-exposed~~] personnel, [~~that~~] records are kept of the monitoring results, and [~~that~~] timely notifications are made, as required by §289.203 of this chapter [~~title~~];

(E) investigating and reporting to the department [~~agency~~] each known or suspected case of radiation exposure to an individual or radiation level detected over the [~~in excess of~~] limits established by this chapter and each theft or loss of each source [~~source(s)~~] of radiation, determining [~~to determine~~] the cause, and taking [~~to take~~] steps to prevent its recurrence;

(F) having a thorough knowledge of management policies and administrative procedures of the licensee or registrant;

(G) assuming control and having the authority to institute corrective actions including shutdown of operations, when necessary in emergency situations or unsafe conditions;

(H) maintaining records as required by this chapter (see subsection (ee)(5) of this section);

(I) ensuring the proper storing, labeling, transport, and use of sources of radiation, storage, and [~~and/or~~] transport containers;

(J) ensuring [~~that~~] inventories are performed as specified in [~~accordance with~~] subsection (k) of this section;

(K) ensuring [~~that~~] personnel are complying with this chapter, the conditions of the license or the registration, and the operating, safety, and emergency procedures of the licensee or registrant; and

(L) serving as the primary contact with the department [~~agency~~].

(t) Security.

(1) A logging supervisor must be physically present at a temporary job site [~~jobsite~~] whenever radioactive material is being handled or is not stored and locked in a vehicle or storage place. The logging supervisor may leave the job site [~~jobsite in order~~] to obtain assistance if a sealed source becomes lodged in a well.

(2) During well logging, except when sealed sources are below ground or in shipping or storage containers, the logging supervisor or other individual designated by the logging supervisor must [~~shall~~] maintain direct surveillance of the operation to prevent unauthorized entry into a restricted area, as defined in §289.201(b) of this chapter [~~title~~], or §289.231(c) of this chapter [~~title~~], as applicable.

(u) Handling tools. The licensee must [~~shall~~] provide and require the use of tools that [~~will~~] assure remote handling of sealed sources, other than low activity calibration sources.

(v) Tracer studies.

(1) Appropriate protective clothing and equipment must [~~shall~~] be used by all personnel handling radioactive tracer material. Precautions must [~~shall~~] be taken to avoid ingestion or inhalation of radioactive material and to avoid contamination of field stations, temporary job sites, vehicles, associated equipment, and clothing.

(2) Licensees may not [~~No licensee shall~~] permit the injection of radioactive material into usable quality groundwater (3,000 parts per million (ppm) total dissolved solids or less) without prior written authorization from the department [~~agency~~].

(3) The well operator must [~~shall~~] contact the licensee when a decision is made to reverse the radioactive tracer material out of a well. The licensee must [~~shall~~] be onsite [~~on site~~] and present at the well when radioactive tracer material is reversed out of a well.

(w) Particle accelerators. Licensees or registrants must not [~~No licensee or registrant shall~~] permit above-ground testing of particle accelerators that results in the production of radiation except in areas or facilities controlled or shielded to meet the requirements of §289.202(f) or (n) of this chapter [~~title~~], or §289.231(m) or (o) of this chapter [~~title~~], as applicable.

(x) Radioactive markers. The licensee may use radioactive markers in wells only if the individual markers contain quantities of radioactive material not exceeding the quantities specified in §289.251(l)(2) of this subchapter (relating to Exemptions, General Licenses, and General License Acknowledgements) [~~title~~]. The use of markers is subject only to the provisions of this subsection and subsection (k) of this section.

(y) Uranium sinker bars. The licensee may use a depleted uranium sinker bar in well logging service operations only if it is legibly impressed with the wording "DANGER (or CAUTION), RADIOACTIVE-DEPLETED URANIUM, NOTIFY CIVIL AUTHORITIES (OR NAME OF COMPANY) IF FOUND."

(z) Energy compensation source (ECS).

(1) The licensee may use an ECS [~~energy compensation source~~] that is contained within a logging tool or other tool components.

(2) For well logging applications with a surface casing for protecting freshwater [~~fresh water~~] aquifers, use of the ECS is only subject to the requirements of subsections (j), (k), and (l) of this section.

(3) For well logging applications without a surface casing for protecting freshwater [~~fresh water~~] aquifers, use of the ECS is only subject to the requirements of subsections (e), (j), (k), (l), (dd), and (ee)(4)(A) [~~(ee)(4) and (dd)~~] of this section.

(aa) Tritium neutron generator target source.

(1) Use of a tritium neutron generator target source, containing quantities not exceeding 30 curies (Ci) (1,110 gigabecquerels (GBq)) and in a well with a surface casing to protect freshwater [~~fresh water~~] aquifers, is subject to the requirements of this section, except subsections (e), (m), and (dd) of this section.

(2) Use of a tritium neutron generator target source, containing quantities exceeding 30 Ci (1,110 GBq) or in a well without a surface casing to protect freshwater [~~fresh water~~] aquifers, is subject to the requirements of this section, except subsection (m) of this section.

(bb) Radiation surveys.

(1) Radiation surveys (and calculations for neutron sources) must [~~shall~~] be made and recorded for each area where radioactive materials are stored.

(2) Radiation surveys (and calculations for neutron sources) of the radiation levels in occupied positions and on the exterior of each vehicle used to transport radioactive materials must [~~shall~~] be made and recorded. Such surveys (and calculations for neutron sources) must [~~shall~~] include all sources of radiation transported in the vehicle.

(3) If the sealed source assembly is removed from the logging tool before departing the job site, a survey of the tool to verify that the logging tool is free of contamination must [~~shall~~] be made and recorded.

(4) If the encapsulation of the sealed source has been damaged by an operation or is likely to have been damaged by an operation, the licensee must [~~shall~~] immediately conduct a radiation survey and make a record of that survey, including a contamination survey, during and after the operation.

(5) Radiation surveys must [~~shall~~] be made and recorded at the job site and [~~and/or~~] well head for each tracer operation except for those utilizing hydrogen-3, carbon-14, sulfur-35, or krypton-85. These surveys must [~~shall~~] include measurements of radiation levels before and after the operation.

(6) Records required as specified in [~~accordance with~~] paragraphs (1) - (5) of this subsection must [~~shall also~~] include the dates, the identification of personnel [~~individual(s)~~] making the survey, the unique identification of survey instruments [~~instrument(s)~~] used, radiation measurements in milliroentgen per hour (mR/hr), calculations in millirem per hour (mrem/hr) or microsievert per hour (Sv/hr) [~~(microsievert per hour (Sv/hr))~~], and an exact description of the location of the survey. Each licensee or registrant must [~~shall~~] make and maintain records of these surveys as specified in [~~accordance with~~] subsection (ee)(5) of this section.

(cc) Records/documents for inspection by the department [agency].

(1) Each licensee or registrant must [shall] maintain the records/documents specified in subsection (ee)(5) of this section [for inspection by the agency].

(2) Each licensee or registrant maintaining additional authorized use/storage locations from which well logging service operations are conducted must [shall] have copies of the records/documents specified in subsection (ee)(5)(B) - (E) and (G) - (O) of this section that are specific to the site, available at each site [for inspection by the agency].

(3) Records/documents required as specified in [accordance with] paragraph (2) of this subsection must [shall] be maintained as specified in [accordance with] subsection (ee)(5) of this section.

(4) Each licensee or registrant conducting well logging service operations at a temporary job site must [shall] have copies of the records/documents specified in subsection (ee)(5)(B), (C), (I), (K), (L), and (N) of this section available at that site [for inspection by the agency].

(5) Records/documents required by paragraph (4) of this subsection must [shall] be maintained at the temporary job site for the period of operation at that site [for inspection by the agency].

(dd) Notification of incidents and lost sources; abandonment procedures for irretrievable sources.

(1) Notification of incidents and sources lost in other than downhole well logging operations must [shall] be made as specified in [accordance with] appropriate provisions of §289.202 of this chapter [title], or §289.231 of this chapter [title], as applicable.

(2) Whenever a sealed source or a device containing radioactive material has been ruptured or is likely to have been ruptured, the licensee must [shall] notify the department [agency] immediately by telephone and submit written notification within 30 days. The written notification must [shall] designate [the following]:

(A) the well or other location;

(B) [a description of] the magnitude and extent of the escape of radioactive material;

(C) [an assessment of] the consequences of the rupture; and

(D) [an explanation of] the efforts planned or being taken to mitigate these consequences.

(3) Whenever a sealed source is separated from the logging tool and is lost downhole, the licensee must [shall] notify the department [agency] immediately by telephone before [prior to] beginning source recovery operations.

(4) Whenever a sealed source or device containing radioactive material is lost downhole, the licensee must [shall do the following]:

(A) consult with the well operator, well owner, drilling contractor, or landowner [land owner] regarding methods to retrieve the source or device that may reduce the likelihood that the source or device will be damaged or ruptured during the logging tool recovery (fishing) operations;

(B) continuously monitor the circulating fluids from the well, if any, during logging tool recovery (fishing) operations to check for contamination resulting from damage to the sealed source with an appropriate radiation detection instrument or a logging tool with a radiation detector [monitor with a radiation survey instrument (or logging tool adjusted to detect gamma emissions from source(s) lost downhole), at the surface for the presence of radioactive contamination during logging tool recovery (fishing) operations]; and

(C) notify the department [agency] immediately by telephone and submit written notification within 30 days if radioactive contamination is detected at the surface or if the source appears to be damaged.

(5) When efforts to recover the radioactive source are not successful, the licensee must [shall do the following]:

(A) notify the department [agency] by telephone of the circumstances that resulted in the inability to retrieve the source and obtain [agency] approval from the department to implement abandonment procedures, or that the licensee implemented abandonment before receiving [agency] approval from the department because the licensee believed there was an immediate threat to public health and safety; and

(B) advise the well operator of the Railroad Commission of Texas requirements regarding abandonment and an appropriate method of abandonment, that includes [shall include the following]:

(i) the immobilization and sealing in place of the radioactive source with a cement plug;

(ii) a means to prevent inadvertent intrusion on the source, such as the setting of a whipstock or other deflection device, unless the source is not accessible to any subsequent drilling operations; and

(iii) the mounting of a permanent identification plaque, containing information required by paragraph (6) of this subsection, at the surface of the well;

(C) notify the department [agency] by telephone, giving the circumstances of the loss; and

(D) file a written report with the department [agency] within 30 days of the abandonment, providing [the following information]:

(i) the date of occurrence;

(ii) a description of the radioactive source involved, including radionuclide, activity, chemical and physical form, and manufacturer, model number and serial number;

(iii) the surface location and identification of the well;

(iv) the results of efforts to immobilize and seal the source in place;

(v) the depth of the radioactive source;

(vi) the depth of the top of the cement plug;

(vii) the depth of the well; and

(viii) the information contained on the permanent identification plaque.

(6) Whenever a sealed source containing radioactive material is abandoned downhole, the licensee must [shall] provide a permanent plaque (an example of a suggested plaque is shown in subsection (ee)(3) of this section) for posting on the well or wellbore. This plaque must [shall meet the following requirements]:

(A) be constructed of long-lasting material such as stainless steel, brass, bronze, or monel. The size of the plaque should be convenient for use on active or inactive wells; for example, a

7-inch (17 cm) square. Letter size of the word "CAUTION" should be approximately twice the letter size of the rest of the information; for example, 1/2 inch (1.27 cm) and 1/4 inch (0.63 cm) letter size, respectively; and

(B) contain the following engraved information on its face:

(i) the word "CAUTION;"

(ii) the radiation symbol (color not required);

(iii) the date of abandonment;

(iv) the name of the well operator or well owner;

(v) the well name and well identification number [~~number(s)~~] or other designation;

(vi) radionuclides [~~radionuclide(s)~~] and activities [~~activity(ies)~~] of the sources [~~source(s)~~];

(vii) the source depth and the plug back depth (depth to the top of the plug); and

(viii) an appropriate warning, depending on the specific circumstances of each abandonment, such as [~~the following~~]:

(I) "Do not drill below plug back depth;"

(II) "Do not enlarge casing;" or

(III) "Do not re-enter hole before contacting Radiation Control, Texas Department of State Health Services."

(7) The licensee must [~~shall~~] immediately notify the department [~~agency~~] by telephone and confirming letter if the licensee knows or has reason to believe that radioactive material has been lost in or to an underground potable water source. Such notice must [~~shall~~] designate well location and describe the magnitude and extent of loss of radioactive material, consequences of such loss, and efforts taken or planned to mitigate these consequences.

(8) In the event of an uncontrolled release of radioactive tracer material to the environment, the licensee must [~~shall~~] notify the department [~~agency~~] by telephone within 24 hours and submit written notification within 30 days.

(ee) Appendices.

(1) Subjects to be included in training courses for well logging service operations and [~~and/or~~] tracer studies are as follows:

(A) fundamentals of radiation safety that include:

(i) characteristics of radiation;

(ii) units of radiation dose (rem) and activity;

(iii) significance of radiation dose specifying radiation protection standards and biological effects of radiation;

(iv) levels of radiation from sources of radiation;

(v) methods of controlling radiation dose specifying time, distance, and shielding;

(vi) radiation safety practices, specifying prevention of contamination and methods of decontamination; and

(vii) discussion of ingestion and [~~,~~] inhalation pathways;

(B) radiation detection instrumentation to be used that includes:

(i) use of radiation survey instruments specifying operation, calibration, and limitations;

(ii) survey techniques; and

(iii) use of individual monitoring devices;

(C) equipment to be used that specifies;

(i) handling equipment and remote handling tools;

(ii) sources of radiation;

(iii) storage control, disposal, and transport of equipment and sources of radiation;

(iv) operation and control of equipment; and

(v) maintenance of equipment;

(D) pertinent federal and state requirements;

(E) the licensee's or registrant's written operating, safety, and emergency procedures;

(F) the licensee's or registrant's record keeping procedures; and

(G) case histories and potential consequences of accidents in well logging service operations and tracer studies.

(2) In addition to the subjects for training courses required in paragraph (1) of this subsection, individuals performing tracer studies must also complete training in the following subjects:

(A) sources of contamination;

(B) contamination detection and control;

(C) decontamination techniques and limits;

(D) survey techniques for tracer materials; and

(E) packaging requirements for transportation of radioactive materials, especially residual materials from tracer studies.

(3) The following is an example of a plaque for identifying wells containing sealed sources of radioactive material abandoned downhole:
Figure: 25 TAC §289.253(ee)(3) (No change.)

(4) The licensee's or registrant's operating, safety, and emergency procedures must [~~shall~~] include descriptions of and instructions in [~~at least the following~~]:

(A) the handling and use of sources of radiation in wells without surface casing for protecting freshwater [~~fresh water~~] aquifers, if appropriate;

(B) the handling and use of sources of radiation to be employed so that no individual is likely to be exposed to radiation doses over [~~in excess of~~] the limits established in §289.202 of this chapter [~~title~~], or §289.231 of this chapter [~~title~~], as applicable. Every reasonable effort must [~~shall~~] be made to keep radiation exposures and releases of radioactive material in soils and effluents to unrestricted areas as low as is reasonably achievable;

(C) methods and occasions for conducting radiation surveys;

(D) methods and occasions for locking and securing sources of radiation;

(E) personnel monitoring, including bioassays, and the use of individual monitoring devices;

(F) removing [~~removal of~~] radioactive material from storage, transporting [~~transportation of~~] radioactive material to field locations and temporary job sites, including packaging of sources of radiation in the vehicles, placarding of vehicles, securing sources of radiation during transportation, and returning [~~return~~] to storage;

(G) minimizing exposure of individuals during routine use and in the event of an accident;

(H) [~~procedures for~~] notifying proper personnel in the event of an accident or well excursion;

(I) maintaining [~~maintenance of~~] records;

(J) using, inspecting, and maintaining [~~use, inspection, and maintenance of~~] source holders, logging tools, source handling tools, storage containers, transport containers, and injection tools;

(K) actions to be taken if [~~procedures to be followed in the event~~] a sealed source is lost or lodged downhole;

(L) [~~procedures to be used for~~] picking up, receiving, handling, and opening packages containing radioactive material;

(M) surveying [~~procedures to be used for surveys of~~] temporary job sites and equipment, and decontamination of vehicles, associated equipment, and clothing following tracer studies;

(N) storing and disposing [~~storage and disposal~~] of radioactive waste;

(O) [~~procedures for~~] laundering contaminated clothing, if applicable;

(P) the licensee's or registrant's management structure;

(Q) posting of radiation areas and labeling radioactive material containers;

(R) actions to be taken if there is [~~procedures to be followed in the event of~~] an uncontrolled release of radioactive tracer material to the environment; and

(S) actions to be taken if a sealed source is ruptured, including actions preventing [~~to prevent~~] the spread of contamination and minimizing [~~minimize~~] inhalation and ingestion of radioactive material, and actions to obtain suitable radiation survey instruments as required by subsection (i) of this section.

(5) The following records/documents must [~~shall~~] be maintained by the licensee or registrant for inspection by the department [~~agency~~].

Figure: 25 TAC §289.253(ee)(5)

[~~Figure: 25 TAC §289.253(ee)(5)~~]

§289.255. Radiation Safety Requirements and Licensing and Registration Procedures for Industrial Radiography.

(a) Purpose.

(1) The requirements in this section establish radiation safety requirements and licensing and registration procedures for using sources of radiation for industrial radiography and for certification of industrial radiographers.

(2) The requirements in this section apply to licensees and registrants who possess sources of radiation for industrial radiography, including radiation machines, accelerators, and sealed radioactive sources.

(3) Each licensee and registrant is responsible for ensuring compliance with this chapter, license and registration conditions, and orders of the department [~~agency~~].

(4) Each licensee and registrant is responsible for ensuring [~~that~~] radiographic personnel performing activities under a license or registration comply with this chapter, license and registration conditions, and orders of the department [~~agency~~].

(b) Scope.

(1) The requirements of this section are in addition to and not in substitution for other applicable requirements of this chapter.

(2) The requirements of the following sections of this chapter apply to all licensed industrial radiographic operations:

(A) §289.201 of this chapter [~~title~~] (relating to General Provisions for Radioactive Material);

(B) §289.202 of this chapter [~~title~~] (relating to Standards for Protection Against Radiation from Radioactive Materials);

(C) §289.203 of this chapter [~~title~~] (relating to Notices, Instructions, and Reports to Workers; Inspections);

(D) §289.204 of this chapter [~~title~~] (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services);

(E) §289.205 of this chapter [~~title~~] (relating to Hearing and Enforcement Procedures);

(F) §289.251 of this subchapter [~~title~~] (relating to Exemptions, General Licenses, and General License Acknowledgements);

(G) §289.252 of this subchapter [~~title~~] (relating to Licensing of Radioactive Material); and

(H) §289.257 of this subchapter [~~title~~] (relating to Packaging and Transportation of Radioactive Material).

(3) The requirements of the following sections of this chapter apply to all registered industrial radiographic operations:

(A) §289.203 of this chapter [~~title~~];

(B) §289.204 of this chapter [~~title~~];

(C) §289.205 of this chapter [~~title~~];

(D) §289.226 of this chapter [~~title~~] (relating to Registration of Radiation Machine Use and Services); and

(E) §289.231 of this chapter [~~title~~] (relating to General Provisions and Standards for Protection Against Machine-Produced Radiation).

(4) The requirements of §289.228 of this chapter [~~title~~] (relating to Radiation Safety Requirements for Industrial Radiation Machines) apply to persons using analytical and other industrial radiation machines subject to this section.

(5) The requirements of §289.229 of this chapter [~~title~~] (relating to Radiation Safety Requirements for Accelerators, Therapeutic Radiation Machines, Simulators and Electronic Brachytherapy Devices) apply to persons using accelerators subject to this section.

(c) Definitions. The following words and terms[~~,~~] when used in this section[~~, shall~~] have the following meaning[~~,~~] unless the context clearly indicates otherwise.

[~~(1) Additional authorized use/storage site--Authorized use/storage locations specifically named on a license or certificate of registration other than the main site specified on a license or certificate of registration or other than temporary job sites.~~]

(1) [~~(2)~~] ANSI--American National Standards Institute.

(2) [~~(3)~~] Annual refresher safety training--A review conducted or provided by the licensee or registrant for its employees on radiation safety aspects of industrial radiography. The review may include, as appropriate, the results of internal audits, new procedures or equipment, new or revised regulations, accidents or errors that have been observed, and should also provide opportunities for employees to ask safety questions.

(3) [~~(4)~~] Associated equipment--Equipment, [~~that is~~] used in conjunction with a radiographic exposure device used to make radiographic exposures, that drives, guides, or comes in contact with the source, (such as, guide tube, control tube, control cable (drive cable), removable source stop, "J" tube, and collimator when it is used as an exposure head).

(4) [~~(5)~~] Cabinet x-ray system--An x-ray system with the x-ray tube installed in an enclosure independent of existing architectural structures except the floor on which it may be placed. An x-ray tube used within a shielded part of a building, or x-ray equipment that may temporarily or occasionally incorporate portable shielding, is not considered a cabinet x-ray system. The cabinet x-ray system is intended to:

(A) contain at least that portion of a material being irradiated;

(B) provide radiation attenuation; and

(C) exclude personnel from its interior during generation of radiation.

(5) [~~(6)~~] Certifiable cabinet x-ray system--An existing uncertified x-ray system [~~that has been~~] modified to meet the certification requirements specified in 21 Code of Federal Regulations (CFR) [~~Title 21, Code of Federal Regulations (CFR),~~] §1020.40.

(6) [~~(7)~~] Certification identification (ID) card--The document issued by the department [~~agency~~] to individuals who have completed the requirements stated in subsection (e)(2)(A) of this section.

(7) [~~(8)~~] Certified cabinet x-ray system--An x-ray system that has been certified as specified in [~~accordance with~~] 21 CFR [~~Title 21, CFR,~~] §1010.2 as being manufactured and assembled on or after April 10, 1975, as specified in [~~according to~~] the provisions of 21 CFR [~~Title 21, CFR,~~] §1020.40.

(8) [~~(9)~~] Certifying entity--An entity that is:

(A) an independent certifying organization;

(B) an Agreement State whose industrial radiographer certification program meets the applicable parts of 10 CFR [~~Title 10, CFR,~~] Part 34, Appendix A, Parts II and III for radioactive material; or

(C) a radiation control agency whose x-ray or [~~and/or~~] combination certification requirements are found to be equivalent to criteria established by the Conference of Radiation Control Program Directors [~~Directions~~], Inc. [~~(CRCPD)~~].

(9) [~~(10)~~] Collimator--A radiation shield [~~that is~~] placed on the end of a guide tube or directly onto a radiographic exposure device to restrict the size of the radiation beam when the sealed source is cranked into position to make a radiographic exposure.

(10) [~~(11)~~] Conference of Radiation Control Program Directors, Inc. (CRCPD)--A 501(c)(3) nonprofit, non-governmental, professional organization dedicated to radiation protection to serve as a common forum for the many governmental radiation protection agencies to communicate with each other and to promote uniform radiation protection regulations and activities.

(11) [~~(12)~~] Control cable (drive cable)--The cable [~~that is~~] connected to the source assembly and used to drive the source from and return it to the shielded position.

(12) [~~(13)~~] Control mechanism (drive mechanism)--A device enabling [~~that enables~~] the source assembly to be moved from and returned to the shielded position. A drive mechanism is also known as a crank assembly.

(13) [~~(14)~~] Control tube--A protective sheath for guiding the control cable. The control tube connects the control drive mechanism to the radiographic exposure device.

(14) [~~(15)~~] Crank-out device--The control cable, control tube, and drive mechanism used to move the sealed source to and from the shielded position to make an industrial radiographic exposure.

(15) [~~(16)~~] Exposure head--A device that locates the gamma radiography sealed source in the selected working position. An exposure head is also known as a source stop.

(16) Field station--A facility where licensed material or radiation machines are stored or used and from which equipment is dispatched to temporary job sites.

[~~(17) Fluoroscopic imaging assembly--A subsystem in which x-ray photons produce a fluoroscopic image. It includes the image receptors such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and source assembly.~~]

[~~(18) GED--General educational development.~~]

(17) [~~(19)~~] Guide tube--A flexible or rigid tube, such as a "J" tube, for guiding the source assembly and the attached control cable from the exposure device to the exposure head. The guide tube may also include the connections necessary for attachment to the exposure device and to the exposure head.

(18) [~~(20)~~] Independent certifying organization--An independent organization meeting [~~that meets all of~~] the criteria of 10 CFR [~~Title 10, CFR,~~] Part 34, Appendix A, for radioactive material, or comparable standards for x-ray machines.

(19) [~~(21)~~] Industrial radiography (radiography)--A nondestructive [~~nondestructive~~] testing method using ionizing radiation, such as gamma rays or x-rays [~~x rays~~], to make radiographic images for the purpose of detecting flaws in objects without destroying them.

(20) [~~(22)~~] Lay-barge radiography--Industrial radiography performed on any water vessel used for laying pipe.

(21) [~~(23)~~] Lock-out survey--A radiation survey performed to determine [~~that~~] a sealed source is in its fully shielded position before moving the radiographic exposure device or source changer to a different temporary job site or before securing the radiographic exposure device or source changer against unauthorized removal.

(22) [~~(24)~~] Offshore--Within the territorial waters of the State of Texas. The territorial waters of Texas extend to the three marine league line or nine nautical miles from the Texas coast.

(23) [~~(25)~~] On-the-job training (hands-on experience)--Experience in all [~~of the~~] areas considered to be directly involved in the radiography process. The hours of on-the-job training do not include safety meetings, classroom training, travel, darkroom activities, film development and interpretation, or use of a cabinet x-ray unit.

(24) [~~(26)~~] Permanent radiographic installation--An enclosed [~~A~~] shielded room, cell, or vault, not located at a temporary job site [~~jobsite~~], in which radiography is performed and meets the criteria of subsection (n) of this section.

[(27) Permanent storage site--Any location that is specifically named on a license or certificate of registration and that is used only for storage of sources of radiation.]

(25) [(28)] Personal supervision--Guidance and instruction provided to a radiographer trainee by a radiographer trainer [who is] present at the site, in visual contact with the trainee while the trainee is using sources of radiation, associated equipment, and survey meters, and in such proximity that immediate assistance can be given, if required.

(26) [(29)] Pipeliners--A directional beam radiographic exposure device.

(27) [(30)] Platform radiography--Industrial radiography performed on an offshore platform or other structure over a body of water.

(28) [(31)] Practical examination--A demonstration through practical application of the safety rules and principles in industrial radiography including use of all appropriate equipment and procedures.

(29) [(32)] Radiation safety officer (RSO)--An individual named by the licensee or registrant and listed on the license or certificate of registration having [who has] a knowledge of, responsibility for, and authority to enforce appropriate radiation protection rules, standards, and practices on behalf of the licensee or registrant and who meets the requirements of subsection (e)(4) of this section.

(30) [(33)] Radiographer--Any individual who has successfully completed the [training, testing, and documentation] requirements of subsection (e)(2)(A) of this section, performs industrial radiographic operations, or provides visual surveillance of industrial radiographic operations while in attendance during transport or at the site where the sealed source or sources are being used, and [who] is responsible to the licensee or registrant for assuring compliance with the requirements of the department's [agency's] regulations and conditions of the license or certificate of registration. These individuals may be referred to as certified industrial radiographers or certified radiographers. [The individual may also:]

[(A) perform industrial radiographic operations; or]

[(B) be in attendance at the site where the sources of radiation are being used.]

(31) [(34)] Radiographer certification--Written approval received from a certifying entity stating [that] an individual has satisfactorily met certain established radiation safety, testing, and experience criteria.

(32) [(35)] Radiographer trainee--Any individual who has successfully completed the training and documentation requirements of subsection (e)(1)(A) of this section and uses [who shall use] sources of radiation and associated equipment or radiation survey instruments under the personal supervision of a radiographer trainer.

(33) [(36)] Radiographer trainer--A radiographer who instructs and supervises radiographer trainees during on-the-job training and [who] meets the requirements of subsection (e)(3) of this section.

(34) [(37)] Radiographic exposure device--Any instrument containing a sealed source fastened or contained therein, where [in which] the sealed source or shielding [thereof] may be moved, or otherwise changed, from a shielded to unshielded position for purposes of making a radiographic exposure (e.g., camera).

(35) [(38)] Radiographic operations--All activities associated with the presence of x-ray machines or radioactive sources in a radiographic exposure device during the use of the machine or device or transport (except when being transported by a common or contract transport). Radiographic operations include surveys to confirm the adequacy of boundaries, setting up equipment, and any activity inside restricted area boundaries.

(36) [(39)] Radiographic personnel--Any radiographer, radiographer trainer, or radiographer trainee.

(37) [(40)] Residential location--Any area where a structure or structures are located, in which people [lodge or] live, and the grounds on which these structures are located, including [, but not limited to,] houses, apartments, condominiums, and garages.

(38) [(41)] S-tube--A tube through which the radioactive source travels when inside a radiographic exposure device.

(39) [(42)] Shielded position--The location within the radiographic exposure device or source changer where the sealed source is secured and restricted from movement.

(40) [(43)] Shielded-room radiography--Industrial radiography conducted in a room shielded so radiation levels at every location on the exterior meet the limitations specified in §289.202(n) of this chapter [title] or §289.231(o) of this chapter [title], as applicable. A shielded room is also known as a bay or bunker.

(41) [(44)] Source assembly (pigtail)--An assembly consisting [that consists] of the sealed source and a connector that attaches the source to the control cable. The source assembly may also include a ball stop used to secure the source in the shielded position.

(42) [(45)] Source changer--A device designed and used to replace sealed sources in radiographic exposure devices, including those used to transport and store sealed sources.

(43) [(46)] Storage area--Any location, facility, or vehicle [that is] used to store and secure a radiation machine, radiographic exposure device, a storage container, or a sealed source when it is not in use [used for radiographic operations]. Storage areas are locked or have a physical barrier to prevent accidental exposure, tampering, or unauthorized removal of the machine, device, container, or source.

(44) [(47)] Storage container--A device in which the sealed source is secured and stored.

[(48) Storage facility--A structure designed to house one or more sources of radiation to provide security and shielding at a permanent storage site. A storage facility is also known as a vault.]

(45) [(49)] Temporary job site--A [Any] location where radiographic operations are conducted and where licensed or registered sources of radiation may be stored [industrial radiography is performed] other than the specific use location or locations [location(s)] listed on a license or certificate of registration. [If use of sources of radiation is authorized at a temporary job site, storage incident to that use is also authorized.]

(46) [(50)] Trainee status card--The document issued by the department [agency] following completion of the requirements of subsection (e)(1)(A) of this section.

(47) [(51)] Transport container--A package that is designed to provide radiation safety and security when sealed sources are transported and meets all applicable requirements of the United States Department of Transportation (DOT).

(48) [(52)] Underwater radiography--Industrial radiography performed when the radiographic exposure device or [and/or] related equipment are beneath the surface of the water.

(d) Exemptions.

(1) Uses of certified and certifiable cabinet x-ray systems are exempt from the requirements of this section except for the requirements of subsections (a), (b)(3), (c), and (t)(8) of this section.

(2) Industrial uses of hand-held light intensified imaging devices are exempt from the requirements in this section if the exposure rate 18 inches from the source of radiation to any individual does not exceed 2 millirem per hour (mrem/hr) (0.02 millisievert per hour (mSv/hr)). Devices with exposure rates that exceed the 2 mrem/hr (0.02 mSv/hr) level must [~~shall~~] meet the applicable requirements of this section and §289.252 of this subchapter [~~title~~] or §289.226 of this chapter [~~title~~], as applicable. This exemption will apply only to those radiation machines that do not allow a person or body part to be exposed to the radiation beam.

(3) Radiation machines determined by the department [~~agency~~] to constitute a minimal threat to human health and safety as specified in [~~accordance with~~] §289.231(ll)(3) of this chapter [~~title,~~] are exempt from the requirements in this section except for the requirements of paragraph (1) of this subsection.

(4) Facilities that utilize radiation machines for industrial radiography only at permanent radiographic installations are exempt from the requirements of this section except for the requirements of subsections (a), (b)(1), (b)(3) - (5), (c), (e) [~~(e)(1)~~], (j), (k), (n), (o), (t)(1), (t)(2), (t)(5), and (t)(7).

(e) Requirements for qualifications of radiographic personnel.

(1) Radiographer trainee. Licensees or registrants must not [~~No licensee or registrant shall~~] permit any individual to act as a radiographer trainee until the individual possesses the original or a copy of a department-issued [~~an agency-issued~~] trainee status card or certification ID card.

(A) To obtain a department-issued [~~an agency-issued~~] trainee status card, the licensee, registrant, or the individual must [~~shall~~] document to the department [~~agency~~] on RC Form 255-E, or equivalent, that such individual has successfully completed a course of at least 40 hours on the applicable subjects outlined in subsection (x)(1) of this section. [~~The course shall be one accepted by the agency, another agreement state, or the United States Nuclear Regulatory Commission (NRC).~~]

(B) The trainee must [~~shall~~] carry a copy of the completed RC Form 255-E[,] in the interim period after submitting documentation to the department [~~agency~~] and before receiving a trainee status card. The copy of the completed RC Form 255-E [~~that was~~] submitted to the department [~~agency~~] may be used in lieu of the trainee status card for a period of 30 days from the date recorded by the trainee on the documentation.

(C) The individual must [~~shall~~] notify the department, [~~agency~~] in writing, of the need for a replacement trainee status card. The individual must [~~shall~~] carry a copy of documentation of the request while performing industrial radiographic operations until a replacement trainee status card is received from the department [~~agency~~].

(D) Records required by subparagraph (A) of this paragraph must [~~shall~~] be made and maintained as specified in [~~accordance with~~] subsection (v)(1) of this section.

(E) Each licensee and registrant must [~~shall~~] maintain, for [~~agency~~] inspection by the department, clear and legible records demonstrating all [~~that demonstrate that~~] the applicable requirements of this paragraph are met. A copy of the trainee status card will satisfy the documentation requirements of this paragraph.

(2) Radiographer. Licensees or registrants must not [~~No licensee or registrant shall~~] permit any individual to act as a radiographer until the individual possesses a valid radiographer certification.

(A) To obtain a radiographer certification, an individual must [~~shall~~] submit the fee as prescribed in subsection (h)(1) of this section and [~~comply with the following~~]:

(i) complete the requirements of paragraph (1)(A) of this subsection;

(ii) document to the department [~~Agency~~] on RC Form 255-R[,] completion of on-the-job training as a radiographer trainee supervised by a radiographer trainer who meets the requirements of subsection (e)(3) of this section [~~one or more radiographer trainers authorized on a license or certificate of registration~~];

(I) The radiographer trainee must [~~shall~~] carry a legible trainee status card as specified in [~~accordance with~~] paragraph (1) of this subsection while obtaining the on-the-job training specified in subclauses (II) - (VII) of this clause.

(II) The on-the-job training must [~~shall~~] include at least 200 hours of active participation in radioactive materials industrial radiographic operations or 120 hours of active participation in x-ray industrial radiographic operations, as applicable.

(III) Individuals performing industrial radiography utilizing radioactive materials and x-ray machines must [~~shall~~] complete both segments (320 hours) of on-the-job training.

(IV) The hours of on-the-job training do not include safety meetings, classroom training, travel, darkroom activities, film development and interpretation, or use of a cabinet x-ray unit.

(V) One year of documented experience of on-the-job training as authorized by another agreement state or the United States Nuclear Regulatory Commission (NRC) [~~NRC~~] may be substituted for the requirements of subclauses (II) or (III) of this clause. The documentation must [~~shall~~] be submitted to the department [~~agency~~] on RC Form 255-OS or equivalent.

(VI) The trainee must [~~shall~~] be under the personal supervision of a radiographer trainer whenever a radiographer trainee:

(-a-) uses radiation machines, radiographic exposure devices, or associated equipment; or

(-b-) performs radiation surveys required by:

(-1-) subsection (t)(6) of this section to determine [~~that~~] the radiation machine has stopped producing radiation; or

(-2-) subsection (u)(9) of this section to determine [~~that~~] the sealed source has returned to the shielded position after an exposure.

(VII) The personal supervision must [~~shall~~] include [~~the following.~~]:

(-a-) the [~~The~~] radiographer trainer's physical presence at the site where the sources of radiation are being used;

(-b-) the [~~The~~] availability of the radiographer trainer to give immediate assistance if required; and

(-c-) the [~~The~~] radiographer trainer's direct observation of the trainee's performance of the operations referred to in this section.

(iii) successfully complete within the last five years the appropriate department-administered [~~agency-administered~~] examination prescribed in subsection (g)(2) of this section or the appropriate examination of another certifying entity that affords the same or

comparable certification standards as those afforded by this clause and clauses (i) and (ii) of this subparagraph; and

(iv) possesses a current certification ID card issued as specified in [~~accordance with~~] subsection (h)(2) of this section or by another certifying entity affording [~~that affords~~] the same or comparable certification standards as those afforded by this clause or clauses (i) - (iii) of this subparagraph.

(B) Reciprocal recognition by the department [~~agency~~] of an individual radiographer certification may be granted as specified in [~~according to~~] subsection (h)(5)(A) and (B) of this section.

(C) Once an individual has completed the requirements of paragraph (2)(A)(iv) of this subsection, the licensee or registrant is not required to submit the documentation referenced in paragraph (2)(A)(i) and (ii) of this subsection for renewal of a radiographer certification.

(D) Records required by subparagraph (A) of this paragraph must [~~shall~~] be made and maintained as specified in [~~accordance with~~] subsection (v)(1) of this section.

(E) Each licensee and registrant must [~~shall~~] maintain for [~~agency~~] inspection by the department, clear and legible records demonstrating [~~that demonstrate that~~] the applicable requirements of this paragraph are met for all industrial radiographic personnel. A copy of the certification ID card will satisfy the documentation requirements of this paragraph.

(3) Radiographer trainer.

(A) Licensees or registrants must not [~~No licensee or registrant shall~~] permit any individual to act as a radiographer trainer until:

(i) it has been documented to the department [~~agency~~] on RC Form 255-T or equivalent the [~~that such~~] individual has:

(I) met the radiographer certification requirements of paragraph (2)(A) of this subsection; and

(II) documented 2000 hours [~~one year~~] of direct [~~documented~~] experience as a certified radiographer.

(ii) the [~~such~~] individual is in receipt of a valid trainer certification ID card issued by the department [~~agency~~] and under which the individual is acting as a radiographer trainer; and

(iii) determination is made by the department [~~agency that~~] the individual is not currently under order from the department [~~agency~~] prohibiting the individual from acting as a radiographer trainer.

(B) The specific duties of the radiographer trainer include[~~, but are not limited to, the following~~]:

(i) providing personal supervision to any radiographer trainee at the site where the sources of radiation are being used; and

(ii) preventing any unauthorized use of a source of radiation by a radiographer trainee.

(4) RSO for industrial radiography.

[~~(A)~~] An RSO must [~~shall~~] be designated on every industrial radiography license and certificate of registration issued by the department [~~agency~~]. The RSO's qualifications must be submitted to the department. A single individual may be designated as RSO for more than one license or certificate of registration if authorized by the department [~~agency~~].

(A) The minimum qualifications for industrial radiography RSOs are:

(i) completion of requirements for a radiographer trainer of subsection (e)(3)(A) of this section; and

(ii) formal training in the establishment and maintenance of a radiation protection program.

(B) The department considers alternatives when the RSO has appropriate training and experience in the field of ionizing radiation and has adequate formal training with respect to the establishment and maintenance of a radiation safety protection program.

[~~(B) The RSO's qualifications shall be submitted to the agency and shall include as a minimum:~~]

[~~(i)~~ ~~possession of a high school diploma or a certificate of high school equivalency based on the GED test;~~]

[~~(ii)~~ ~~completion of the training and testing requirements of paragraphs (1)(A) and (2)(A)(iii) of this subsection; and~~]

[~~(iii)~~ ~~two years of documented radiation protection experience, including knowledge of industrial radiographic operations with at least 40 hours of active participation in industrial radiographic operations.~~]

(C) The specific duties of the RSO include[~~, but are not limited to, the following~~]:

(i) establishing and overseeing operating, safety, emergency, and as low as reasonably achievable (ALARA) procedures, and to review them regularly to ensure that the procedures are current and conform with the requirements of this chapter;

(ii) overseeing and approving all phases of the training program for radiographic personnel so that appropriate and effective radiation protection practices are taught;

(iii) ensuring [~~that~~] required radiation surveys and leak tests are performed and documented as specified in [~~accordance with~~] this chapter, including any corrective measures when levels of radiation exceed established limits;

(iv) ensuring [~~that~~] personnel monitoring devices are calibrated and used properly by occupationally exposed [~~occupationally-exposed~~] personnel;

(v) ensuring [~~that~~] timely notifications to employees are made as specified in [~~required by~~] §289.203 of this chapter [~~title~~];

(vi) ensuring [~~that~~] timely notifications to the department [~~agency~~] are made as specified in [~~required by~~] this section and §289.202 of this chapter [~~title~~] or §289.231 of this chapter [~~title~~], as applicable;

(vii) ensuring [~~that~~] any required interlock switches and warning signals are functioning and [~~that~~] radiation signs, ropes, and barriers are properly posted and positioned;

(viii) investigating, determining the cause, taking steps to prevent the recurrence, and reporting to the department [~~agency~~] each:

(I) known or suspected case of radiation exposure to an individual or radiation level detected over the [~~in excess of~~] limits established by this chapter; and

(II) theft or loss of sources [~~a source(s)~~] of radiation;

(ix) having a thorough knowledge of management policies and administrative procedures of the licensee or registrant;

(x) assuming control and having the authority to institute corrective actions, including shutdown of operations, when necessary, in emergency situations or unsafe conditions;

(xi) maintaining records as specified in [~~as required by this chapter in accordance with~~] subsection (v)(1) of this section;

(xii) ensuring the proper storing, labeling, transport, and use of exposure devices and sources of radiation;

(xiii) ensuring [~~that~~] inventory and inspection and maintenance programs are performed as specified in [~~accordance with~~] subsections (k) and (m) of this section;

(xiv) ensuring [~~that~~] personnel are complying with the requirements of this chapter and the conditions of the license or the certificate of registration; and

(xv) ensuring [~~that~~] the operating, safety, and emergency procedures of the licensee or registrant are met as specified in [~~accordance with~~] subsections (t)(5)(A) - (C) and (G) and (u)(8)(A) - (C) and (I) of this section.

(f) Additional requirements.

(1) Licensees or registrants must not [~~No licensee or registrant shall~~] permit any individual to act as a radiographer trainee, radiographer, radiographer trainer, or RSO until the [~~such~~] individual has met the certification requirements as specified in [~~accordance with~~] subsection (e) of this section, as applicable, and has:

(A) received copies of and demonstrated an understanding of the following by successful completion of a written or oral examination administered by the licensee or registrant covering this material:

(i) the requirements contained in this section and the applicable requirements of §289.201 of this chapter [~~title~~], §289.202 of this chapter [~~title~~], §289.203 of this chapter [~~title~~], §289.231 of this chapter [~~title~~], and §289.257 of this subchapter [~~title~~];

(ii) the appropriate license and certificate of registration conditions [~~of the license(s) and certificate(s) of registration~~];

(iii) the licensee's or registrant's operating, safety, and emergency procedures; and

(B) demonstrated competence in the use of sources of radiation, radiographic exposure devices, associated equipment, related handling tools, and radiation survey instruments[~~,~~] that may be employed in industrial radiographic assignments by successful completion of a practical examination administered by the licensee or registrant covering such use.

(2) A radiographer and radiographer trainer must [~~shall~~] ensure [~~that~~] radiographic operations to which the individual is assigned are conducted as specified in [~~accordance with~~] the requirements of this section.

(3) Records of the administration of and the examinations required by paragraph (1) of this subsection must [~~shall~~] be made and maintained as specified in [~~accordance with~~] subsection (v)(1) of this section. Records must [~~shall~~] include [~~the following~~]:

(A) copies of written tests administered by the licensee or registrant;

(B) dates of oral and practical examinations and names of individuals conducting and receiving the oral and practical examinations; and

(C) a list of items tested and the results of the oral and practical examinations.

(g) Application and fee for radiographer certification examinations.

(1) Application.

(A) An application for taking the examination must [~~shall~~] be on forms prescribed and furnished by the department [~~agency~~].

(B) The non-refundable and non-transferable application fee for examination is [~~shall be~~] $120.

(C) The appropriate fee must [~~shall~~] be submitted with the application for examination [~~when filing with the agency~~].

(D) The application and the non-refundable and non-transferable fee must [~~shall~~] be submitted to the department [~~agency~~] on or before the dates specified by the department [~~agency~~].

(E) Applicants who fail to appear at a scheduled exam and do not reschedule 48 hours before [~~prior to~~] their assigned exam session must [~~shall~~] apply for a future exam session and submit the appropriate fee, as specified in [~~accordance with~~] subparagraphs (A) - (D) of this paragraph.

(2) Examination. The examination must [~~shall~~] be given for the purpose of determining the qualifications of applicants.

(A) The scope of the examination and the methods of procedure, including determination of the passing score, are [~~shall be~~] prescribed by the department [~~agency~~]. The examination assesses [~~will assess~~] the applicant's knowledge to safely use sources of radiation and related equipment and the applicant's knowledge of this section, and the applicable requirements of §289.201 of this chapter [~~title~~], §289.202 of this chapter [~~title~~], and §289.231 of this chapter [~~title~~].

(B) The examination is [~~will be~~] administered by the department [~~agency~~] or persons authorized by the department [~~agency~~].

(C) A candidate failing an examination may apply for re-examination as specified in [~~accordance with~~] paragraph (1) of this subsection [~~and will be re-examined~~]. A candidate may [~~shall~~] not retake the same version of the department-administered [~~agency-administered~~] examination.

(D) The examination is [~~shall~~] normally [~~be~~] offered once each month. Times, dates, and locations of the examination are [~~will be~~] furnished by the department [~~agency~~].

(E) The examination is [~~will be~~] in the English language.

(F) To take the examination, an individual must [~~shall~~] present a government-issued photo identification card, such as a driver's license, at the time of the examination.

(G) Calculators will be permitted during the examination. Calculators [~~However, calculators~~] or computers with preprogrammed data or formulas, including exposure calculators, are [~~will~~] not [~~be~~] permitted during the examination.

(H) The examination is [~~will be~~] a "closed-book" examination.

(I) Any individual observed by a department [~~an agency~~] proctor [~~to be~~] compromising the integrity of the examination will [~~shall~~] be required to surrender the examination, the answer sheet, and all scratch paper. The [~~Such~~] individual is [~~will~~] not [~~be~~] allowed to complete the examination, forfeits [~~will forfeit~~] the examination fee, and leaves [~~will leave~~] the examination site to avoid disturbing other examinees. The [~~Such~~] individual must [~~shall~~] wait 90 days before

taking a new examination and must [~~shall~~] resubmit a new application and a $120 non-refundable and non-transferable examination fee.

(J) Examination material must [~~shall~~] be returned to the department [~~agency~~] at the end of the examination. No photographic or other copying of examination questions or materials is [~~shall be~~] permitted. Disclosure by any individual of the contents of any examination before [~~prior to~~] its administration is prohibited.

(K) The names and scores of individuals taking the examination are [~~shall be~~] a public record.

(h) Radiographer certification.

(1) An application for radiographer certification must [~~shall~~] be on RC Form 255-R, RC Form 255-OS, or equivalent.

(A) The non-refundable fee for radiographer certification is [~~shall be~~] $110.

(B) The appropriate fee must [~~shall~~] be submitted with the application for radiographer certification when filing with the department [~~agency~~].

(2) A certification ID card will [~~shall~~] be issued to each individual [~~who~~] successfully completing [~~completes~~] the requirements of subsection (e)(2)(A)(i) - (iii) of this section.

(A) Each individual's certification ID card contains [~~shall contain~~] the individual's photograph. The department takes [~~agency will take~~] the photograph at the time the examination is administered.

(B) The certification ID card remains the property of the department [~~agency~~] and may be revoked or suspended under the provisions of paragraph (4) of this subsection.

(C) Any individual who needs to replace a certification ID card must [~~shall~~] submit to the department [~~agency~~] a written request for a replacement certification ID card, stating the reason a replacement certification ID card is needed. A non-refundable fee of $35 must [~~shall~~] be paid to the department [~~agency~~] for each replacement of a certification ID card. The prescribed fee must [~~shall~~] be submitted with the written request for a replacement certification ID card. The individual must [~~shall~~] carry a copy of the request while performing industrial radiographic operations until a replacement certification ID card is received from the department [~~agency~~].

(D) Each certification ID card is valid for a period of five years, unless revoked or suspended as specified in [~~accordance with~~] paragraph (4) of this subsection. Each certification ID card expires at the end of the calendar day, in the month and year stated on the certification ID card.

(3) Renewal of a radiographer certification.

(A) Applications for examination to renew a radiographer certification must [~~shall~~] be filed as specified in [~~accordance with~~] subsection (g)(1) of this section.

(B) The examination for renewal of a radiographer certification must [~~shall~~] be administered as specified in [~~accordance with~~] subsection (g)(2) of this section.

(C) A renewal certification ID card will [~~shall~~] be issued as specified in [~~accordance with~~] paragraph (2) of this subsection.

(4) Suspension or revocation of a radiographer certification.

(A) Any radiographer violating [~~who violates~~] the requirements of this chapter, or providing [~~provides~~] any material false statement in the application or any statement of fact required by [~~in accordance with~~] this chapter, may be required to show cause at a formal hearing why the radiographer certification should not be suspended or revoked as specified in [~~accordance with~~] §289.205 of this chapter [~~title~~].

(B) When a department [~~an agency~~] order has been issued for an industrial radiographer to cease and desist from the use of sources of radiation or the department [~~agency~~] suspends or revokes the individual's radiographer certification, the radiographer must [~~shall~~] surrender the certification ID card to the department [~~agency~~] until the order is changed or the suspension expires.

(C) An individual whose radiographer certification has been suspended or revoked by the department [~~agency~~] or another certifying entity must [~~shall~~] comply with the process and [~~and/or~~] conditions of the suspension or revocation orders before certification is reinstated[~~,~~] or the individual is permitted [~~by the agency~~] to apply for a new certification.

(5) Reciprocity of a radiographer certification.

(A) Reciprocal recognition by the department [~~agency~~] of an individual radiographer certification is [~~will be~~] granted if [~~provided that~~]:

(i) the individual holds a valid certification in the appropriate category and class issued by a certifying entity, as defined in subsection (c) of this section;

(ii) the requirements and procedures of the certifying entity issuing the certification afford the same or comparable certification standards as those afforded by subsection (e)(2)(A)(i) - (iii) of this section; and

(iii) the individual submits a legible copy of the certification to the department before conducting radiographic operations in [~~agency prior to entry into~~] Texas.

(B) Enforcement actions with the department [~~agency~~], another agreement state, or the NRC or sanctions by an independent certifying entity are [~~may be~~] considered when reviewing a request for reciprocal recognition from a licensee, registrant, or certified radiographer.

(C) Certified radiographers [~~who are~~] granted reciprocity by the department must [~~agency shall~~] maintain the certification upon which the reciprocal recognition was granted, or before [~~prior to~~] the expiration of such certification, must [~~shall~~] meet the requirements of paragraph (3) of this subsection.

(i) Receipt, transfer, and disposal of industrial radiography sealed sources [~~of radiation~~] and radiography exposure devices using depleted uranium (DU) for shielding.

(1) Each licensee and registrant must [~~shall~~] make and maintain records as specified in [~~accordance with~~] subsection (v)(1) of this section, showing the receipt, transfer, and disposal of industrial radiography sealed sources [~~of radiation~~] and radiography exposure devices using DU for shielding.

(2) These records must [~~shall~~] include [~~the following~~], as appropriate:

(A) date of receipt, transfer, or disposal;

(B) name of the individual making the record;

(C) radionuclide;

(D) number of curies (becquerels) or mass (for DU);

(E) manufacturer, model, and serial number of each source of radiation or [~~and/or~~] device;

(F) for the person transferring the source of radiation, the name of the transferee, the number of the transferee's radioactive material license authorizing possession of the material, and the regulatory agency issuing the license to the transferee; and

(G) for the person receiving the source of radiation, the name of the transferor, the number of the transferor's radioactive material license authorizing possession of the material, and the regulatory agency issuing the license to the transferor.

(j) Radiation survey instruments.

(1) Each licensee and registrant must [~~shall~~] have a sufficient number of calibrated, appropriate, and operable radiation survey instruments at each location where sources of radiation are present to perform the radiation surveys required by this section and §289.202(p)(1) and (3) of this chapter [~~title~~] and §289.231(s)(1) and (2) of this chapter [~~title~~], as applicable. These radiation survey instruments must [~~shall~~] be capable of measuring a range from 2 mrem/hr (0.002 mSv/hr) through 1 rem per hour (rem/hr) (0.01 sievert per hour (Sv/hr)).

(2) Each radiation survey instrument must [~~shall~~] be calibrated:

(A) by a person licensed or registered by the department [~~agency~~], another agreement state, or the NRC to perform such service;

(B) at energies appropriate for the licensee's or registrant's use;

(C) at intervals not to exceed six months and after each instrument servicing other than battery replacement;

(D) at two points located approximately one-third and two-thirds of full-scale on each scale for linear scale instruments; for logarithmic scale instruments, at mid-range of each decade, and at two points of at least one decade; and for digital instruments, at three points between 2 and 1,000 mrem/hr (0.02 and 10 mSv/hr); and

(E) to demonstrate an accuracy within plus or minus 20 percent [~~20%~~] of the true radiation level at each point checked.

(3) Each radiation survey instrument must [~~shall~~] be checked with a radiation source at the beginning of each day of use and at the beginning of each work shift to ensure it is operating properly.

(4) Records of the calibrations required by paragraph (2) of this subsection must [~~shall~~] be maintained as specified in [~~accordance with~~] subsection (v)(1) of this section.

(k) Inventory [~~Quarterly inventory~~].

(1) Each licensee and registrant must [~~shall~~] perform a physical inventory at intervals not to exceed three months to account for all sources of radiation and for devices containing DU received or possessed except for radiation machines utilized for industrial radiography at permanent radiographic installations. Each registrant utilizing radiation machines for industrial radiography at permanent radiographic installations must perform physical inventories and maintain inventory records as required by §289.226(m)(9) of this chapter.

(2) Records of the quarterly inventories required by paragraph (1) of this subsection must [~~shall~~] be made and maintained as specified in [~~accordance with~~] subsection (v)(1) of this section.

(3) The record must [~~shall~~] include, [~~the following~~] for each source of radiation, as appropriate:

(A) manufacturer, model, and serial number;

(B) radionuclide;

(C) number of curies (except for DU);

(D) location of each source of radiation;

(E) date of the inventory; and

(F) name of the individual making the inventory.

(l) Utilization logs.

(1) Each licensee and registrant must [~~shall~~] make and maintain current logs of the use, removal, and return to storage of each source of radiation. The information must [~~shall~~] be recorded in the log when the source is removed from and returned to storage. The logs must [~~shall~~] include:

(A) a unique identification, for example, make, model, and serial number, of [~~the following~~]:

(i) each radiation machine;

(ii) each radiographic exposure device containing a sealed source or transport and storage container in which the sealed source is located; and

(iii) each sealed source;

(B) the name and signature of the radiographer using the source of radiation;

(C) the locations [~~location(s)~~] and dates [~~date(s)~~] where each source of radiation is used; and

(D) the dates [~~date(s)~~] each source of radiation is removed from storage and returned to storage.

(2) Utilization logs must [~~may~~] be kept on clear legible records containing all the information required by paragraph (1) of this subsection.

(3) Records of utilization logs must [~~shall~~] be made and maintained as specified in [~~accordance with~~] subsection (v)(1) of this section.

(m) Inspection and maintenance of radiation machines, radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments.

(1) Each day before using equipment, the radiographer must [~~shall~~]:

(A) perform visual and operational checks on radiation machines, survey instruments, radiographic exposure devices, transport and storage containers, associated equipment, and source changers to ensure [~~that~~]:

(i) the equipment is in good working condition;

(ii) the sources are adequately shielded in radiographic exposure devices; and

(iii) required labeling is present and legible;

(B) determine the survey instrument is responding using check sources or other appropriate means; and

(C) remove the equipment from service until repaired if equipment problems are found.

(2) Each licensee and registrant must [~~shall~~] perform and must [~~shall~~] have written procedures for the following:

(A) inspection and routine maintenance of radiation machines, radiographic exposure devices, source changers, associated equipment, transport and storage containers, and survey instruments at intervals not to exceed three months to ensure the proper functioning

of components important to safety. All appropriate components must [shall] be maintained as specified in [accordance with] manufacturers' specifications. Radiation machines, radiographic exposure devices, transport containers, and source changers being stored are exempted from this requirement provided [that] each radiation machine, radiographic exposure device, transport container, or source changer is inspected and repaired before [prior to] being returned to service. This inspection and maintenance program must [shall] cover, at [as] a minimum, the items listed in subsection (x)(2) of this section; and

(B) inspection and maintenance necessary to maintain the Type B packaging used to transport radioactive material. The inspection and maintenance program must [shall] include procedures to assure [that] Type B packages are shipped and maintained as specified in [accordance with] the certificate of compliance or other approval.

(3) Records of daily checks of equipment, equipment problems found in daily checks and quarterly inspections, and of any maintenance performed as specified in [accordance with] paragraph (1) of this subsection must [shall] be made and maintained as specified in [accordance with] subsection (v)(1) of this section.

(4) The record must [shall] include [the following]:

(A) date of check or inspection;

(B) name of inspector;

(C) equipment involved;

(D) any problems found; and

(E) what repairs or maintenance, if any, were done.

(n) Permanent radiographic installations.

(1) Permanent radiographic installations must [shall] have high radiation area entrance controls (for example, a control device that energizes a conspicuous visible and audible alarm signal or [and/or] continuous direct or electronic surveillance) as described in §289.202(s)(1) - (4) of this chapter [title] or §289.231(t)(1) - (4) of this chapter [title], or, if applicable, §289.229 of this chapter [title].

(2) The entrance controls must [shall] be tested for proper operation at the beginning of each day of equipment use.

(3) The alarm system must [shall] be tested for proper operation with a source of radiation each day before the installation is used for radiographic operations. The test must [shall] include a check for the visible and audible signals.

(4) Entrance control devices reducing [that reduce] the radiation level upon entry (designated in paragraph (1) of this subsection) must [shall] be tested monthly.

(5) If an entrance control device or alarm is operating improperly, it must [shall] be immediately labeled as defective and repaired within seven calendar days. The facility may continue to be used during this seven-day period, provided the licensee or registrant implements the continuous surveillance requirements of subsection (q) of this section, ensures [that] radiographic personnel use an alarming ratemeter, and complies with the requirements of subsection (u)(8)(G) of this section.

(6) Records of alarm systems and entrance control tests and repairs required by this subsection must [shall] be made and maintained as specified in [accordance with] subsection (v)(1) of this section.

(o) Notifications [Notification of incidents].

(1) The department must [agency shall] be notified of the loss or theft of sources of radiation, overexposures, and excessive levels as specified in [accordance with] §289.202(ww) - (yy)[,] and (bbb) of this chapter [title] or §289.231(gg) - (jj) of this chapter [title], as applicable.

(2) In addition, whenever one of the following events occurs, each licensee or registrant must [shall] make the initial notification report by telephone to the department [agency] within 24 hours and submit a written report to the department [agency] within 30 days:

(A) a source assembly cannot be returned to the fully shielded [fully-shielded] position and properly secured;

(B) the source assembly becomes unintentionally disconnected from the control cable;

(C) any component critical to safe operation of the radiographic exposure device fails to properly perform its intended function;

(D) an indicator on a radiation machine fails to show that radiation is being produced;

(E) an exposure switch on a radiation machine fails to terminate production of radiation when turned to the off position; or

(F) a safety interlock fails to terminate x-ray production.

(3) As specified in paragraph (2) of this subsection, the [The] licensee or registrant must [shall] include [the following information] in each report submitted [in accordance with paragraph (2) of this subsection]:

(A) a description of the equipment problem;

(B) the cause of each incident, if known;

(C) the manufacturer and model and serial number of equipment involved in the incident;

(D) the location, time, and date of the incident;

(E) the action [actions] taken to establish normal operations;

(F) the corrective action [actions] taken or planned to prevent recurrence; and

(G) the names of personnel involved in the incident.

(4) Any licensee conducting radiographic operations or storing radioactive material at any location not listed on the license for a period more than 180 days in a calendar year must notify the department before exceeding the 180 days.

(5) Any registrant conducting radiographic operations or storing radiation machines at any location not listed on the certificate of registration for a period more than 90 days in a calendar year must notify the department before exceeding the 90 days.

(p) Individual monitoring.

(1) The individual monitoring program must [shall] meet the applicable requirements of §289.202 of this chapter [title] or §289.231 of this chapter [title].

(2) During industrial radiographic operations, the following applies: [shall apply.]

(A) Licensees or registrants must not [No licensee or registrant shall] permit an individual to act as a radiographer, radiographer trainer, or radiographer trainee unless each individual wears, on the trunk of the body at all times during radiographic operations:

(i) an individual monitoring device meeting [that meets] the applicable requirements of §289.202(p)(4) and

(5) [§289.202(p)(3) and (4)], (q), and (r) of this chapter [title] or §289.231(s)(3) of this chapter [title];

(ii) a direct-reading pocket dosimeter or an electronic personal dosimeter; and

(iii) an operable alarming ratemeter.

(B) For permanent radiographic installations where other appropriate alarming or warning devices are in routine use, the wearing of an alarming ratemeter is not required.

(C) Pocket dosimeters must [shall] meet the criteria in ANSI 13.5-1972 at the time of manufacture and must [shall] have a range of zero to 200 mrem (2 mSv). Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters.

(D) Pocket dosimeters must [shall] be recharged at the start of each work shift.

(E) As a minimum, direct-reading pocket dosimeters must [shall] be recharged and electronic personal dosimeters reset, and "start" readings recorded:

(i) immediately before checking out any source of radiation from an authorized use or storage site [location] for the purposes of conducting industrial radiographic operations; and

(ii) before beginning radiographic operations on any subsequent calendar day (if the source of radiation has not been checked back into an authorized use or storage site).

(F) Whenever radiographic operations are concluded for the day, the "end" readings on pocket dosimeters or electronic personal dosimeters must [shall] be recorded and the accumulated occupational doses for that day determined and recorded.

(G) If an individual's pocket dosimeter is discharged beyond its range (for example, goes "off-scale"), or if an individual's electronic personal dosimeter reads greater than 200 mrem (2 mSv) and the possibility of radiation exposure cannot be ruled out as the cause, industrial radiographic operations by that individual must [shall] cease and the individual's monitoring device requiring processing must be sent for processing [shall be processed] immediately. The individual's monitoring device not requiring processing must be evaluated immediately. The individual must [shall] not return to work with sources of radiation until a determination of the radiation exposure has been made. This determination must [shall] be made by the RSO or the RSO's designee. The results of this determination must [shall] be included in the records maintained as specified in [accordance with] paragraphs (5) and (6) of this subsection and subsection (v)(1) of this section.

(H) Each individual monitoring device must [shall] be assigned to and worn by only one individual.

(I) Film badges must [shall] be replaced at periods not to exceed one month and all other individual monitoring devices requiring replacement must [personnel dosimeters processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor shall] be replaced at least quarterly [periods not to exceed three months]. After replacement, each individual monitoring device requiring processing must [shall] be returned to the supplier for processing within 14 calendar days of the exchange date specified by the [personnel monitoring] supplier or as soon as practicable. All individual monitoring devices must be evaluated at least quarterly or promptly after replacement, whichever is more frequent. Circumstances preventing meeting these time limits must be documented, and those records must be available for review by the department. [In circumstances that make it impossible to return each individual monitoring device within 14 calendar days, such circumstances shall be documented and available for review by the agency.]

(J) If an individual monitoring device is lost or damaged, the worker must [shall] cease work immediately until a replacement individual monitoring device is provided and the exposure is calculated for the time period from issuance to loss or damage of the individual monitoring device. The results of the calculated exposure and the time period for which the individual monitoring device was lost or damaged must [shall] be included in the records maintained as specified in [accordance with] paragraph (6) of this subsection and subsection (v)(1) of this section.

(3) Pocket dosimeters or electronic personal dosimeters must [shall] be checked for correct response to radiation at periods not to exceed one year. Acceptable dosimeters must [shall] read within plus or minus 20 percent [20%] of the true radiation exposure.

(4) Each alarming ratemeter must [shall]:

(A) be checked without being exposed to radiation before [prior to] use at the start of each work shift, to ensure [that] the audible alarm is functioning properly;

(B) be set to give an alarm signal at a preset dose rate of 500 mrem/hr (5 mSv/hr) or lower with an accuracy of plus or minus 20 percent [20%] of the true radiation dose rate;

(C) require special means to change the preset alarm function;

(D) be calibrated for correct response to radiation at intervals not to exceed one year; and

(E) have an audible alarm sufficient to be heard by the individual wearing the alarming ratemeter in a work environment or have other visual or physical notification of alarming conditions.

(5) The following records required by this subsection must [shall] be made and maintained by the licensee or registrant for inspection by the department [agency] as specified in [accordance with] the following time requirements and subsection (v)(1) of this section.

(A) Records of pocket dosimeter or electronic personal dosimeter readings and yearly operational response checks must [shall] be maintained for three years. If the dosimeter readings were used to determine external radiation dose (for example, no individual monitoring device exposure records exist), the records must [shall] be maintained for department [agency] inspection until disposal is authorized by the department [agency].

(B) Records of pocket dosimeter and electronic personal dosimeter readings of personnel exposures must [shall] be maintained for three years.

(C) Records of estimates of exposures resulting from [as a result of] off-scale personal direct-reading dosimeters[,] or lost or damaged individual monitoring devices must [shall] be maintained until disposal is authorized by the department [agency].

(6) The following records required by this subsection must [shall] be maintained as specified in [accordance with] the following time requirements and subsection (v)(1) of this section.

(A) Records of alarming ratemeter calibrations must [shall] be maintained for three years.

(B) Records of individual monitoring device results must [received from the device processor shall] be maintained until disposal is authorized by the department [agency].

(q) Access control.

(1) During each industrial radiographic operation, radiographic personnel must [~~shall~~] maintain continuous visual surveillance of the operation to protect against unauthorized entry into a radiation area or high radiation area, except at permanent radiographic installations where all entryways are locked and the requirements of subsection (n) of this section are met.

(2) Radiographic exposure devices must [~~shall~~] not be left unattended except when in storage or physically secured against unauthorized removal or tampering.

(r) Posting. All areas where [~~in which~~] industrial radiography is being performed must [~~shall~~] be posted conspicuously as specified in [~~accordance with~~] §289.202 of this chapter [~~title~~] or §289.231 of this chapter [~~title~~], as applicable, including the following.

(1) Radiation areas. Each radiation area must [~~shall~~] be posted conspicuously with a sign or signs [~~sign(s)~~] displaying the radiation caution symbol and the words "CAUTION, RADIATION AREA" or "DANGER, RADIATION AREA."

(2) High radiation area. Each high radiation area must [~~shall~~] be posted conspicuously with a sign or signs [~~sign(s)~~] displaying the radiation caution symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA."

(3) Whenever practicable, ropes or [~~and/or~~] barriers must [~~shall~~] be used in addition to appropriate signs to designate areas as specified in [~~accordance with~~] §289.202(n)(1) of this chapter [~~title~~] or §289.231(o)(1) of this chapter [~~title~~], as applicable, and to help prevent unauthorized entry.

(4) During pipeline industrial radiographic operations, sufficient radiation signs and other barriers must [~~shall~~] be posted to prevent unmonitored individuals from entering the area as specified in [~~accordance with~~] §289.202(n)(1) of this chapter [~~title~~] or §289.231(o)(1) of this chapter [~~title~~], as applicable.

(5) In lieu of the requirements of subsection (r)(1) and (2) of this section, a restricted area may be established as specified in [~~accordance with~~] §289.202(n)(1) of this chapter [~~title~~] or §289.231(o)(1) of this chapter [~~title~~], as applicable, and be posted as specified in [~~accordance with~~] subsection (r)(1) and (2) of this section; [~~,~~] for example, both signs may be posted at the same location at the boundary of the restricted area.

(6) Exceptions listed in §289.202(bb) of this chapter [~~title~~] or §289.231(y) of this chapter [~~title~~], as applicable, do not apply to industrial radiographic operations.

(s) Specific requirements for radiographic personnel performing industrial radiography.

(1) At a job site, the following must [~~shall~~] be supplied by the licensee or registrant:

(A) at least one operable, calibrated survey instrument for each exposure device or radiation machine in use;

(B) an individual monitoring device that meets the requirements of §289.202(p)(4) and (5) [~~§289.202(p)(3) and (4)~~], (q), and (r) of this chapter [~~title~~] or §289.231(s)(3) of this chapter [~~title~~], as applicable, for each worker;

(C) an operable, calibrated pocket dosimeter or electronic personal dosimeter with a range of zero to 200 mrem (2 mSv) for each worker;

(D) an operable, calibrated, alarming ratemeter for each worker; and

(E) the appropriate barrier ropes and signs.

(2) Each radiographer at a job site must [~~shall~~] carry a valid certification ID card issued by the department [~~agency~~] or another certifying entity whose certification offers the same or comparable certification standards.

(3) Each radiographer trainee at a job site must [~~shall~~] carry a trainee status card issued by the department [~~agency~~] or equivalent documentation as specified in [~~accordance with~~] subsection (e)(1) of this section.

(4) Radiographic personnel must [~~shall~~] not perform radiographic operations if any of the items in paragraphs (1) - (3) of this subsection are not available at the job site or are inoperable. Radiographic personnel must [~~shall~~] ensure [~~that~~] the items listed in paragraph (1) of this subsection, radiographic exposure devices, and radiation machines are used as specified in [~~accordance with~~] the requirements of this section.

(5) During an inspection by the department [~~agency~~], a department [~~an agency~~] inspector may terminate an operation if any of the items in paragraphs (1) - (3) of this subsection are not available and operable or if the required number of radiographic personnel are not present. Operations must [~~shall~~] not resume [~~be resumed~~] until all required conditions are met.

(t) Radiation safety and registration requirements for the use of radiation machines.

(1) Registration requirements for industrial radiographic operations.

(A) Radiation machines used in industrial radiographic operations must [~~shall~~] be registered as specified in [~~accordance with~~] §289.226 of this chapter [~~title~~].

(B) In addition to the registration requirements in §289.226(e) and (i) of this chapter [~~title~~], an application for a certificate of registration must [~~shall~~] include: [~~the following information.~~]

(i) a [~~A~~] schedule or description of the program for training radiographic personnel that specifies:

(I) initial training;

(II) annual refresher training;

(III) on-the-job training;

(IV) procedures for administering the oral and written examination to determine the knowledge, understanding, and ability of radiographic personnel to comply with the requirements of this chapter, the conditions of the certificate of registration, and the registrant's operating, safety, and emergency procedures; and

(V) procedures for administering the practical examination to demonstrate competence in the use of sources of radiation and radiation survey instruments [~~that may be~~] employed in industrial radiographic assignments.

(ii) written [~~Written~~] operating, safety, and emergency procedures [~~that are made~~] available to each individual operating a radiation machine, including any restrictions of the operating technique required for the safe operation of the particular x-ray system;

(I) The registrant must [~~shall~~] document that each individual operating a radiation machine has read the operating and safety procedures and must [~~shall~~] maintain this documentation for inspection by the department [~~agency~~]. The documentation must [~~shall~~] include [~~the following~~]:

(-a-) name and signature of the individual;

(-b-) date the individual read the operating and safety procedures; and

(-c-) initials of the RSO;

(II) The operating and safety procedures must [~~shall~~] include[~~, but are not limited to,~~] the items listed in subsection (x)(3) of this section;

(iii) a [~~A~~] description of the internal audit program to ensure [~~that~~] radiographic personnel follow the requirements of this chapter, the conditions of the certificate of registration, and the registrant's operating, safety, and emergency procedures at intervals not to exceed six months;

(iv) a [~~A~~] list and description of all field stations and permanent radiographic installations [~~, descriptions of permanent storage use sites, and the location(s) where all records required by this section and other sections of this chapter will be maintained. Radiographic equipment shall not be stored or used at a permanent site unless such site is specifically authorized by the certificate of registration. A storage site is permanent if radiation machines are stored at that location and if one or more of the following applies:~~]

~~*(I)* the registrant establishes telephone service that is used for contracting or providing industrial radiographic services for the registrant;~~]

~~*(II)* industrial radiographic services are advertised for or from the site;~~]

~~*(III)* radiation machines stored at that location are used for industrial radiographic operations conducted at other sites; or~~]

~~*(IV)* the registrant conducts radiographic operations or stores radiation machines at any location not listed on the certificate of registration for a period in excess of 90 days in a calendar year, in which case the registrant shall notify the agency prior to exceeding the 90 days];~~

(v) a [~~A~~] description of the organization of the industrial radiographic program, including delegations of authority and responsibility for operation of the radiation safety program; and

(vi) procedures [~~Procedures~~] for verifying and documenting the certification status of radiographers and for ensuring that the certification of individuals acting as radiographers remains valid.

(C) A certificate of registration is [~~will be~~] issued if the requirements of this paragraph of this subsection and §289.226(e) and (i) of this chapter [~~title~~] are met.

(2) Locking of radiation machines. The control panel of each radiation machine must [~~shall~~] be equipped with a locking device preventing [~~that will prevent~~] the unauthorized use of an x-ray system or the accidental production of radiation. The radiation machine must [~~shall~~] be kept locked and the key removed [~~at all times~~] except when under the direct visual surveillance of a radiographer.

(3) Permanent storage precautions for the use of radiation machines. Radiation machines must [~~shall~~] be secured while in storage to prevent tampering or removal by unauthorized individuals.

(4) Requirements for radiation machines used in industrial radiographic operations.

(A) Equipment used in industrial radiographic operations involving radiation machines manufactured after October 1, 1987 must [~~, shall~~] be certified at the time of manufacture to meet the criteria set forth by ANSI N43.5 (relating to Radiological Safety Standards for the Design of Radiographic and Industrial X-Ray Equipment), except accelerators used in industrial radiography.

(B) The registrant's name and city or town of an authorized use site listed on the certificate of registration must [~~shall~~] be prominently displayed with a durable, legible, clearly visible label [~~label(s)~~] on both sides of all vehicles used to transport radiation machines for temporary job site use.

(5) Operating and internal audit requirements for the use of radiation machines.

(A) Each registrant must [~~shall~~] conduct an internal audit program to ensure [~~that~~] the requirements of this chapter, the conditions of the certificate of registration, and the registrant's operating, safety, and emergency procedures are followed by radiographic personnel.

(B) Each radiographer's and radiographer trainee's performance during an actual radiographic operation must [~~shall~~] be audited and documented at intervals not to exceed six months.

(C) If a radiographer or a radiographer trainee has not participated in a radiographic operation during the six months since the last audit, the radiographer or the radiographer trainee must [~~shall~~] demonstrate knowledge of the training requirements of subsection (f)(1) of this section by an oral or written and practical examination administered by the registrant before the individual can next participate in a radiographic operation.

(D) The department [~~agency~~] may consider alternatives in those situations where the individual serves as both radiographer and RSO.

(E) In those operations where a single individual serves as both radiographer and RSO and performs all radiography operations, an audit program is not required.

(F) The registrant must [~~shall~~] provide annual refresher safety training, as defined in subsection (c) of this section, for each radiographer trainee, radiographer, or radiographer trainer at intervals not to exceed 12 months.

(G) Individuals [~~No individual~~], other than a radiographer or a radiographer trainee, [~~who is~~] under the personal supervision of a radiographer trainer, must not [~~shall~~] manipulate controls or operate radiation machines used in industrial radiographic operations. Only one radiographer is required to operate radiation machines during industrial radiography.

(H) Radiographic operations must [~~shall~~] not be conducted at storage sites unless specifically authorized by the certificate of registration.

(I) Records of annual refresher training and audits of job performance specified in this subsection must [~~shall~~] be made and maintained as specified in [~~accordance with~~] subsection (v)(1) of this section.

(J) Records of annual refresher safety training and audits of job performance made as specified in [~~accordance with~~] this subsection must [~~shall~~] include [~~the following~~]:

(i) list of the topics discussed during the refresher safety training;

(ii) dates the annual refresher safety training was conducted;

(iii) names of the instructors and attendees; and

(iv) for audits of job performance, [~~the~~] records must [~~shall also~~] include a list showing the items checked and any non-compliance observed by the RSO or designee.

(6) Radiation surveys for the use of radiation machines.

(A) Industrial radiographic operations must not [~~No industrial radiographic operation shall~~] be conducted unless at least one calibrated and operable radiation survey instrument, as described in subsection (j) of this section, is used for each radiation machine energized.

(B) A physical radiation survey must [~~shall~~] be made after each radiographic exposure using radiation machines to determine [~~that~~] the machine is "off."

(C) All potential radiation areas where industrial radiographic operations are [~~to be~~] performed must [~~shall~~] be posted as specified in [~~accordance with~~] subsection (r) of this section, based on estimated dose rates, before industrial radiographic operations begin. An area survey must [~~shall~~] be performed during the first radiographic exposure to confirm the requirements of [~~that~~] subsection (r) of this section [~~requirements~~] have been met and [~~that~~] unrestricted areas do not have radiation levels over [~~in excess of~~] the limits specified in §289.231(o)(1)(B) of this chapter [~~title~~].

(D) Records of the surveys required by subparagraph (C) of this paragraph must [~~shall~~] be made and maintained as specified in [~~accordance with~~] subsection (v)(1) of this section. If a survey was used to determine an individual's exposure due to loss of personnel monitoring data, the records of the survey must [~~shall~~] be maintained for [~~agency~~] inspection by the department until disposal is authorized by the department [~~agency~~].

(7) Requirements for radiation machines in shielded rooms.

(A) Radiation machines in shielded rooms must[~~, shall~~] comply with all applicable requirements of this section.

(B) Radiation machines in shielded rooms must [~~shall~~] be evaluated at intervals not to exceed one year to ensure compliance with the applicable requirements of this section and §289.231(o)(1) - (3) of this chapter [~~title~~].

(C) Records of the annual evaluation of radiation machines in shielded rooms required by subparagraph (B) of this paragraph must [~~shall~~] be made and maintained as specified in [~~accordance with~~] subsection (v)(1) of this section.

(8) Requirements for certified and certifiable cabinet x-ray systems.

(A) Certified and certifiable cabinet x-ray systems, including those designed to allow admittance of individuals, are exempt from the requirements of this section except [~~that~~]:

(i) Registrants must not [~~No registrant shall~~] permit any individual to operate a cabinet x-ray system until the individual has received a copy of and instruction in the operating procedures for the unit.

(ii) Tests for proper operation of interlocks must [~~shall~~] be conducted and recorded at intervals not to exceed 12 months.

(iii) The registrant must [~~shall~~] perform an evaluation to determine compliance with §289.231(o)(1) - (3) of this chapter [~~title~~] and 21 CFR [~~Title 21, CFR,~~] §1020.40 at intervals not to exceed one year.

(B) Records of operating instructions in cabinet x-ray systems required by subparagraph (A)(i) of this paragraph and interlock tests required by subparagraph (A)(ii) of this paragraph must [~~shall~~] be made and maintained as specified in [~~accordance with~~] subsection (v)(1) of this section.

(C) Records of the evaluation of certified cabinet x-ray systems required by subparagraph (A)(iii) of this paragraph must [~~shall~~] be made and maintained as specified in [~~accordance with~~] subsection (v)(1) of this section.

(9) All reciprocal recognition of certificates of registration by the department are [~~agency will be~~] granted as specified in [~~accordance with~~] §289.226(s) of this chapter [~~title~~].

(u) Radiation safety and licensing requirements for the use of sealed sources.

(1) Licensing requirements for industrial radiographic operations.

(A) Sealed sources used in industrial radiographic operations must [~~shall~~] be licensed as specified in [~~accordance with~~] §289.252 of this subchapter [~~title~~].

(B) In addition to the licensing requirements in §289.252 of this subchapter [~~title~~], an application for a license must [~~shall~~] include [~~the following information~~].

(i) A schedule or description of the program for training radiographic personnel specifying [~~that specifies~~]:

(I) initial training;

(II) annual refresher training;

(III) on-the-job training;

(IV) procedures for administering the oral and written examinations to determine the knowledge, understanding, and ability of radiographic personnel to comply with the requirements of this chapter, the conditions of the license, and the licensee's operating, safety, and emergency procedures; and

(V) procedures for administering the practical examination to demonstrate competence in the use of sources of radiation, radiographic exposure devices, related handling tools, and radiation survey instruments [~~that may be~~] employed in industrial radiographic assignments.

(ii) Written operating, safety, and emergency procedures [~~that~~] are made available to each individual operating a sealed source in radiographic operations, including any restrictions of the operating technique required for the safe operation of the particular sealed source.

(I) The licensee must [~~shall~~] document [~~that~~] each individual operating a sealed source in radiographic operations has read the operating and safety procedures and must [~~shall~~] maintain this documentation for inspection by the department [~~agency~~]. The documentation must [~~shall~~] include [~~the following~~]:

(-a-) name and signature of the individual;

(-b-) date the individual read the operating and safety procedures; and

(-c-) initials of the RSO.[~~;~~]

(II) The operating and safety procedures must [~~shall~~] include[~~, but are not limited to,~~] the items listed in subsection (x)(3) of this section.[~~;~~]

(iii) A description of the internal audit program to ensure [~~that~~] radiographic personnel follow the requirements of this chapter, the conditions of the license, and the licensee's operating, safety, and emergency procedures at intervals not to exceed six months.

(iv) A list and description of all field stations and permanent radiographic installations.[~~, descriptions of permanent storage and use sites, and the location(s) where all records required by this~~

section and other sections of this chapter will be maintained. If records are to be maintained at a headquarters office in Texas and no use or storage is authorized for the site, this site will be designated as the main site. Radioactive material shall not be stored or used at a permanent use site unless such site is specifically authorized by the license. Any licensee conducting radiographic operations or storing radioactive material at any location not listed on the license for a period in excess of 180 days in a calendar year, shall notify the agency prior to exceeding the 180 days. A storage site is permanent if radioactive material is stored at that location and if any one or more of the following applies:]

[(I) the licensee establishes telephone service that is used for contracting or providing industrial radiographic services for the licensee;]

[(II) industrial radiographic services are advertised for or from the site;]

[(III) radioactive material stored at that location is used for industrial radiographic operations conducted at other sites; or]

[(IV) the licensee conducts radiographic operations or stores radioactive material at any location not listed on the license for a period in excess of 180 days in a calendar year.]

(v) A description of the organization of the industrial radiographic program, including delegations of authority and responsibility for operation of the radiation safety program.

(vi) A description of the program for inspection and maintenance of radiographic exposure devices and transport and storage containers, including items in subsection (x)(2) of this section and the applicable items in subsection (m) of this section.

(vii) If a license application includes underwater radiography, as a minimum, a description of:

(I) radiation safety procedures and radiographer responsibilities unique to the performance of underwater radiography;

(II) radiographic equipment and radiation safety equipment unique to underwater radiography; and

(III) methods for gas-tight encapsulation of equipment.

(viii) If a license application includes offshore platform or [and/or] lay-barge radiography, as a minimum, a description of:

(I) transport procedures for radioactive material to be used in industrial radiographic operations;

(II) storage areas [facilities] for radioactive material; and

(III) methods for restricting access to radiation areas.[;]

(ix) Procedures [for] verifying and documenting the certification status of radiographers and [for] ensuring that the certification of individuals acting as radiographers remains valid.

(x) If the applicant intends to perform leak testing of sealed sources or exposure devices containing DU shielding, the applicant must [shall] describe the procedures for performing the leak test and the qualifications of the person authorized to do the leak test.

(xi) If the applicant intends to analyze its own wipe samples, the application must [shall] include a description of the procedures to be followed. The description must [shall] include [at least the following]:

(I) instruments to be used;

(II) methods of performing the analysis; and

(III) pertinent experience of the individual or individuals analyzing [person(s) who will analyze] the wipe samples.[; and]

(xii) If the applicant intends to perform "in-house" calibrations of survey instruments, the applicant must [shall] describe methods to be used and the relevant experience of the individual or individuals performing [person(s) who will perform] the calibrations. All calibrations must [shall] be performed as specified in [accordance with] subsection (j) of this section.

(C) A license is [will be] issued if the requirements of this paragraph [of this subsection] and §289.252 of this subchapter [title] are met.

(2) Limits on external radiation levels from storage containers and source changers. The maximum exposure rate limits for storage containers and source changers are 200 mrem/hr (2 mSv/hr) at any exterior surface, and 10 mrem/hr (0.1 mSv/hr) at 1 meter from any exterior surface with the sealed source in the shielded position.

(3) Locking of radiographic exposure devices, storage containers, and source changers.

(A) Each radiographic exposure device, storage container, and source changer must [shall] have a lock or outer locked container designed to prevent unauthorized or accidental removal or exposure of a sealed source. Each exposure device and source changer must [shall] be kept locked and, if a keyed lock, the key removed [at all times] except when under the direct visual surveillance of a radiographer or an individual specifically authorized by the department [agency], except at a permanent radiographic installation.

(B) Each radiographic exposure device, storage container, and source changer must [shall] be locked and the key removed from any keyed lock before [prior to] being transported from one location to another and before [also prior to] being stored at a given location.

(4) Permanent storage precautions for the use of sealed sources.

(A) Radiographic exposure devices, source changers, and transport containers containing [that contain] sealed sources must [shall] be secured while in storage to prevent tampering or removal by unauthorized individuals.

(B) Radiographic exposure devices, source changers, or transport containers containing [that contain] radioactive material must [may] not be stored in residential locations unless specifically authorized by the department. [This section does not apply to storage of radioactive material in a vehicle in transit for use at temporary job sites, if the licensee complies with paragraph (9)(G) of this subsection and if the vehicle does not constitute a permanent storage location as described in paragraph (1)(B)(iv) of this subsection.]

(5) Performance requirements for industrial radiography equipment. Equipment used in industrial radiographic operations must [shall] meet the following minimum criteria.

(A) Each radiographic exposure device, source assembly, sealed source, and associated equipment must [shall] meet the criteria set forth by ANSI N432-1980. This publication is available online at http://pbadupws.nrc.gov/docs/ML0508/ML050840139.pdf and may be purchased from the American National Standards Institute, Inc., 25 West 43rd Street, New York, New York 10036; Telephone (212) 642-4900.

(i) All newly manufactured radiographic exposure devices and associated equipment acquired by licensees after September 1, 1993, must [~~shall~~] comply with the requirements of this section.

(ii) All radiographic exposure devices and associated equipment in use after January 1, 1996, must [~~shall~~] comply with the requirements of this section.

(iii) In lieu of subparagraph (A) of this paragraph, equipment used in industrial radiographic operations need not comply with §8.9.2(c) of the Endurance Test in ANSI N432-1980, if the prototype equipment has been tested using a torque value representative of the torque [~~that~~] an individual using the radiography equipment can realistically exert on the lever or crankshaft of the drive mechanism.

(B) Engineering analysis may be submitted by a licensee to demonstrate the applicability of previously performed testing on similar individual radiography equipment components. Upon review, the department [~~agency~~] may find this an acceptable alternative to actual testing of the component as specified in [~~accordance with~~] subparagraph (A) of this paragraph.

(C) In addition to the requirements specified in subparagraph (A) of this paragraph the following requirements apply to radiographic exposure devices, source changers, source assemblies, and sealed sources.

(i) Radiographic exposure devices intended for use as Type B transport containers must [~~shall~~] meet the applicable requirements of §289.257 of this subchapter [~~title~~].

(ii) Modification of radiographic exposure devices, source changers, source assemblies, and associated equipment is prohibited, unless the design of any replacement component, including source holder, source assembly, controls, or guide tubes does [~~would~~] not compromise the design safety features of the system.

(D) In addition to the requirements specified in subparagraphs (A) - (C) of this paragraph, radiographic exposure devices, source assemblies, and associated equipment allowing [~~that allow~~] the source to move outside the device must [~~shall~~] meet the following criteria.

(i) The source assembly must [~~shall~~] be designed so [~~that~~] the source does [~~will~~] not become disconnected if cranked outside the guide tube. The source assembly [~~shall be such that it~~] cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.

(ii) The control cable must [~~shall~~] be positively connected to the source assembly before the source assembly can be driven out of the fully shielded position in a radiographic exposure device or source changer.

(iii) The radiographic exposure device must [~~shall~~] automatically secure the source assembly when it is cranked back into the fully shielded position within the radiographic exposure device. This securing system may [~~shall~~] only be released by means of a deliberate operation on the radiographic exposure device.

(iv) The outlet nipple, lock box, and control cable fittings of each radiographic exposure device must [~~shall~~] be equipped with safety plugs or covers installed during storage and transportation to [~~that will~~] protect the source assembly from damage and from other foreign matter, such as water, mud, or sand[~~, during storage and transportation~~].

(v) Each sealed source or source assembly must [~~shall~~] have attached to it or engraved on it, a durable, legible, visible label with the words "DANGER. RADIOACTIVE." The label may not interfere with the safe operation of the exposure device or associated equipment.

(vi) Guide tubes must [~~shall~~] be used when moving the source out of the radiographic exposure device.

(vii) Guide tubes must [~~shall~~] be able to withstand a crushing test [~~that~~] closely approximating [~~approximates~~] the crushing forces [~~that are~~] likely to be encountered during use, and be able to withstand a kinking resistance test [~~that~~] closely approximating [~~approximates~~] the kinking forces [~~that are~~] likely to be encountered during use.

(viii) An exposure head, endcap, or similar device designed to prevent the source assembly from extending beyond the end of the guide tube must [~~shall~~] be attached to the outermost end of the guide tube during radiographic operations.

(ix) The guide tube exposure head connection must [~~shall~~] be able to withstand the tensile test for control units as specified in ANSI N432-1980.

(x) Source changers must [~~shall~~] provide a system for ensuring [~~that~~] the source is [~~will~~] not [~~be~~] accidentally withdrawn from the changer when connecting or disconnecting the control cable to or from a source assembly.

(6) Leak testing, repair, opening, and replacement of sealed sources and devices. Leak testing, repair, opening, and replacement of sealed sources and devices must [~~shall~~] be performed according to the following criteria.

(A) Leak testing of sealed sources must [~~shall~~] be done as specified in [~~accordance with~~] §289.201(g) of this chapter [~~title~~], except records of leak tests must [~~shall~~] be maintained as specified in [~~accordance with~~] subsection (v)(1) of this section.

(B) The replacement, leak testing analysis, repair, opening, or any modification of a sealed source must [~~shall~~] be performed only by persons specifically authorized to do so by the department [~~agency~~], the NRC, or another agreement state.

(C) Each exposure device using DU shielding and an "S" tube configuration must [~~shall~~] be tested for DU contamination.

(i) Tests for DU contamination must [~~shall~~] be performed at intervals not to exceed 12 months.

(ii) The analysis must [~~shall~~] be capable of detecting the presence of 0.005 microcuries (185 becquerels (Bq)) [~~(185 Bq)~~] of radioactive material on the test sample and must [~~shall~~] be performed by a person specifically authorized by the department [~~agency~~], the NRC, or an agreement state to perform the analysis.

(iii) Should such testing reveal the presence of DU contamination, the exposure device must [~~shall~~] be removed from use until an evaluation of the wear of the S-tube has been made.

(iv) Should the evaluation reveal [~~that~~] the S-tube is worn through, the device may not be used again.

(v) DU-shielded [~~DU shielded~~] devices do not have to be tested for DU contamination while in storage and not in use.

(vi) The device must [~~shall~~] be tested for DU contamination before using or transferring the [~~such a~~] device, if the interval of storage exceeds 12 months.

(D) A record of the DU leak test must [~~shall~~] be made and maintained as specified in [~~accordance with~~] subsection (v)(1) of this section.

(7) Labeling and storage.

(A) Each transport container must [~~shall~~] have permanently attached to it a durable, legible, clearly visible label having [~~label(s) that has~~], at [~~as~~] a minimum, the standard trefoil radiation caution symbol conventional colors[~~,~~] (for example, magenta, purple, or black on a yellow background), having a minimum diameter of 25 millimeters, and the following wording: "CAUTION. RADIOACTIVE MATERIAL. NOTIFY CIVIL AUTHORITIES (OR NAME OF COMPANY)" or "DANGER. RADIOACTIVE MATERIAL. NOTIFY CIVIL AUTHORITIES (OR NAME OF COMPANY)." In addition, transport containers must [~~shall~~] meet applicable requirements of the DOT.

(B) Radiographic exposure devices, source changers, and storage containers must [~~shall~~] be physically secured to prevent tampering or removal by unauthorized personnel. The licensee must [~~shall~~] store radioactive material in a manner that will minimize danger from explosion or fire.

(C) The licensee must [~~shall~~] lock and physically secure the transport package containing radioactive material in the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal.

(D) The licensee's name and city or town of an authorized use site listed on the license must [~~shall~~] be prominently displayed with a durable, legible, and clearly visible label [~~label(s)~~] on both sides of all vehicles used to transport radioactive material for temporary job site use.

(E) The licensee must [~~shall~~] ensure [~~that~~] each radiographic exposure device has attached to it a durable, legible, and clearly visible label bearing [~~the following~~]:

(i) the chemical symbol and mass number of the radionuclide in the device;

(ii) the activity and the date on which this activity was last measured;

(iii) the manufacturer, model, and serial number of the sealed source;

(iv) the licensee's name, address, and telephone number; and

(v) at [~~as~~] a minimum, the standard radiation caution symbol as defined in §289.202 of this chapter [~~title~~], and the following wording: "CAUTION. RADIOACTIVE MATERIAL--DO NOT HANDLE. NOTIFY CIVIL AUTHORITIES (OR NAME OF COMPANY)" or "DANGER. RADIOACTIVE MATERIAL--DO NOT HANDLE. NOTIFY CIVIL AUTHORITIES (OR NAME OF COMPANY)."

(F) Each radiographic exposure device must [~~shall~~] have a permanently stamped, legible, and clearly visible unique serial number.

(8) Operating and internal audit requirements for the use of sealed sources of radiation.

(A) Each licensee must [~~shall~~] conduct an internal audit program to ensure [~~that~~] the requirements of this chapter, the conditions of the license, and the licensee's operating, safety, and emergency procedures are followed by radiographic personnel.

(B) Each radiographer's and radiographer trainee's performance during an actual radiographic operation must [~~shall~~] be audited and documented at intervals not to exceed six months.

(C) If a radiographer or a radiographer trainee has not participated in a radiographic operation during the six months since the last audit, the radiographer or the radiographer trainee must [~~shall~~] demonstrate knowledge of the training requirements of subsection (f)(1) of this section by an oral or written and practical examination administered by the licensee before these individuals can next participate in a radiographic operation.

(D) The department [~~agency~~] may consider alternatives in those situations where the individual serves as both radiographer and RSO.

(E) In those operations where a single individual serves as both radiographer and RSO, and performs all radiography operations, an audit program is not required.

(F) Each licensee must [~~shall~~] provide annual refresher safety training, as defined in subsection (c) of this section, for each radiographer and radiographer trainee at intervals not to exceed 12 months.

(G) Whenever radiographic operations are performed at a location other than a permanent radiographic installation, the radiographer must be accompanied by at least one other qualified radiographer or an individual who has, at minimum, met the requirements of subsection (e)(1) of this section. The additional qualified individual must observe the operations and be capable of providing immediate assistance to prevent unauthorized entry. Radiographic operations must not be performed if only one qualified individual is present.

[~~(G) Each licensee shall provide, as a minimum, two radiographic personnel for each exposure device in use for any industrial radiography conducted at a location other than at a permanent radiographic installation (shielded room, bay, or bunker) meeting the requirements of subsection (n)(1) of this section. If one of the personnel is a radiographer trainee, the other shall be a radiographer trainer authorized by the license.~~]

(H) Collimators must [~~shall~~] be used in industrial radiographic operations using [~~that use~~] crank-out devices except when physically impossible.

(I) Individuals [~~No individual~~] other than a radiographer or a radiographer trainee, [~~who is~~] under the personal supervision of a radiographer trainer, must not [~~shall~~] manipulate controls or operate radiographic exposure devices and associated equipment used in industrial radiographic operations.

(J) All radiographic operations conducted at locations of use authorized on the license must be conducted in a permanent radiographic installation, unless specifically authorized by the department.

[~~(J) Radiographic operations shall not be conducted at storage sites unless specifically authorized by the license.~~]

(K) Records of annual refresher training and audits of job performance specified in this subsection must [~~shall~~] be made and maintained as specified in [~~accordance with~~] subsection (v)(1) of this section.

(L) Records of annual refresher safety training and audits of job performance made as specified in [~~accordance with~~] this subsection must [~~shall~~] include [~~the following~~]:

(i) list of the topics discussed during the refresher safety training;

(ii) dates the annual refresher safety training was conducted;

(iii) names of the instructors and attendees; and

(iv) for audits of job performance, the records must [~~shall~~] also include a list showing the items checked and any non-compliance observed by the RSO or designee.

(9) Radiation surveys for the use of sealed sources of radiation.

(A) Industrial radiographic operations must not [~~No industrial radiographic operation shall~~] be conducted unless at least one calibrated and operable radiation survey instrument, as described in subsection (j) of this section, is used at each site where radiographic exposures are made.

(B) A survey with a radiation survey instrument meeting the requirements of subsection (j)(1) - (3) of this section must [~~shall~~] be made after each radiographic exposure to determine [~~that~~] the sealed source has been returned to its fully shielded position, and before exchanging films, repositioning the exposure head, or dismantling equipment. The entire circumference of the radiographic exposure device must [~~shall~~] be surveyed. If the radiographic exposure device has a source guide tube, the survey must [~~shall~~] also include the source guide tube and any collimator.

(C) All potential radiation areas where industrial radiographic operations are [~~to be~~] performed must [~~shall~~] be posted as specified in [~~accordance with~~] subsection (r) of this section, based on calculated dose rates, before industrial radiographic operations begin. An area survey must [~~shall~~] be performed during the first radiographic exposure (for example, with the sealed source in the exposed position) to confirm [~~that~~] the requirements of subsection (r) of this section have been met.

(D) Each time re-establishment of the restricted area is required, the requirements of subparagraph (C) of this paragraph must [~~shall~~] be met.

(E) The requirements of subparagraph (D) of this paragraph do not apply to pipeline industrial radiographic operations when the conditions of exposure, including[~~, but not limited to,~~] the radiographic exposure device, duration of exposure, source strength, pipe size, and pipe thickness, remain constant.

(F) A lock-out survey, in which all accessible surfaces of the radiographic exposure device or source changer are surveyed, must [~~shall~~] be performed.

(G) Surveys must [~~shall~~] be performed in the storage area [~~location~~] to ensure [~~that~~] radiation levels do not exceed the limits specified in §289.202(n)(1) of this chapter [~~title~~]. These surveys must [~~shall~~] be performed initially with the maximum amount of radioactive material present in the storage area [~~location~~] and thereafter at the time of the quarterly inventory and whenever storage conditions change.

(H) A survey meeting the requirements of subparagraph (B) of this paragraph must [~~shall~~] be performed on the radiographic exposure device and the source changer after every sealed source exchange.

(I) Records of the surveys required by subparagraphs (C), (D), and (F) - (H) of this paragraph must [~~shall~~] be made and maintained as specified in [~~accordance with~~] subsection (v)(1) of this section. If a survey was used to determine an individual's exposure due to loss of personnel monitoring data, the records of the survey must [~~shall~~] be maintained for [~~agency~~] inspection by the department until disposal is authorized by the department [~~agency~~].

(10) Requirements for shielded rooms containing sealed sources.

(A) Shielded rooms containing sealed sources must [~~shall~~] comply with all applicable requirements of this section.

(B) Shielded rooms containing sealed sources must [~~shall~~] be evaluated at intervals not to exceed one year to ensure compliance with the applicable requirements of this section and §289.202(n)(1) - (3) of this chapter [~~title~~].

(C) Tests for proper operation of interlocks must [~~shall~~] be conducted and recorded as specified in [~~accordance with~~] subsection (n) of this section.

(D) Records of evaluations required by subparagraph (B) of this paragraph must [~~shall~~] be made and maintained as specified in [~~accordance with~~] subsection (v)(1) of this section.

(E) Records of interlock tests required by subparagraph (C) of this paragraph must [~~shall~~] be made and maintained as specified in [~~accordance with~~] subsection (v)(1) of this section.

(11) Underwater, offshore platform, and lay-barge radiography.

(A) Underwater, offshore platform, and [~~and/or~~] lay-barge radiography must [~~shall~~] not be performed unless specifically authorized in a license issued by the department as specified [~~agency~~] in [~~accordance with~~] paragraph (1) of this subsection.

(B) In addition to the other requirements of this section, the following requirements apply to the performance of offshore platform or lay-barge radiography.

(i) Cobalt-60 sources with activities more than [~~in excess of~~] 20 curies (Ci) (nominal) (3.7 terabecquerels) and iridium-192 sources with activities more than [~~in excess of~~] 100 Ci [~~curies~~] (nominal) (740 gigabecquerels) must [~~shall~~] not be used in the performance of offshore platform or lay-barge radiography.

(ii) Collimators must [~~shall~~] be used for all industrial radiographic operations performed on offshore platforms or lay-barges.

(12) Prohibitions.

(A) Industrial radiography performed with a sealed source [~~that is~~] not fastened to or contained in a radiographic exposure device (fishpole technique) is prohibited unless specifically authorized in a license issued by the department [~~agency~~].

(B) Retrieval of disconnected sources or sources that cannot be returned by normal means to a fully shielded position or automatically secured in the radiographic exposure device must [~~, shall~~] not be performed unless specifically authorized by a license condition.

(13) All reciprocal recognition of licenses by the department are [~~agency will be~~] granted as specified in [~~accordance with~~] §289.252(ee) of this subchapter [~~title~~].

(v) Record/document requirements. Each licensee and registrant must [~~shall~~] maintain the following records/documents at each site at the time intervals specified and make them available to the department [~~agency~~] for inspection.

(1) Time requirements for record keeping. The following are time requirements for record keeping.
Figure: 25 TAC §289.255(v)(1)
[~~Figure: 25 TAC §289.255(v)(1)~~]

(2) Records and documents required at additional authorized use/storage sites.

(A) Each licensee or registrant maintaining additional authorized use/storage sites where industrial radiography operations are performed must [~~shall~~] maintain copies of the following records

and documents specific to that site available at each site for inspection by the department [agency] for a period of three years:

(i) a copy of the appropriate license or certificate of registration authorizing the use of licensed or registered sources of radiation;

(ii) operating, safety, and emergency procedures as specified in [accordance with] subsection (x)(3) of this section;

(iii) applicable sections of this chapter as listed in the license or certificate of registration;

(iv) records of receipt, transfer, and disposal of sources of radiation and devices using DU for shielding at the additional site as specified in [accordance with] subsection (i) of this section;

(v) records of the latest survey instrument calibrations in use at the site as specified in [accordance with] subsection (j) of this section;

(vi) records of the latest calibrations of alarming ratemeters and operational checks of pocket dosimeters and [and/or] electronic personal dosimeters as specified in [accordance with] subsection (p) of this section;

(vii) inventories as specified in [accordance with] subsection (k) of this section;

(viii) utilization records for each radiographic exposure device and radiation machine dispatched from that location as specified in [accordance with] subsection (l) of this section;

(ix) records of equipment problems identified in daily checks of equipment as specified in [accordance with] subsection (m) of this section, if applicable;

(x) records of alarm systems and entrance control checks as specified in [accordance with] subsection (n) of this section;

(xi) training records as specified in [accordance with] subsection (f) of this section;

(xii) records of direct-reading dosimeter readings as specified in [accordance with] subsection (p) of this section;

(xiii) audits as specified in [accordance with] subsections (t)(5)(A) - (C) and (u)(8)(A) - (C) of this section;

(xiv) latest radiation survey records as specified in [accordance with] subsections (t)(6)(D) and (u)(9)(I) of this section;

(xv) records of interlock testing as specified in [accordance with] subsections (t)(8)(A)(ii) and (u)(10)(C) of this section;

(xvi) records of annual evaluation of cabinet x-ray systems as specified in [accordance with] subsection (t)(7)(C) of this section;

(xvii) records of leak tests for specific devices and sources at the additional site as specified in [accordance with] subsection (u)(6) of this section;

(xviii) shipping papers for the transportation of sources of radiation as specified in [accordance with] §289.257 of this subchapter [title];

(xix) a copy of the NRC license, agreement state license, or state certificate of registration authorizing the use of sources of radiation, when operating under reciprocity as specified in [accordance with] §289.226 of this chapter [title] and §289.252 of this subchapter [title]; and

(xx) individual monitoring records as specified in [accordance with] subsection (p) of this section.

(B) The following records required for each additional authorized use site as specified in [accordance with] this subsection must [shall] also be maintained at the main authorized site:

(i) records of receipt, transfer, and disposal of sources of radiation and devices using DU for shielding at the additional site as specified in [accordance with] subsection (i) of this section;

(ii) inventories as specified in [accordance with] subsection (k) of this section; and

(iii) individual monitoring records as specified in [accordance with] subsection (p) of this section.

(3) Records required at temporary job sites. Each licensee and registrant conducting industrial radiography at a temporary job site must [shall] have the following records available at that site for [agency] inspection by the department:

(A) a copy of the appropriate license or certificate of registration or equivalent document authorizing the use of sources of radiation;

(B) operating, safety, and emergency procedures as specified in [accordance with] subsection (x)(3) of this section;

(C) applicable sections of this chapter as listed in the license or certificate of registration;

(D) latest radiation survey records required as specified in [accordance with] subsections (t)(6)(D) and (u)(9)(I) of this section for the period of operation at the site;

(E) the daily pocket dosimeter records for the period of operation at the site;

(F) utilization records for each radiographic exposure device or radiation machine used at that location as specified in [accordance with] subsection (l) of this section;

(G) the latest instrument calibration and leak test records for devices at the site. Acceptable records include tags or labels [that are] attached to the devices or survey instruments and decay charts for sources [that have been] manufactured within the last six months; and

(H) a copy of the NRC license, agreement state license, or state certificate of registration authorizing the use of sources of radiation, when operating under reciprocity as specified in [accordance with] §289.226 of this chapter [title] or §289.252 of this subchapter [title].

(w) Form of records. Each record required by this chapter must include all pertinent information and be stored in a legible and reproducible format throughout the specified retention period. The licensee or registrant must maintain adequate safeguards against tampering with and loss of records.

[(1) Each record required by this section shall be legible throughout the specified retention period.]

[(2) The record shall be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of reproducing a clear copy throughout the required retention period.]

[(3) The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period.]

[(4) Records, such as letters, drawings, and specifications, shall include all pertinent information, such as stamps, initials, and signatures.]

[(5) The licensee or registrant shall maintain adequate safeguards against tampering with and loss of records.]

(x) Appendices.

(1) Subjects to be included in training courses for radiographer trainees. Training provided to qualify individuals as radiographer trainees in compliance with subsection (e)(1)(A) of this section must [shall] be presented on a formal basis. The training must [shall] include the following subjects.

(A) Fundamentals of radiation safety, including [to include the following]:

(i) characteristics of radiation;

(ii) units of radiation dose in rem [rems] (sieverts) and quantity of radioactivity in curies (becquerels);

(iii) significance of radiation dose, including [to include]:

(I) radiation protection standards;

(II) biological effects of radiation dose;

(III) hazards of exposure to radiation; and

(IV) case histories of radiography accidents;

(iv) levels of radiation from sources of radiation; and

(v) methods of controlling radiation dose, including [to include]:

(I) working time;

(II) working distances; and

(III) shielding.

(B) Radiation detection instrumentation, including [to include the following]:

(i) use, operation, calibration, and limitations of radiation survey instruments;

(ii) survey techniques; and

(iii) use of individual monitoring devices.

(C) Radiographic equipment to be used, including [the following]:

(i) remote handling equipment;

(ii) operation and control of radiographic exposure devices and sealed sources, including pictures or models of source assemblies (pigtails);

(iii) storage and transport containers, source changers;

(iv) operation and control of x-ray equipment;

(v) collimators;

(vi) storage, control, and disposal of radioactive material; and

(vii) inspection and maintenance of equipment.

(D) Requirements of pertinent federal and state regulations.

(E) Generic written operating, safety, and emergency procedures (see subsection (x)(3) of this section).

(2) General requirements for inspection of industrial radiographic equipment.

(A) Radiographic exposure devices must [shall] be inspected for:

(i) abnormal surface radiation levels anywhere on camera, collimator, or guide tube;

(ii) condition of safety plugs;

(iii) proper operation of locking mechanism;

(iv) condition of pigtail connector;

(v) condition of carrying device (straps, handle, etc.); and

(vi) proper and legible labeling.

(B) Guide tubes must [shall] be inspected for:

(i) rust, dirt, or sludge buildup inside the guide tube;

(ii) condition of guide tube connector;

(iii) condition of source stop; and

(iv) kinks or damage that could prevent proper operation.[; and]

[(v) presence of radioactive contamination.]

(C) Control cables and drive mechanisms must [shall] be inspected for:

(i) proper drive mechanism with camera, as appropriate;

(ii) changes in general operating characteristics;

(iii) condition of connector on control cable;

(iv) control cable flexibility, wear, and rust;

(v) excessive wear or damage to crank-out devices;

(vi) damage to control cable conduit that could prevent the cable from moving freely;

(vii) proper connector mating between the control cable and the pigtail; and

(viii) proper operation of source position indicator, if applicable.[; and]

[(ix) presence of radioactive contamination.]

(D) Pipeliners must [shall] be inspected for:

(i) abnormal surface radiation;

(ii) changes in the general operating characteristics of the unit;

(iii) proper operation of shutter mechanism;

(iv) chafing or binding of shutter mechanism;

(v) damage to the device that might impair its operation;

(vi) proper operation of locking mechanism;

(vii) proper drive mechanism with camera, as appropriate;

(viii) condition of carrying device (strap, handle, etc.); and

(ix) proper and legible labeling.

(E) X-ray equipment must [~~shall~~] be inspected for:

(i) change in the general operating characteristics of the unit;

(ii) wear of electrical cables and connectors;

(iii) proper and legible labeling of console;

(iv) proper console with machine, as appropriate;

(v) proper operation of locking mechanism;

(vi) proper operation of timer run-down cutoff; and

(vii) damage to tube head housing that might result in excessive radiation levels.

(3) Operating, safety, and emergency procedures. The licensee's or registrant's operating, safety, and emergency procedures must [~~shall~~] include instructions in [~~at least the following~~]:

(A) handling and use of sources of radiation for industrial radiography so [~~such that~~] no individual is likely to be exposed to radiation doses more than [~~that exceed~~] the limits established in §289.202 of this chapter [~~title~~];

(B) methods and occasions for conducting radiation surveys, including lock-out survey requirements;

(C) methods for controlling access to industrial radiography areas;

(D) methods and occasions for locking and securing sources of radiation;

(E) personnel monitoring and the use of personnel monitoring equipment, including steps to be taken immediately, by industrial radiographic personnel, in the event a pocket dosimeter is found to be off-scale (see subsection (p)(2)(G) of this section);

(F) methods of transporting equipment to field locations, including packing of sources of radiation in the vehicles, placarding of vehicles, and controlling of sources of radiation during transportation, including applicable DOT requirements;

(G) methods [~~or procedures~~] for minimizing exposure of individuals in the event of an accident, including procedures for a disconnect accident, a transportation accident, and loss of a sealed source;

(H) [~~procedures for~~] notifying proper personnel in the event of an accident;

(I) specific posting requirements;

(J) maintenance of records (see subsection (v)(1) of this section);

(K) inspection, maintenance, and operational checks of radiographic exposure devices, source changers, storage containers, transport containers, source guide tubes, crank-out devices, and radiation machines;

(L) method of testing and training as specified in [~~accordance with~~] subsections (e) and (f) of this section; and

(M) source recovery [~~procedures~~] if the licensee is authorized to perform source recovery.

§289.256. Medical and Veterinary Use of Radioactive Material.

(a) Purpose.

(1) This section establishes requirements for [~~the~~] medical and veterinary use of radioactive material and [~~for~~] the issuance of specific licenses authorizing [~~the~~] medical and veterinary use of radioactive material. Unless otherwise exempted, persons must not [~~no person shall~~] manufacture, produce, receive, possess, use, transfer, own, or acquire radioactive material for medical or veterinary use except as authorized in a license issued as specified in [~~accordance with~~] this section.

(2) A person who manufactures, produces, receives, possesses, uses, transfers, owns, or acquires radioactive material before [~~prior to~~] receiving a license is subject to the requirements of this chapter.

(3) A specific license is not needed for a person who:

(A) receives, possesses, uses, or transfers radioactive material as specified in [~~accordance with the regulations in~~] this chapter under the supervision of an authorized user as provided in subsection (s) of this section, unless prohibited by license condition; or

(B) prepares unsealed radioactive material for medical or veterinary use as specified in [~~accordance with the regulations in~~] this chapter under the supervision of an authorized nuclear pharmacist or authorized user as provided in subsection (s) of this section, unless prohibited by license condition.

(b) Scope.

(1) In addition to the requirements of this section, all licensees, unless otherwise specified, are subject to the requirements of:

(A) §289.201 of this chapter [~~title~~] (relating to General Provisions for Radioactive Material);[~~,~~]

(B) §289.202 of this chapter [~~title~~] (relating to Standards for Protection Against Radiation from Radioactive Materials);[~~,~~]

(C) §289.203 of this chapter [~~title~~] (relating to Notices, Instructions, and Reports to Workers; Inspections);[~~,~~]

(D) §289.204 of this chapter [~~title~~] (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services) ;[~~,~~]

(E) §289.205 of this chapter [~~title~~] (relating to Hearing and Enforcement Procedures);[~~,~~]

(F) §289.252 of this subchapter [~~title~~] (relating to Licensing of Radioactive Material);[~~,~~] and

(G) §289.257 of this subchapter [~~title~~] (relating to Packaging and Transportation of Radioactive Material).

(2) Veterinarians who receive, possess, use, transfer, own, or acquire radioactive material in the practice of veterinary medicine must [~~shall~~] comply with the requirements of this section except for subsections (d), (dd), and (uuu) of this section.

(3) An entity that is a "covered entity" as that term is defined in HIPAA (the Health Insurance Portability and Accountability Act of 1996, 45 Code of Federal Regulations (CFR) [~~Title 45, Code of Federal Regulations (CFR),~~] Parts 160 and 164) may be subject to privacy standards governing how information identifying [~~that identifies~~] a patient can be used and disclosed. Failure to follow HIPAA requirements may result in the department making a referral of a potential violation to the United States Department of Health and Human Services.

(4) In accordance with the requirements of the Texas Medical Board, 22 Texas Administrative Code (TAC) [~~Title 22, Texas Ad-~~

ministrative Code (TAC),] Chapter 160, medical licensees must use the services of a licensed medical physicist for activities falling within the medical physicist scope of practice as identified in 22 TAC §160.17 unless exempted under 22 TAC §160.5.

(c) Definitions. The following words and terms when used in this section [shall] have the following meaning unless the context clearly indicates otherwise.

(1) Address of use--The building or buildings [that are] identified on the license [and] where radioactive material may be prepared, received, used, or stored.

(2) Area of use--A portion of an address of use [that has been] set aside for the purpose of preparing, receiving, using, or storing radioactive material.

(3) Associate radiation safety officer (ARSO)--An individual who:

(A) meets the requirements in subsections (h) and (m) of this section; and

(B) is currently identified as an ARSO for the types of use of radioactive material for which the individual has been assigned duties and tasks by the radiation safety officer (RSO) on:

(i) a specific medical or veterinary use license issued by the department, the United States Nuclear Regulatory Commission (NRC), or an agreement state; or

(ii) a medical use permit issued by an NRC master material licensee.

(4) Authorized medical physicist--An individual who [meets the following]:

(A) meets the requirements in subsections (j) and (m) of this section; or

(B) is identified as an authorized medical physicist or teletherapy physicist on [one of the following]:

(i) a specific medical or veterinary use license issued by the department, the NRC, or an agreement state;

(ii) a medical use permit issued by an NRC master material licensee;

(iii) a permit issued by an NRC[,] or agreement state broad scope medical use licensee; or

(iv) a permit issued by an NRC master material license broad scope medical use permittee; and

(C) holds a current Texas license under the Medical Physics Practice Act, Texas Occupations Code[,] Chapter 602, in therapeutic radiological physics for uses in subsections (rr) and (ddd) of this section.

(5) Authorized nuclear pharmacist--A pharmacist who [meets the following]:

(A) meets the requirements in subsections (k) and (m) of this section; or

(B) is identified as an authorized nuclear pharmacist on [one of the following]:

(i) a specific license issued by the department, the NRC, or an agreement state authorizing [that authorizes] medical use or the practice of nuclear pharmacy;

(ii) a permit issued by an NRC master material licensee authorizing [that authorizes] medical use or the practice of nuclear pharmacy;

(iii) a permit issued by the department, the NRC, or an agreement state licensee of broad scope authorizing [that authorizes] medical use or the practice of nuclear pharmacy; or

(iv) a permit issued by an NRC master material license broad scope medical use permittee authorizing [that authorizes] medical use or the practice of nuclear pharmacy; or

(C) is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy [that has been] authorized to identify authorized nuclear pharmacists; or

(D) is designated as an authorized nuclear pharmacist as specified in [accordance with] §289.252(r) of this subchapter [title]; and

(E) holds a current Texas license under the Texas Pharmacy Act, Texas Occupations Code[,] Chapters 551 - 566, 568, and 569, as amended, and who is certified as an authorized nuclear pharmacist by the Texas State Board of Pharmacy.

(6) Authorized user--An authorized user is defined as follows:

(A) for human use, a physician licensed by the Texas Medical Board; or a dentist licensed by the Texas State Board of Dental Examiners; or a podiatrist licensed by the Texas State Board of Podiatric Medicine who:

(i) meets the requirements in subsection (m) and subsections (gg), (jj), (nn) - (qq), (zz), (aaa), (ccc), or (ttt) of this section; or

(ii) is identified as an authorized user on [any of the following]:

(I) a department [an agency], NRC, or agreement state license authorizing [that authorizes] the medical use of radioactive material;

(II) a permit issued by an NRC master material licensee authorizing [that is authorized to permit] the medical use of radioactive material;

(III) a permit issued by a specific licensee of broad scope issued by the department, the NRC, or an agreement state authorizing the medical use of radioactive material; or

(IV) a permit issued by an NRC master material licensee of broad scope authorizing [that is authorized to permit] the medical use of radioactive material.

(B) for veterinary use, an individual who is[,] a veterinarian licensed by the Texas State Board of Veterinary Medical Examiners; and

(i) is certified by the American College of Veterinary Radiology for the use of radioactive materials in veterinary medicine; or

(ii) has received training as specified in [accordance with] subsections (gg), (jj), (nn) - (qq), (zz), (aaa), (ccc), and (ttt) of this section as applicable; or

(iii) is identified as an authorized user on [any of the following]:

(I) a department [~~an agency~~], NRC, or agreement state license authorizing [~~that authorizes~~] the veterinary use of radioactive material;

(II) a permit issued by an NRC master material licensee authorizing [~~that is authorized to permit~~] the medical use of radioactive material;

(III) a permit issued by a specific licensee of broad scope issued by the department, the NRC, or an agreement state authorizing the medical or veterinary use of radioactive material; or

(IV) a permit issued by an NRC master material licensee of broad scope authorizing [~~that authorizes~~] the medical use of radioactive material.

(7) Brachytherapy--A method of radiation therapy in which plated, embedded, activated, or sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, intraluminal, or interstitial application.

(8) Brachytherapy sealed source--A sealed source or a manufacturer-assembled source train[~~,~~] or a combination of these sources [~~that is~~] designed to deliver a therapeutic dose within a distance of a few centimeters.

(9) High dose-rate remote afterloader--A device [~~that~~] remotely delivering [~~delivers~~] a dose rate more than [~~in excess of~~] 1200 rads (12 gray (Gy)) per hour at the point or surface where the dose is prescribed.

(10) Institutional Review Board (IRB)--Any board, committee, or other group formally designated by an institution and approved by the United States Food and Drug Administration (FDA) to review, approve the initiation of, and conduct periodic review of biomedical research involving human subjects.

(11) Low dose-rate remote afterloader--A device [~~that~~] remotely delivering [~~delivers~~] a dose rate of less than or equal to 200 rads (2 Gy) per hour at the point or surface where the dose is prescribed.

(12) Management--The chief executive officer or other individual delegated the authority to manage, direct, or administer the licensee's activities.

(13) Manual brachytherapy--A type of brachytherapy in which the sealed sources, for example, seeds and ribbons, are manually inserted either into the body cavities [~~that are~~] in close proximity to a treatment site or directly in the tissue volume.

(14) Medical event--An event meeting [~~that meets~~] the criteria in subsection (uuu)(1) of this section.

(15) Medical institution--An organization in which several medical disciplines are practiced.

(16) Medical use--The intentional internal or external administration of radioactive material, or the radiation from radioactive material, to patients or human research subjects under the supervision of an authorized user.

(17) Medium dose-rate afterloader--A device [~~that~~] remotely delivering [~~delivers~~] a dose rate greater than 200 rads (2 Gy) and less than or equal to 1200 rads (12 Gy) per hour at the point or surface where the dose is prescribed.

(18) Mobile nuclear medicine service--A licensed service authorized to transport radioactive material to, and medical or veterinary use of the material at, the client's address. Services transporting calibration sources only are not considered mobile nuclear medicine licensees.

(19) Ophthalmic physicist--An individual who:

(A) meets the requirements in subsections (m) and (xx)(1)(B) of this section; and

(B) is identified as an ophthalmic physicist on:

(i) a specific medical use license issued by the department, the NRC, or an agreement state;

(ii) a permit issued by a department [~~an agency~~], NRC, or agreement state broad scope medical use licensee;

(iii) a medical use permit issued by an NRC master material licensee; or

(iv) a permit issued by an NRC master material licensee broad scope medical use permittee.

(20) Output--The exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit, a brachytherapy source, a remote afterloader unit, or a gamma stereotactic radiosurgery unit, for a specified set of exposure conditions.

(21) Patient--A human or animal under medical care and treatment.

(22) Patient intervention--Actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

(23) Permanent facility--A building or buildings [~~that are~~] identified on the license within the State of Texas and where radioactive material may be prepared, received, used, or stored. This may also include an area or areas where administrative activities related to the license are performed.

(24) Preceptor--An individual who provides, directs, or verifies the training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, an RSO, or an ARSO.

(25) Prescribed dosage--The specified activity or range of activity of unsealed radioactive material as documented in a written directive or specified in [~~accordance with~~] the directions of the authorized user for procedures in subsections (ff) and (hh) of this section.

(26) Prescribed dose--Prescribed dose means [~~one of the following~~]:

(A) for gamma stereotactic radiosurgery, the total dose as documented in the written directive;

(B) for teletherapy, the total dose and dose per fraction as documented in the written directive;

(C) for brachytherapy, either the total sealed source strength and exposure time, or the total dose, as documented in the written directive; or

(D) for remote afterloaders, the total dose and dose per fraction as documented in the written directive.

(27) Pulsed dose-rate remote afterloader--A special type of remote afterloading device using [~~that uses~~] a single sealed source capable of delivering dose rates greater than 1200 rads (12 Gy) per hour, but is approximately one-tenth of the activity of typical high dose-rate remote afterloader sealed sources and is used to simulate the radiobiology of a low dose-rate [~~dose rate~~] remote afterloader treatment by inserting the sealed source for a given fraction of each hour.

(28) Radiation safety officer (RSO)--For purposes of this section, an individual who:

(A) meets the requirements in subsections (h) and (m) of this section; or

(B) is identified as an RSO on [~~one of the following~~]:

(i) a specific license issued by the department, the NRC, or an agreement state authorizing [~~that authorizes~~] the medical or veterinary use of radioactive material; or

(ii) a permit issued by an NRC master material licensee authorizing [~~that authorizes~~] the medical or veterinary use of radioactive material.

(29) Sealed source and device registry--The national registry containing [~~that contains~~] all [~~the~~] registration certificates, generated by both the NRC and [~~the~~] agreement states, summarizing [~~that summarize~~] the radiation safety information for sealed sources and devices and describing [~~describe~~] the licensing and use conditions approved for the product.

(30) Stereotactic radiosurgery--The use of external radiation in conjunction with a guidance device to very precisely deliver a dose to a tissue volume using [~~by the use of~~] three-dimensional coordinates.

(31) Technologist--A person (nuclear medicine technologist) skilled in the performance of nuclear medicine procedures under the supervision of a physician.

(32) Teletherapy--Therapeutic irradiation in which the sealed source is at a distance from the patient or human or animal research subject.

(33) Therapeutic dosage--The specified activity or range of activity of radioactive material [~~that is~~] intended to deliver a radiation dose to a patient or human or animal research subject for palliative or curative treatment.

(34) Therapeutic dose--A radiation dose delivered from a sealed source containing radioactive material to a patient or human or animal research subject for palliative or curative treatment.

(35) Treatment site--The anatomical description of [~~the~~] tissue intended to receive a radiation dose, as described in a written directive.

(36) Type of use--Use of radioactive material as specified under [~~the following subsections~~]:

(A) uptake, dilution, and excretion studies in subsection (ff) of this section;

(B) imaging and localization studies in subsection (hh) of this section;

(C) therapy with unsealed radioactive material in subsection (kk) of this section;

(D) manual brachytherapy with sealed sources in subsection (rr) of this section;

(E) sealed sources for diagnosis in subsection (bbb) of this section;

(F) sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit in subsection (ddd) of this section; or

(G) other medical or veterinary uses of radioactive material or a radiation source approved for medical or veterinary use in subsection (q) of this section.

(37) Unit dosage--A dosage prepared for medical or veterinary use for administration as a single dosage to a patient or human or animal research subject without any further modification of the dosage after it is initially prepared.

(38) Veterinary use--The intentional internal or external administration of radioactive material, or the radiation from radioactive material, to animal patients under the supervision of an authorized user.

(39) Written directive--An authorized user's written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in subsection (t) of this section.

(d) Provisions for research involving human subjects.

(1) A licensee may conduct research involving human subjects only if it uses the radioactive materials specified on its license for the uses authorized on the license.

(2) The licensee may conduct research specified in paragraph (1) of this subsection provided [~~that~~]:

(A) the research is conducted, funded, supported, or regulated by a federal agency implementing [~~that has implemented~~] the Federal Policy for the Protection of Human Subjects as required by 10 CFR [~~Title 10, CFR,~~] §35.6 (Federal Policy); or

(B) the licensee has applied for and received approval of a specific amendment to its license before conducting the research.

(3) Before conducting research as specified in paragraph (1) of this subsection, the licensee must [~~shall~~] obtain [~~the following~~]:

(A) "informed consent," as defined and described in the Federal Policy, from the human research subjects; and

(B) review and approval of the research from an Institutional Review Board (IRB) [~~IRB~~] as required by 45 CFR [~~Title 45, CFR,~~] Part 46, and 21 CFR [~~Title 21, CFR,~~] Part 56, and in accordance with the Federal Policy.

(4) Nothing in this subsection relieves licensees from complying with the other requirements of this chapter.

(e) Implementation.

(1) If a license condition exempted a licensee from a provision of this section or §289.252 of this subchapter [~~title~~] on the effective date of this rule, then the license condition continues to exempt the licensee from the requirements in the corresponding provision until there is a license amendment or license renewal modifying or removing [~~that modifies or removes~~] the license condition.

(2) When a requirement in this section differs from the requirement in an existing license condition, the requirement in this section governs [~~shall govern~~].

(3) Licensees must [~~shall~~] continue to comply with any license condition requiring [~~that requires~~] implementation of procedures required by subsections (ggg) and (mmm) - (ooo) of this section until there is a license amendment or renewal modifying [~~that modifies~~] the license condition.

(f) Specific requirements for the issuance of licenses. In addition to the requirements in §289.252(e) of this subchapter [~~title~~] and subsections (n) - (q) of this section, as applicable, a license is [~~will be~~] issued if the department determines [~~that~~]:

(1) the applicant satisfies any applicable special requirement in this section;

(2) qualifications of the designated RSO as specified in subsection (h) of this section are adequate for the purpose requested in the application; and

(3) the [~~following~~] information submitted by the applicant is approved, including:

(A) an operating, safety, and emergency procedures manual to include specific information on [~~the following~~]:

(i) radiation safety precautions and instructions;

(ii) methodology for measurement of dosages or doses to be administered to patients or human or animal research subjects;

(iii) calibration, maintenance, and repair of instruments and equipment necessary for radiation safety; and

(iv) waste disposal procedures; and

(B) any additional information required by this chapter [~~that is~~] requested by the department to assist in its review of the application; and

(C) qualifications of the [~~following~~]:

(i) RSO as specified in [~~accordance with~~] subsection (c)(28) of this section;

(ii) authorized users as specified [~~user(s)~~] in [~~accordance with~~] subsection (c)(6) of this section as applicable to the uses [~~use(s)~~] being requested;

(iii) authorized medical physicist as specified in [~~accordance with~~] subsection (c)(4) of this section, if applicable;

(iv) authorized nuclear pharmacist as specified in [~~accordance with~~] subsection (c)(5) of this section, if applicable;

(v) ophthalmic physicist as specified in [~~accordance with~~] subsection (c)(19) of this section, if applicable;

(vi) Radiation Safety Committee (RSC), as specified in [~~accordance with~~] subsection (i) of this section, if applicable; and

(vii) ARSO as specified in [~~accordance with~~] subsection (c)(3) of this section, if applicable; and

(4) the applicant's permanent facility is located in Texas.

(g) Authority and responsibilities for the radiation protection program.

(1) In addition to the radiation protection program requirements of §289.202(e) of this chapter [~~title~~], a licensee's management must [~~shall~~] approve in writing:

(A) requests for a license application, renewal, or amendment before submittal to the department; and

(B) any individual before being allowed [~~allowing that individual~~] to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist.

(2) A licensee's management must [~~shall~~] appoint an RSO who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the RSO, must [~~shall~~] ensure [~~that~~] radiation safety activities are being performed according to [~~in accordance with~~] licensee-approved procedures and regulatory requirements. A licensee's management may appoint, in writing, one or more ARSO to support the RSO. The RSO, with written agreement of the licensee's management, must assign the specific duties and tasks to each ARSO. These duties and tasks are restricted to the types of use for which the ARSO is listed on a license. The RSO may delegate duties and tasks to the ARSO but must [~~shall~~] not delegate the authority or responsibilities for implementing the radiation protection program.

(3) Every licensee must [~~shall~~] establish in writing the authority, duties, and responsibilities of the RSO and ensure [~~that~~] the RSO is provided sufficient authority, organizational freedom, time, resources, and management prerogative to perform the following duties:

(A) establish and oversee operating, safety, emergency, and as low as reasonably achievable (ALARA) procedures, and to review them at least annually to ensure [~~that the~~] procedures are current and conform with this chapter;

(B) ensure [~~that~~] required radiation surveys and leak tests are performed and documented as specified in [~~accordance with~~] this chapter, including any corrective measures when levels of radiation exceed established limits;

(C) ensure [~~that~~] individual monitoring devices are used properly by occupationally exposed [~~occupationally-exposed~~] personnel, [~~that~~] records are kept of the monitoring results, and [~~that~~] timely notifications are made as specified in [~~accordance with~~] §289.203 of this chapter [~~title~~];

(D) investigate and [~~cause a~~] report [~~to be submitted~~] to the department for each known or suspected case of radiation exposure to an individual or radiation level detected over the [~~in excess of~~] limits established by this chapter and each theft or loss of sources [~~source(s)~~] of radiation, to determine the causes [~~cause(s)~~], and [~~to~~] take steps to prevent a recurrence;

(E) investigate and [~~cause a~~] report [~~to be submitted~~] to the department for each known or suspected case of release of radioactive material to the environment over the [~~in excess of~~] limits established by this chapter;

(F) have a thorough knowledge of management policies and administrative procedures of the licensee;

(G) identify radiation safety problems;

(H) assume control and initiate, recommend, or provide corrective actions, including shutdown of operations when necessary, in emergency situations or unsafe conditions;

(I) verify implementation of corrective actions;

(J) ensure [~~that~~] records are maintained as required by this chapter;

(K) ensure [~~the~~] proper storing, labeling, transport, use, and disposal of sources of radiation, storage, and [~~and/or~~] transport containers;

(L) ensure [~~that~~] inventories are performed in accordance with the activities for which the license application is submitted;

(M) ensure [~~that~~] personnel are complying with this chapter, the conditions of the license, and the operating, safety, and emergency procedures of the licensee; and

(N) serve as the primary contact with the department.

(4) The RSO must [~~shall~~] ensure [~~that the~~] duties listed in paragraph (3)(A) - (N) of this subsection are performed.

(5) The RSO must [~~shall~~] be onsite [~~on site~~] periodically, commensurate with the scope of licensed activities, to satisfy the requirements of paragraphs (3) and (4) of this subsection.

(6) The RSO, or staff designated by the RSO, must [~~shall~~] be capable of physically arriving at the licensee's authorized use sites

[~~site(s)~~] within a reasonable time of being notified of an emergency situation or unsafe condition.

(7) For up to 60 days each calendar year, a licensee may permit an authorized user or an individual qualified to be an RSO, under subsections (h) and (m) of this section, to function as a temporary RSO and to perform the duties of an RSO as specified in [~~accordance with~~] paragraph (3) of this subsection, provided the licensee takes the actions required in paragraphs (2), (3), and (9) of this subsection, and notifies the department as specified in [~~accordance with~~] subsection (r)(5) of this section. Records of qualifications and dates of service must [~~shall~~] be maintained as specified in [~~accordance with~~] subsection (xxx) of this section for inspection by the department.

(8) A licensee may simultaneously appoint more than one temporary RSO as specified in [~~accordance with~~] paragraph (7) of this subsection, if needed to ensure [~~that~~] the licensee has a temporary RSO satisfying [~~that satisfies~~] the requirements to be an RSO for each of the different types of uses of radioactive material permitted by the license.

(9) The licensee must [~~shall~~] maintain records, as specified in [~~accordance with~~] subsection (xxx) of this section, as follows.

(A) A licensee must [~~shall~~] retain a record of actions taken by the licensee's management as specified in [~~accordance with~~] paragraph (1) of this subsection. The record must include a summary of the actions taken and a signature of licensee management.

(B) The authority, duties, and responsibilities of the RSO as required by paragraph (3) of this subsection, and a signed copy of each RSO's agreement to be responsible for implementing the radiation safety program, as required by paragraph (2) of this subsection. The records must include the signature of the RSO and licensee management.

(C) A copy of the written document appointing the ARSO, for each ARSO appointed under paragraph (2) of this subsection. The record must include the signature of licensee management.

(h) Training for an RSO and ARSO. Except as provided in subsection (l) of this section, the licensee must [~~shall~~] require the individual fulfilling the responsibilities of an RSO or an individual assigned duties and tasks as an ARSO as specified in [~~accordance with~~] subsection (g) of this section for licenses for medical or veterinary use of radioactive material, to be an individual who:

(1) is certified by a specialty board whose certification process has been recognized by the department, the NRC, or an agreement state and who meets the requirements in paragraph (4) of this subsection. The names of board certifications [~~that have been~~] recognized by the department, the NRC, or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page.[~~:~~]

(A) To [~~to~~] have its certification process recognized, a specialty board must [~~shall~~] require all candidates for certification to:

(i) hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

(ii) have five or more years of professional experience in health physics (graduate training may be substituted for no more than two years of the required experience) including at least three years in applied health physics; and

(iii) pass an examination, administered by diplomates of the specialty board evaluating[~~, which evaluates~~] knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

(B) to have its certification process recognized, a specialty board must [~~shall~~] require all candidates for certification to:

(i) hold a master's or doctoral [~~doctor's~~] degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(ii) have two years of full-time practical training or [~~and/or~~] supervised experience in medical physics as follows:

(I) under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the department, the NRC, or an agreement state; or

(II) in clinical nuclear medicine facilities providing diagnostic or [~~and/or~~] therapeutic services under the direction of physicians who meet the requirements for authorized users in subsections (l), (jj), or (nn) of this section; and

(iii) pass an examination, administered by diplomates of the specialty board, assessing [~~that assesses~~] knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

(2) has [~~completed all of the following~~]:

(A) completed a structured educational program consisting of both:

(i) 200 hours of classroom and laboratory training in [~~the following areas~~]:

(I) radiation physics and instrumentation;

(II) radiation protection;

(III) mathematics pertaining to the use and measurement of radioactivity;

(IV) radiation biology; and

(V) radiation dosimetry; and

(ii) one year of full-time radiation safety experience under the supervision of the individual identified as the RSO on a department [~~an agency~~], NRC, or agreement state license or on a permit issued by an NRC master material licensee authorizing [~~that authorizes~~] similar types [~~type(s)~~] of use [~~use(s)~~] of radioactive material. An ARSO may provide supervision for those areas for which the ARSO is authorized on a department [~~an agency~~], NRC, or an agreement state license or a permit issued by an NRC master material licensee. The full-time radiation safety experience must involve [~~the following~~]:

(I) shipping, receiving, and performing related radiation surveys;

(II) using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments [~~instrument~~] used to measure radionuclides;

(III) securing and controlling radioactive material;

(IV) using administrative controls to avoid mistakes in the administration of radioactive material;

(V) using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

(VI) using emergency procedures to control radioactive material; and

(VII) disposing of radioactive material; and

(B) [~~has~~] obtained written attestation, signed by a preceptor RSO or ARSO experienced [~~who has experience~~] with the radiation safety aspects of similar types of use of radioactive material for which the individual is seeking approval as an RSO or an ARSO. The[~~,~~ ~~and the~~] written attestation must state [~~that~~] the individual has satisfactorily completed the requirements in paragraphs (2)(A) and (4) of this subsection, and is able to independently fulfill the radiation safety-related duties as an RSO or as an ARSO for a medical or veterinary use license; or

(3) meets one of the following:

(A) is a medical physicist [~~who has been~~] certified by a specialty board whose certification process has been recognized by the department, the NRC, or an agreement state as specified in [~~accordance with~~] subsection (j)(1) of this section, [~~and~~] has experience with the radiation safety aspects of similar types of use of radioactive material for which the licensee is seeking [~~the~~] approval of the individual as the RSO or [~~an~~] ARSO, and [~~who~~] meets the requirements in paragraph (4) of this subsection;

(B) is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on a department [~~an agency~~], NRC, or another agreement state's license; [~~,~~] a permit issued by an [~~a~~] NRC master material licensee; [~~,~~] a permit issued by the department, the NRC, or another agreement state licensee of broad scope; [~~,~~] or a permit issued by an [~~a~~] NRC master material license broad scope permittee, has experience with the radiation safety aspects of similar types of use of radioactive material for which the licensee is seeking the approval of the individual as the RSO or ARSO, and who meets the requirements in paragraph (4) of this subsection; or

(C) has experience with the radiation safety aspects of the types of use of radioactive material for which the individual is seeking simultaneous approval both as the RSO and the authorized user on the same new medical or veterinary use license or new medical use permit issued by an [~~a~~] NRC master material licensee [~~license~~]. The individual must also meet the requirements in paragraph (4) of this subsection; and

(4) has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval, and this training requirement may be satisfied by completing training [~~that is~~] supervised by an RSO, an ARSO, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the types [~~type(s)~~] of use for which the licensee is seeking approval.

(i) Radiation safety committee (RSC). Licensees of broad scope and licensees who are authorized for two or more different types of uses of radioactive material requiring a written directive under [~~in accordance with~~] subsections (q), (kk), (rr), and (ddd) of this section, or two or more types of therapeutic units under subsections (q) and [~~subsection~~] (ddd) of this section, must [~~shall~~] establish an RSC to oversee all uses of radioactive material permitted by the license.

(1) The RSC must [~~for licenses for medical use with broad scope authorization shall~~] be composed of the following individuals as approved by the department:

(A) an authorized user of [~~users from~~] each type of use permitted by [~~of radioactive material authorized on~~] the license;

(B) the RSO;

(C) a representative of the nursing service, if applicable;

(D) a representative of management who is neither an authorized user nor the RSO; and

(E) [~~may include~~] other members as the licensee deems appropriate.

[~~(2) The RSC for licenses for medical and veterinary use authorized for two or more different types of uses of radioactive material in accordance with subsections (kk), (rr), and (ddd) of this section, or two or more types of units in accordance with subsection (ddd) of this section shall be composed of the following individuals as approved by the department:~~]

[~~(A) an authorized user of each type of use permitted by the license;~~]

[~~(B) the RSO;~~]

[~~(C) a representative of nursing service, if applicable;~~]

[~~(D) a representative of management who is neither an authorized user nor the RSO; and~~]

[~~(E) may include other members as the licensee deems appropriate.~~]

(2) [~~(3)~~] Duties and responsibilities of the RSC.

(A) For licensees without broad scope authorization, the duties and responsibilities of the RSC include [~~the following~~]:

(i) meeting as often as necessary to conduct business but no less than three times a year;

(ii) reviewing summaries of [~~the following~~] information presented by the RSO, including:

(I) doses over the occupational or public limits [~~over-exposures~~];

(II) significant incidents, including spills, contamination, or medical events; and

(III) items of non-compliance following an inspection;

(iii) reviewing the program for maintaining doses ALARA, and providing any necessary recommendations to ensure doses are ALARA; and

(iv) reviewing the audit of the radiation safety program and acting upon the findings.

(B) For licensees of broad scope, the duties and responsibilities of the RSC include the items in subparagraph (A) of this paragraph and [~~the following~~]:

(i) reviewing the overall compliance status for authorized users;

(ii) sharing responsibility with the RSO to conduct periodic audits of the radiation safety program;

(iii) developing criteria to evaluate training and experience of new authorized user applicants;

(iv) evaluating and approving authorized user applicants who request authorization to use radioactive material at the facility; and

(v) reviewing and approving permitted program and procedural changes before implementation.

(3) [~~(4)~~] Records documenting the RSC meetings must [~~shall~~] be made and maintained for inspection by the department as specified in [~~accordance with~~] subsection (xxx) of this section.

The record must [~~shall~~] include the date, names of individuals in attendance, minutes of the meeting, and any actions taken.

(j) Training for an authorized medical physicist. Except as provided in subsection (l) of this section, the licensee must [~~shall~~] require the authorized medical physicist to be:

(1) an individual [~~who is~~] certified by a specialty board whose certification process has been recognized by the department, the NRC, or an agreement state and who meets the requirements in paragraph (3) of this subsection. The names of board certifications [~~that have been~~] recognized by the department, the NRC, or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board must [~~shall~~] require all candidates [~~for certification~~] to [~~meet the following~~]:

(A) hold a master's or doctoral [~~doctor's~~] degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(B) complete two years of full-time practical training or [~~and/or~~] supervised experience in medical physics as follows:

(i) under the supervision of a medical physicist who is certified in medical physics by a specialty board whose certification process has been recognized by the department, the NRC, or an agreement state; or

(ii) in clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians meeting [~~who meet~~] the requirements for authorized users in subsections (l), (zz), or (ttt) of this section; and

(C) pass an examination, administered by diplomates of the specialty board, assessing [~~that assesses~~] knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

(2) an individual who:

(A) holds a post graduate degree and experience, including [~~to include~~]:

(i) a master's or doctoral [~~doctor's~~] degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and

(ii) completion of one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual meeting [~~who meets~~] the requirements for an authorized medical physicist for the types [~~type(s)~~] of use for which the individual is seeking authorization. This[~~, and this~~] training and work experience must [~~shall~~] be conducted in clinical radiation facilities providing [~~that provide~~] high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services and must [~~shall~~] include:

(I) performing sealed source leak tests and inventories;

(II) performing decay corrections;

(III) performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(IV) conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(B) has obtained written attestation [~~that~~] the individual has satisfactorily completed the requirements in paragraphs (2)(A) and (3) of this subsection[~~,~~] and is able to independently fulfill the radiation safety-related duties as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The[~~, and the~~] written attestation must [~~shall~~] be signed by a preceptor authorized medical physicist meeting [~~who meets~~] the requirements in subsection (l) of this section, this subsection, or equivalent NRC or agreement state requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

(3) an individual trained [~~who has training~~] for the types [~~type(s)~~] of use for which authorization is sought, including [~~that includes~~] hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the types [~~type(s)~~] of use for which the individual is seeking authorization.

(k) Training for an authorized nuclear pharmacist. Except as provided in subsection (l) of this section, the licensee must [~~shall~~] require the authorized nuclear pharmacist to be a pharmacist who:

(1) is certified by a specialty board whose certification process has been recognized by the department, the NRC, or an agreement state. The names of board certifications [~~that have been~~] recognized by the department, the NRC, or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board must [~~shall~~] require all candidates for certification to:

(A) have graduated from a pharmacy program accredited by the Accreditation Council for Pharmacy Education [~~(ACPE)~~] or have passed the Foreign Pharmacy Graduate Examination Committee [~~(FPGEC)~~] examination;

(B) hold a current, active license to practice pharmacy in the State of Texas;

(C) provide evidence of having acquired at least 4000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2000 hours of the required training and experience; and

(D) pass an examination in nuclear pharmacy, administered by diplomates of the specialty board, assessing [~~that assesses~~] knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, and research and development; or

(2) has [~~completed~~]:

(A) completed a 700-hour structured educational program, including both:

(i) 200 hours of classroom and laboratory training in [~~the following areas~~]:

(I) radiation physics and instrumentation;

(II) radiation protection;

(III) mathematics pertaining to the use and measurement of radioactivity;

(IV) chemistry of radioactive material for medical use; and

(V) radiation biology; and

(ii) supervised practical experience in a nuclear pharmacy involving [~~the following~~]:

(I) shipping, receiving, and performing related radiation surveys;

(II) using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

(III) calculating, assaying, and safely preparing dosages for patients or human research subjects;

(IV) using administrative controls to avoid medical events in the administration of radioactive material; and

(V) using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

(B) [~~has~~] obtained written attestation, signed by a preceptor authorized nuclear pharmacist, [~~that~~] the individual has satisfactorily completed the requirements in paragraph (2)(A) of this subsection and is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist.

(l) Training for experienced RSO, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist.

(1) An individual identified on a department [~~an agency~~], NRC, or an agreement state license or a permit issued by the department, the NRC, or an agreement state broad scope licensee or master material license permit, or by a master material license permittee of broad scope as an RSO, a teletherapy or medical physicist, an authorized medical physicist, a nuclear pharmacist, or an authorized nuclear pharmacist on or before January 14, 2019, need not comply with the training requirements of subsections (h), (j), and (k) of this section, respectively, except the RSO and authorized medical physicists identified in this paragraph must meet the training requirements in subsections (h)(4) or (j)(3) of this section, as appropriate, for any material or uses for which they were not authorized before this date.

(2) Any individual certified by the American Board of Health Physics in Comprehensive Health Physics; American Board of Radiology; American Board of Nuclear Medicine; American Board of Science in Nuclear Medicine; Board of Pharmaceutical Specialties in Nuclear Pharmacy; American Board of Medical Physics in radiation oncology physics; Royal College of Physicians and Surgeons of Canada in nuclear medicine; American Osteopathic Board of Radiology; or American Osteopathic Board of Nuclear Medicine on or before October 24, 2005, need not comply with the training requirements of subsection (h) of this section to be identified as an RSO or as an ARSO on a department [~~an agency~~], NRC, or agreement state license or NRC master material license permit for those materials and uses [~~that~~] these individuals performed on or before October 24, 2005.

(3) Any individual certified by the American Board of Radiology in therapeutic radiological physics, Roentgen ray and gamma ray physics, x-ray [~~xray~~] and radium physics, or radiological physics, or certified by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2005, need not comply with the training requirements for an authorized medical physicist described in subsection (j) of this section, for those materials and uses [~~that~~] these individuals performed on or before October 24, 2005.

(4) An RSO, a medical physicist, or a nuclear pharmacist[~~,~~] who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical or veterinary uses or in the practice of nuclear pharmacy at a government agency or federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of subsections (h), (j), or (k) of this section, respectively, when performing the same uses. A nuclear pharmacist[~~,~~] who prepared only radioactive drugs containing accelerator-produced radioactive materials, or a medical physicist[~~,~~] who used only accelerator-produced radioactive materials, at the locations and during the time period identified in this paragraph, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates, for the purposes of this chapter.

(5) An individual identified as a physician, dentist, podiatrist, or veterinarian authorized for the medical or veterinary use of radioactive material.

(A) Physicians, dentists, [~~or~~] podiatrists, or veterinarians identified as authorized users for the medical or veterinary use of radioactive material on a license issued by the department, the NRC, or an agreement state; [~~,~~] a permit issued by an NRC master material licensee; [~~,~~] a permit issued by the department, the NRC, or an agreement state broad scope licensee; [~~,~~] or a permit issued by an NRC master material license broad scope permittee on or before January 14, 2019, who perform only those medical or veterinary uses for which they were authorized on or before that date need not comply with the training requirements of subsections (gg) through (ttt) of this section.

(B) Physicians, dentists, [~~or~~] podiatrists, or veterinarians identified as authorized users for the medical or veterinary use of radioactive material on a license issued by the department, the NRC, or an agreement state; [~~,~~] a permit issued by an NRC master material licensee; [~~,~~] a permit issued by the department, the NRC, or an agreement state broad scope licensee; [~~,~~] or a permit issued under [~~by~~] an NRC master material broad scope license [~~of broad scope~~] on or before October 24, 2005, need not comply with the training requirements of subsections (gg) through (ttt) of this section for those materials and uses [~~that~~] these individuals performed on or before October 24, 2005, as follows:

(i) for [~~For~~] uses authorized under subsections (ff) or (hh) of this section, or oral administration of sodium iodide I-131 requiring a written directive for imaging and localization purposes, a physician who was certified on or before October 24, 2005, in nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology by the American Board of Radiology; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or American Osteopathic Board of Nuclear Medicine in nuclear medicine;

(ii) for [~~For~~] uses authorized under subsection (kk) of this section, a physician who was certified on or before October 24, 2005, by the American Board of Nuclear Medicine; the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or the American Osteopathic Board of Radiology after 1984;

(iii) for [~~For~~] uses authorized under subsections (rr) or (ddd) of this section, a physician who was certified on or before October 24, 2005, in radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specializa-

tion in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and

(iv) for [~~For~~] uses authorized under subsection (bbb) of this section, a physician who was certified on or before October 24, 2005, in radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

(C) Physicians, dentists, [~~or~~] podiatrists, or veterinarians who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical or veterinary uses performed at a government agency or federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of subsections (gg) through (ttt) of this section when performing the same medical or veterinary uses. A physician, dentist, [~~or~~] podiatrist, or veterinarian who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical or veterinary uses at the locations and time period identified in this paragraph, qualifies as an authorized user for those materials and uses performed before these dates, for the purposes of this chapter.

(6) Individuals who need not comply with training requirements in this subsection may serve as preceptors for, and supervisors of, applicants seeking authorization on a department [~~an agency~~], NRC, or agreement state license for the same uses for which these individuals are authorized.

(m) Recentness of training. The training and experience specified in subsections (h), (j), and (gg) - (ttt) of this section for medical and veterinary use must [~~shall~~] have been obtained within the seven years preceding the date of application or the individual must [~~shall~~] have had related continuing education and experience since the required training and experience was completed.

(n) Licenses for medical and veterinary [~~veterinarian~~] uses of radioactive material without broad scope authorization. In addition to the requirements of subsection (f) of this section, a license for medical and veterinary [~~veterinarian~~] use of radioactive material as described in the applicable subsections (ff), (hh), (kk), (rr), (bbb), and (ddd) of this section is [~~will be~~] issued if the department approves [~~the following~~] documentation showing [~~submitted by the applicant~~]:

(1) [~~that~~] the physicians [~~physician(s)~~] or veterinarians [~~veterinarian(s)~~] designated on the application as the authorized users are [~~user(s) is~~] qualified as specified in [~~accordance with~~] subsections (gg), (jj), (nn) - (qq), (zz), (aaa), (ccc), and (ttt) of this section, as applicable;

(2) [~~that~~] the radiation detection and measuring instrumentation is appropriate for performing surveys and procedures for the uses involved;

(3) [~~that~~] the radiation safety operating procedures are adequate for the handling and disposal of the radioactive material involved in the uses; and

(4) [~~that~~] an RSC has been established as specified in [~~accordance with~~] subsection (i)(2) of this section, if applicable.

(o) License for medical and veterinary uses of radioactive material with broad scope authorization. In addition to the requirements of subsection (f) of this section, a license for medical or veterinary use of radioactive material with broad scope authorization is [~~will be~~] issued if the department approves [~~the following~~] documentation showing [~~submitted by the applicant~~]:

(1) [~~that~~] the review of authorized user qualifications by the RSC is as specified in [~~accordance with~~] subsections (gg), (jj), (nn) - (qq), (zz), (aaa), (ccc), and (ttt) of this section, as applicable;

(2) [~~that~~] the application is for a license authorizing unspecified forms or [~~and/or~~] multiple types of radioactive material for medical research, diagnosis, and therapy;

(3) [~~that~~] the radiation detection and measuring instrumentation is appropriate for performing surveys and procedures for the uses involved;

(4) [~~that~~] the radiation safety operating procedures are adequate for the handling and disposal of the radioactive material involved in the uses;

(5) [~~that~~] staff has substantial experience in the use of a variety of radioactive material for a variety of human and animal uses;

(6) [~~that~~] the full-time RSO meets the requirements of subsection (h) of this section; and

(7) [~~that~~] an RSC has been established as specified in [~~accordance with~~] subsection (i)(1) of this section.

(p) License for the use of remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units. In addition to the requirements of subsection (f) of this section, a license for the use of remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units is [~~will be~~] issued if the department approves [~~the following~~] documentation showing [~~submitted by the applicant~~]:

(1) [~~that~~] the physicians [~~physician(s)~~] designated on the application as the authorized users are [~~user(s) is~~] qualified as specified in [~~accordance with~~] subsection (ttt) of this section;

(2) [~~that~~] the radiation detection and measuring instrumentation is appropriate for performing surveys and procedures for the uses involved;

(3) [~~that~~] the radiation safety operating procedures are adequate for the handling and disposal of the radioactive material involved in the uses;

(4) [~~of~~] the radioactive isotopes to be possessed;

(5) [~~of~~] the sealed source manufacturer names [~~manufacturer(s) name(s)~~] and the model numbers [~~number(s)~~] of the sealed sources [~~source(s)~~] to be installed;

(6) [~~of~~] the maximum number of sealed sources of each isotope to be possessed, including the activity of each sealed source;

(7) [~~of~~] the manufacturer and model designation [~~name and/or number~~] of the following units, as applicable:

(A) remote afterloader unit;

(B) teletherapy unit; or

(C) gamma stereotactic radiosurgery unit;

(8) [~~that~~] the authorized medical physicist designated on the application is qualified as specified in [~~accordance with~~] subsection (j) of this section;

(9) [~~of~~] the safety procedures and instructions as required by subsection (ggg) of this section;

(10) [~~of~~] the spot check procedures as required by subsections (mmm) - (ooo) of this section, as applicable; and

(11) [~~that~~] an RSC has been established as specified in [~~accordance with~~] subsection (i)(1) or (2) of this section, if applicable.

(q) License for other medical or veterinary uses of radioactive material or a radiation source approved for medical or veterinary use [~~that is~~] not specifically addressed in this section. In addition to the requirements of subsection (f) of this section, a licensee may use radioactive material or a radiation source approved for medical or veterinary use [~~which is~~] not specifically addressed in this section if:

(1) the department approves the following documentation submitted by the applicant:

(A) any additional aspects of the medical or veterinary use of the material [~~that are~~] applicable to radiation safety [~~that are~~] not addressed in, or different [~~differ~~] from, requirements in this section;

(B) identification of and commitment to follow the applicable radiation safety program requirements in this section [~~that are~~] appropriate for the specific medical or veterinary use;

(C) any additional specific information on:

(i) radiation safety precautions and instructions;

(ii) methodology for measurement of dosages or doses to be administered to patients or human or animal research subjects; and

(iii) calibration, maintenance, and repair of instruments and equipment necessary for radiation safety; and

(D) any other information requested by the department in its review of the application; and

(2) the applicant or licensee has received written approval from the department in a license or license amendment and the licensee uses the material in accordance with the regulations and specific conditions the department considers necessary for the medical or veterinary use of the material.

(r) License amendments and notifications.

(1) Requests for amendment of a license or deletion of an authorized use site must [~~shall~~] be filed as specified in [~~accordance with~~] §289.252(aa) of this subchapter [~~title~~].

(2) A licensee must [~~shall~~] apply for and must [~~shall~~] receive a license amendment before [~~the following~~]:

(A) receiving or using radioactive material for a type of use [~~that is~~] authorized by [~~in accordance with~~] this section, but [~~is~~] not authorized on their current license issued under [~~in accordance with~~] this section;

(B) permitting anyone to work as an authorized user, authorized nuclear pharmacist, authorized medical physicist, or ophthalmic physicist[~~,~~] under the license except an individual who is identified as an authorized user, an authorized nuclear pharmacist, authorized medical physicist, or an ophthalmic physicist:

(i) on a department [~~an agency~~], NRC, or agreement state license or other equivalent permit or license recognized by the department authorizing [~~that authorizes~~] the use of radioactive material in medical or veterinary use or in the practice of nuclear pharmacy;

(ii) on a permit issued by a department [~~an agency~~], NRC, or agreement state specific license of broad scope [~~that is~~] authorized to permit the use of radioactive material in medical or veterinary use or in the practice of nuclear pharmacy;

(iii) on a permit issued by an NRC master material licensee [~~that is~~] authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy; or

(iv) by a commercial nuclear pharmacy [~~that has been~~] authorized to identify authorized nuclear pharmacists.

(C) changing RSOs, except as provided in subsection (g)(7) of this section;

(D) receiving radioactive material more than [~~in excess of~~] the amount or in a different form, or receiving a different radionuclide than [~~is~~] authorized on the license;

(E) adding or changing the areas where [~~in which~~] radioactive material is used or stored and [~~are~~] identified in the application or on the license, including areas used as specified in [~~accordance with~~] subsection (ff) or (hh) of this section if the change includes addition or relocation of either an area where positron emission tomography (PET) radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide/PET radioactive drug production area. Other [~~, and other~~] areas of use where radioactive material is used only as specified in [~~accordance with~~] either subsection (ff) or (hh) of this section, are exempt;

(F) changing the addresses [~~address(es)~~] of use identified in the application or on the license;

(G) changing operating, safety, and emergency procedures; however, a licensee may revise its radiation protection program without the department's approval if the revision does not require a license amendment under the other provisions of this paragraph; and

(i) the revision does not reduce the safety of an affected facility;

(ii) the revision is in compliance with the rules in this chapter and the license;

(iii) the revision has been reviewed and approved by the RSO and licensee management;

(iv) the affected individuals are instructed on the revised program before the changes are implemented;

(v) all changes to the radiation protection program are submitted to the department after the provisions of this subparagraph are completed; and

(vi) the licensee retains a record of each change to the radiation protection program as specified in §289.202(mm) of this chapter.

(H) before permitting anyone to work as an ARSO, or before the RSO assigns duties and tasks to an ARSO differing [~~that differ~~] from those for which this individual is authorized on the license; and

(I) before receiving a sealed source from a different manufacturer or of a different model number than authorized by its license unless the sealed source is used for manual brachytherapy, is listed in the Sealed Source and Device Registry, and is in a quantity and for an isotope authorized by the license.

(3) A licensee possessing a Type A specific license of broad scope for medical or veterinary use, issued under §289.252(h)(2) of this subchapter [~~title~~], is exempt from:

(A) the provisions of subsection (q)(1) of this section regarding the need to file an amendment to the license for medical or veterinary use of radioactive material;

(B) the provisions of paragraph (2)(B) of this subsection;

(C) the provisions of paragraph (2)(E) of this subsection regarding additions to or changes in the areas of use at the addresses identified in the application or on the license;

(D) the provisions of paragraph (4) of this subsection;

(E) the provisions of paragraph (5)(A) of this subsection for an authorized user, an authorized nuclear pharmacist, an authorized medical physicist, or an ophthalmic physicist;

(F) the provisions of paragraph (5)(C) of this subsection; and

(G) the provisions of subsection (u)(1) of this section.

(4) A licensee must [~~shall~~] notify the department in the form of a license amendment request[~~,~~] no later than 30 days after the date that the licensee permits an individual to work under the provisions of this subsection [~~§289.256(r)~~] as an authorized user, authorized medical physicist, ophthalmic physicist, or authorized nuclear pharmacist providing [~~that~~] the individual is authorized on a license for the same use. A licensee includes with the notification the following documentation:

(A) a copy of the department, NRC, or agreement state license;

(B) the permit issued by an NRC master material licensee;

(C) the permit issued by the department, the NRC, or an agreement state licensee of broad scope; or

(D) the permit issued by an NRC master material license broad scope permittee.

(5) A licensee must [~~shall~~] notify the department in the form of a license amendment request no later than 30 days after:

(A) an authorized user, an authorized nuclear pharmacist, an RSO, an ARSO, an authorized medical physicist, or an ophthalmic physicist permanently discontinues performance of duties under the license or has a name change;

(B) the licensee permits an individual qualified to be an RSO under subsections (h) and (m) of this section to function as a temporary RSO and to perform the functions of an RSO as specified in [~~accordance with~~] subsection (g)(6) of this section;

(C) the licensee has added to or changed the areas of use identified in the application or on the license where byproduct material is used as specified in [~~accordance with~~] either subsection (ff) or (hh) of this section, if the change does not include addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide/PET radioactive drug production area; or

(D) the licensee obtains a sealed source for use in manual brachytherapy from a different manufacturer or with a different model number than authorized by its license for which it did not require a license amendment as provided in paragraph (1) of this subsection. The notification must include the manufacturer and model number of the sealed source, the isotope, and the quantity per sealed source.

(s) Supervision. A licensee may permit the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user, unless prohibited by license condition.

(1) A licensee who permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user must [~~shall do the following~~]:

(A) instruct the supervised individual in the licensee's written operating, safety, and emergency procedures, written directive procedures, requirements of this chapter, and license conditions with respect to the use of radioactive material; and

(B) require the supervised individual to follow the instructions of the supervising authorized user for medical or veterinary uses of radioactive material, written operating, safety, and emergency procedures established by the licensee, written directive procedures, requirements of this chapter, and license conditions with respect to the medical or veterinary use of radioactive material.

(2) A licensee who permits the preparation of radioactive material for medical or veterinary use by an individual under the supervision of an authorized nuclear pharmacist or authorized user must[~~,~~ ~~shall do the following~~]:

(A) instruct the supervised individual in the preparation of radioactive material for medical or veterinary use, as appropriate to that individual's involvement with radioactive material; and

(B) require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical or veterinary use, the written operating, safety, and emergency procedures established by the licensee, the requirements of this chapter, and license conditions.

(3) A licensee who permits supervised activities as specified in [~~accordance with~~] paragraphs (1) and (2) of this subsection is responsible for the acts and omissions of the supervised individual.

(4) Only an authorized user may authorize the medical or veterinary use of radioactive material.

(t) Written directives.

(1) A written directive must [~~shall~~] be dated and signed by an authorized user before any administration of sodium iodide I-131 greater than 30 microcuries (Ci) (1.11 megabequerels (MBq)), administration of any therapeutic dosage of unsealed radioactive material, or administration of any therapeutic dose of radiation from radioactive material. If, because of the emergent nature of the patient's condition, a delay [~~in order~~] to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive must [~~shall~~] be documented in writing as soon as possible in the patient's record. A written directive must [~~shall~~] be prepared and signed by the authorized user within 48 hours of the oral directive.

(2) The written directive must [~~shall~~] contain the patient or human research subject's name and the following information for each application.

(A) For any administration of quantities greater than 30 Ci (1.11 MBq) of sodium iodide I-131: the dosage.

(B) For an administration of a therapeutic dosage of a radiopharmaceutical other than sodium iodide I-131: the radiopharmaceutical, the dosage, and the route of administration.

(C) For gamma stereotactic radiosurgery: the total dose, the treatment site, and the values for the target coordinate settings per treatment for each anatomically distinct treatment site.

(D) For teletherapy: the total dose, the dose per fraction, the number of fractions, and the treatment site.

(E) For high-dose rate remote afterloading brachytherapy: the radionuclide, the treatment site, the dose per fraction, the number of fractions, and the total dose.

(F) For permanent implant brachytherapy:

(i) before implantation: the treatment site, the radionuclide, and the total source strength; and

(ii) after implantation but before the patient leaves the post-treatment recovery area: the treatment site, the number of sources implanted, the total source strength implanted, and the date.

(G) For all other brachytherapy, including low, medium, and pulsed rate afterloaders:

(i) before implantation: the treatment site, the radionuclide, and the dose;

(ii) after implantation but before completion of the procedure: the radionuclide, the treatment site, the number of sealed sources, the total sealed source strength, exposure time (or the total dose), and the date.

(3) A written revision to an existing written directive.

(A) A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

(B) If, because of the patient's condition, a delay [~~in order~~] to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.

(4) The licensee must [~~shall~~] retain the written directive as specified in [~~accordance with~~] subsection (xxx) of this section for inspection by the department.

(5) Procedures for administrations requiring a written directive.

(A) For any administration requiring a written directive, the licensee must [~~shall~~] develop, implement, and maintain written procedures to provide high confidence [~~that~~]:

(i) the patient's or human research subject's identity is verified before each administration; and

(ii) each administration is in accordance with the written directive.

(B) The procedures required by subparagraph (A) of this paragraph must [~~shall~~], at a minimum, address the following items [~~that are~~] applicable for the licensee's use of radioactive material:

(i) verifying the identity of the patient or human research subject;

(ii) verifying [~~that~~] the administration is in accordance with the treatment plan, if applicable, and the written directive;

(iii) checking both manual and computer-generated dose calculations; [~~and~~]

(iv) verifying [~~that~~] any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by subsections (q) and (ddd) of this section;

(v) determining if a medical event, as defined in subsection (uuu) of this section, has occurred; and

(vi) determining, for permanent implant brachytherapy, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented.

(C) A licensee must [~~shall~~] maintain a copy of the procedures required by subparagraph (A) of this paragraph as specified in [~~accordance with~~] subsection (xxx) of this section.

(u) Suppliers for sealed sources or devices for medical or veterinary use. A licensee may only use the following for medical or veterinary use:

(1) sealed sources or devices manufactured, labeled, packaged, and distributed as specified in [~~accordance with~~] a license issued under §289.252(o) of this subchapter [~~title~~] or equivalent requirements of the NRC or an agreement state;

(2) sealed sources or devices non-commercially transferred from an NRC or agreement state medical or veterinary use licensee; or

(3) teletherapy sources manufactured and distributed as specified in [~~accordance with~~] a license issued by the department, the NRC, or an agreement state.

(v) Possession, use, and calibration of dose calibrators to measure the activity of unsealed radioactive material.

(1) For direct measurements performed as specified in [~~accordance with~~] subsection (x) of this section, the licensee must [~~shall~~] possess and use instrumentation to measure the activity of unsealed radioactive material before it is administered to each patient or human or animal research subject.

(2) The licensee must [~~shall~~] calibrate the instrumentation specified in paragraph (1) of this subsection in accordance with nationally recognized standards or the manufacturer's instructions.

(3) The calibration required by paragraph (2) of this subsection must [~~shall~~] include tests for constancy, accuracy, linearity, and geometry dependence, as appropriate to demonstrate proper operation of the instrument. The tests for constancy, accuracy, linearity, and geometry dependence must [~~shall~~] be conducted at the following intervals:

(A) constancy at least once each day before assay of patient dosages;

(B) linearity at installation, repair, relocation, and at least quarterly thereafter;

(C) geometry dependence at installation; and

(D) accuracy at installation and at least annually thereafter.

(4) The licensee must [~~shall~~] maintain a record of each instrument calibration as specified in [~~accordance with~~] subsection (xxx) of this section. The record must [~~shall~~] include [~~the following~~]:

(A) model and serial number of the instrument and calibration sources;

(B) complete date of the calibration including the month, day, and year;

(C) results of the calibration; and

(D) name of the individual who performed the calibration.

(w) Calibration of survey instruments. A licensee must [~~shall~~] calibrate the survey instruments used to show compliance with this subsection and with §289.202 of this chapter [~~title~~] before first use, annually, and following a repair affecting [~~that affects~~] the calibration. A licensee must [~~shall~~]:

(1) calibrate all scales with readings up to 10 millisieverts (mSv) (1000 millirem (mrem)) per hour with a radiation source;

(2) calibrate two separated readings on each scale or decade [~~that will be~~] used to show compliance;

(3) conspicuously note on the instrument the complete date of the calibration including the month, day, and year;

(4) not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than 20 percent; and

(5) maintain a record of each survey instrument calibration as specified in [~~accordance with~~] subsection (xxx) of this section.

(x) Determination of dosages of unsealed radioactive material for medical or veterinary use.

(1) Before medical or veterinary use, the licensee must [~~shall~~] determine and record the activity of each dosage.

(2) For a unit dosage, this determination must [~~shall~~] be made by:

(A) direct measurement of radioactivity; or

(B) a decay correction, based on the activity or activity concentration determined by [~~the following~~]:

(i) a manufacturer or preparer licensed as specified in [~~accordance with~~] §289.252(r) of this subchapter [~~title~~], or under an equivalent NRC or agreement state license;

(ii) an NRC or agreement state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by the FDA; or

(iii) a PET radioactive drug producer licensed as specified in [~~accordance with~~] §289.252(kk) of this subchapter [~~title~~] or equivalent NRC or agreement state requirements.

(3) For other than unit dosages, this determination must [~~shall~~] be made by:

(A) direct measurement of radioactivity;

(B) combination of measurement of radioactivity and mathematical calculations; or

(C) combination of volumetric measurements and mathematical calculations, based on the measurement made by:

(i) a manufacturer or preparer licensed as specified in [~~accordance with~~] §289.252(r) of this subchapter [~~title~~], or under an equivalent NRC or agreement state license; or

(ii) a PET radioactive drug producer licensed as specified in [~~accordance with~~] §289.252(kk) of this subchapter [~~title~~] or equivalent NRC or agreement state requirements.

(4) Unless otherwise directed by the authorized user, a licensee must [~~shall~~] not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent.

(5) A licensee restricted to only unit doses prepared as specified in [~~accordance with~~] §289.252(r) of this subchapter [~~title~~] need not comply with paragraph (2) of this subsection unless the administration time of the unit dose deviates from the nuclear pharmacy's pre-calibrated time by 15 minutes or more.

(6) A licensee must [~~shall~~] maintain a record of the dosage determination required by this subsection as specified in [~~accordance with~~] subsection (xxx) of this section for inspection by the department. The record must include [~~shall contain the following~~]:

(A) the radiopharmaceutical;

(B) patient's or human or animal research subject's name or identification number, if one has been assigned;

(C) prescribed dosage;

(D) determined dosage or a notation [~~that~~] the total activity is less than 30 Ci (1.1 MBq);

(E) the date and time of the dosage determination; and

(F) the name of the individual who determined the dosage.

(y) Authorization for calibration, transmission, and reference sources.

(1) Any licensee authorized by subsections (n), (o), (p), or (q) of this section for medical or veterinary use of radioactive material may receive, possess, and use any of the following radioactive material for check, calibration, transmission, and reference use:

(A) sealed sources, not exceeding 30 millicuries (mCi) (1.11 gigabecquerel (GBq)) each, manufactured and distributed by a person licensed under §289.252(o) of this subchapter [~~title~~] or equivalent NRC or agreement state regulations;

(B) sealed sources, not exceeding 30 mCi [~~millicuries (mCi)~~] (1.11 GBq [~~gigabecquerel (GBq)~~]) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under §289.252(o) of this subchapter [~~title~~] or equivalent NRC or agreement state regulations, provided the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions;

(C) any radioactive material with a half-life not longer than 120 days in individual amounts not to exceed 15 mCi (0.56 GBq);

(D) any radioactive material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 200 Ci (7.4 MBq) or 1000 times the quantities in §289.202(ggg)(3) of this chapter [~~title~~]; and

(E) technetium-99m in amounts as needed.

(2) Radioactive material in sealed sources authorized by this subsection must [~~shall~~] not be:

(A) used for medical or veterinary use as defined in subsection (c) of this section except as specified in [~~accordance with~~] the requirements in subsection (bbb) of this section; or

(B) combined (i.e., bundled or aggregated) to create an activity greater than the maximum activity of any single sealed source authorized under this section.

(3) A licensee using calibration, transmission, and reference sources as specified in [~~accordance with~~] the requirements in paragraph (1) or (2) of this subsection need not list these sources on a specific medical or veterinary use license.

(z) Requirements for possession of sealed sources and brachytherapy sealed sources. A licensee in possession of any sealed source or brachytherapy source must [~~shall~~]:

(1) follow the radiation safety and handling instructions supplied by the manufacturer and the leakage test requirements as specified in [~~accordance with~~] §289.201(g) of this chapter [~~title~~] and reporting requirements in §289.202(bbb) of this chapter [~~title~~]; and

(2) conduct a physical inventory at intervals not to exceed six months to account for all sealed sources in its possession. Records of the inventory must [~~shall~~] be made and maintained for inspection by the department as specified in [~~accordance with~~] subsection (xxx) of this section and must [~~shall~~] include [~~the following~~]:

(A) model number of each source and serial number if one has been assigned;

(B) identity of each source and its nominal activity;

(C) location of each source;

(D) date of the inventory; and

(E) name [~~identification~~] of the individual who performed the inventory.

(aa) Labeling of vials and syringes. Each syringe and vial containing [~~that contains~~] a radiopharmaceutical must [~~shall~~] be labeled to identify the radioactive drug. Each syringe shield and vial shield must [~~shall~~] also be labeled unless the label on the syringe or vial is visible when shielded.

(bb) Surveys for ambient radiation exposure rate.

(1) In addition to the requirements of §289.202(p) of this chapter [~~title~~] and except as provided in paragraph (2) of this subsection, a licensee must [~~shall~~] survey, with a radiation detection survey instrument, at the end of each day of use, all areas where radioactive material requiring a written directive was prepared for use or administered.

(2) A licensee is not required to [~~does not need to~~] perform the surveys required by paragraph (1) of this subsection in an area [~~area(s)~~] where patients or human research subjects are confined when they cannot be released as specified in [~~accordance with~~] subsection (cc) of this section or an animal that is confined. Once the patient or human or animal research subject is released from confinement, the licensee must [~~shall~~] survey with a radiation survey instrument[~~,~~] the area in which the patient or human or animal research subject was confined.

(3) A record of each survey must [~~shall~~] be retained as specified in [~~accordance with~~] subsection (xxx) of this section for inspection by the department. The record must [~~shall~~] include [~~the following~~]:

(A) date of the survey;

(B) results of the survey;

(C) manufacturer's name, model, and serial number of the instrument used to make the survey; and

(D) name of the individual who performed the survey.

(cc) Release of individuals containing radioactive drugs or implants containing radioactive material.

(1) The licensee may authorize the release from its control, any individual [~~who has been~~] administered radioactive drugs or implants containing radioactive material if the total effective dose equivalent (TEDE) to any other individual from exposure to the released individual is not likely to exceed 0.5 rem (5 mSv). [~~Patients treated with temporary eye plaques may be released from the hospital provided that the procedures ensure that the exposure rate from the patient is less than 5 mrem (0.05 mSv) per hour at a distance of 1 meter from the eye plaque location.~~]

(2) The licensee must [~~shall~~] provide the released individual, or the individual's parent or guardian, with written instructions on actions recommended to maintain doses to other individuals ALARA if the TEDE to any other individual is likely to exceed 0.1 rem (1 mSv). If the TEDE to a nursing infant or child could exceed 0.1 rem (1 mSv), assuming there was no interruption of breast-feeding, the instructions must [~~shall also~~] include [~~the following~~]:

(A) guidance on the interruption or discontinuation of breast-feeding; and

(B) information on the potential consequences, if any, of failure to follow the guidance.

(3) The licensee must [~~shall~~] maintain for inspection by the department, a record as specified in [~~accordance with~~] subsection (xxx) of this section of each patient released according to [~~in accordance with~~] paragraph (1) of this subsection. The record must [~~shall~~] include [~~the following~~]:

(A) the basis for authorizing the release of an individual; and

(B) the instructions provided to a breast-feeding woman[~~.~~] if the radiation dose to the infant or child from continued breast-feeding could result in a TEDE exceeding 0.5 rem (5 mSv).

(dd) Mobile nuclear medicine service. A license for a mobile nuclear medicine service for medical or veterinary use of radioactive material is [~~will be~~] issued if the department approves the documentation submitted by the applicant as specified in [~~accordance with~~] the requirements of subsections (f) and (n) of this section. The clients of the mobile nuclear medicine service must [~~shall~~] be licensed if the client receives or possesses radioactive material to be used by the mobile nuclear medicine service.

(1) A licensee providing mobile nuclear medicine service must [~~shall~~]:

(A) obtain a letter signed by the management of each client for which services are rendered permitting [~~that permits~~] the use of radioactive material at the client's address and clearly delineating [~~delineates~~] the authority and responsibility of the licensee and the client;

(B) check instruments used to measure the activity of unsealed radioactive material for proper function before medical or veterinary use at each client's address or on each day of use, whichever is more frequent. As [~~At~~] a minimum, the check for proper function required by this subparagraph must [~~shall~~] include a constancy check;

(C) have at least one fixed facility where records are [~~may be~~] maintained and radioactive material is [~~may be~~] delivered by manufacturers or distributors each day before the mobile nuclear medicine licensee dispatches [~~dispatching~~] its vehicles [~~vans~~] to client sites;

(D) agree to have an authorized physician user directly supervise each technologist at a reasonable frequency;

(E) check survey instruments for proper operation with a dedicated check source before use at each client's address; and

(F) before leaving a client's address, survey all areas of use to ensure compliance with the requirements of §289.202 of this chapter [~~title~~].

(2) A mobile nuclear medicine service must [~~shall~~] not have radioactive material delivered from the manufacturer or the distributor to the client unless the client has a license allowing possession of the radioactive material. Radioactive material delivered to the client must [~~shall~~] be received and handled in conformance with the client's license.

(3) A licensee providing mobile nuclear medicine services must [~~shall~~] maintain records, for inspection by the department, as specified in [~~accordance with~~] subsection (xxx) of this section including the letter required in paragraph (1)(A) of this subsection and the record of each survey required in paragraph (1)(F) of this subsection.

(ee) Decay-in-storage.

(1) The licensee may hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage and dispose of it without regard to its radioactivity if the licensee [~~does the following~~]:

(A) monitors radioactive material at the surface before disposal and determines [~~that~~] its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and

(B) removes or obliterates all radiation labels, except for radiation labels on materials [~~that are~~] within containers and [~~that will be~~] handled as biomedical waste after it has been released from the licensee.

(2) The licensee must [~~shall~~] retain a record of each disposal as required by paragraph (1) of this subsection as specified in [~~accordance with~~] subsection (xxx) of this section for inspection by the department. The record must [~~shall~~] include [~~the following~~]:

(A) date of the disposal;

(B) manufacturer's name, model number, and serial number of the survey instrument used;

(C) background radiation level;

(D) radiation level measured at the surface of each waste container; and

(E) name of the individual who performed the survey.

(ff) Use of unsealed radioactive material for uptake, dilution, and excretion studies [~~that do~~] not requiring [~~require~~] a written directive. Except for quantities that require a written directive as specified in [~~accordance with~~] subsection (t) of this section, a licensee may use any unsealed radioactive material prepared for medical or veterinary use for uptake, dilution, or excretion studies [~~that meets the following~~]:

(1) [~~is~~] obtained from:

(A) a manufacturer or preparer licensed as specified in [~~accordance with~~] §289.252(r) of this subchapter [~~title~~] or equivalent NRC or agreement state requirements; or

(B) a PET radioactive drug producer licensed as specified in [~~accordance with~~] §289.252(kk) of this subchapter [~~title~~] or equivalent NRC or agreement state requirements; or

(2) excluding production of PET radionuclides, prepared by:

(A) an authorized nuclear pharmacist; or

(B) a physician or veterinarian who is an authorized user and who meets the requirements specified in subsections (jj) or (nn) and (jj)(3)(A)(ii)(VII) of this section; or

(C) an individual under the supervision, as specified in subsection (s) of this section, of the authorized nuclear pharmacist in subparagraph (A) of this paragraph, or the physician or veterinarian who is an authorized user in subparagraph (B) of this paragraph; or

(3) [~~is~~] obtained from and prepared by an NRC or agreement state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an IND protocol accepted by the FDA; or

(4) [~~is~~] prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by the FDA.

(gg) Training for uptake, dilution, and excretion studies. Except as provided in subsection (l) of this section, the licensee must [~~shall~~] require an authorized user of unsealed radioactive material for the uses authorized in subsection (ff) of this section to be [~~a physician who~~]:

(1) a physician [~~is~~] certified by a medical specialty board whose certification process is [~~has been~~] recognized by the department, the NRC, or an agreement state. The names of board certifications [~~that have been~~] recognized by the department, the NRC, or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification recognized, a specialty board must [~~shall~~] require all candidates for certification to:

(A) complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies as described in paragraph (3)(A) of this subsection; and

(B) pass an examination, administered by diplomates of the specialty board, assessing [~~that assesses~~] knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(2) [~~is~~] an authorized user as specified in [~~accordance with~~] subsections (jj) or (nn) of this section or equivalent NRC or agreement state requirements; or

(3) a physician or veterinarian who: [~~has completed 60 hours of training and experience, including a minimum of eight hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies.~~]

(A) completes 60 hours of training and experience, including a minimum of eight hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical or veterinary use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience must [~~shall~~] include [~~the following~~]:

(i) classroom and laboratory training in [~~the following areas~~]:

(I) radiation physics and instrumentation;

(II) radiation protection;

(III) mathematics pertaining to the use and measurement of radioactivity;

(IV) chemistry of radioactive material for medical or veterinary use; and

(V) radiation biology; and

(ii) work experience, under the supervision of an authorized user meeting [~~who meets~~] the requirements of this subsection, subsections (l), (jj), or (nn) of this section, or equivalent NRC or agreement state requirements involving [~~the following~~]:

(I) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(II) performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(III) calculating, measuring, and safely preparing patient or human or animal research subject dosages;

(IV) using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(V) using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(VI) administering dosages of radioactive drugs to patients or human or animal research subjects; and

(B) obtains [~~has obtained~~] written attestation [~~that~~] the individual has satisfactorily completed the requirements in subparagraph (A) of this paragraph and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical or veterinary uses authorized under subsection (ff) of this section. The attestation must be obtained from either:

(i) a preceptor authorized user who meets the requirements of subsection (l) of this section, this subsection, or subsections (jj) or (nn) of this section, or equivalent NRC or agreement state requirements; or

(ii) a residency program director affirming [~~who affirms~~] in writing [~~that~~] the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in subsections (l), (gg), (jj), or (nn) of this section, or equivalent NRC or agreement state requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, [~~or~~] the Royal College of Physicians and Surgeons of Canada, or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subparagraph (A) of this paragraph.

(hh) Use of unsealed radioactive material for imaging and localization studies [~~that do~~] not requiring [~~require~~] a written directive. Except for quantities requiring [~~that require~~] a written directive as specified in [~~accordance with~~] subsection (t) of this section, a licensee may use any unsealed radioactive material prepared for medical or veterinary use for imaging and localization studies [~~that meets the following~~]:

(1) [~~is~~] obtained from:

(A) a manufacturer or preparer licensed as specified in [~~accordance with~~] §289.252(r) of this subchapter [~~title~~] or equivalent NRC or agreement state requirements; or

(B) a PET radioactive drug producer licensed as specified in [~~accordance with~~] §289.252(kk) of this subchapter [~~title~~] or equivalent NRC or agreement state requirements; or

(2) excluding production of PET radionuclides[,] prepared by:

(A) an authorized nuclear pharmacist; or

(B) a physician or veterinarian who is an authorized user and who meets the requirements specified in subsections (jj) or (nn) and (jj)(3)(A)(ii)(VII) of this section; or

(C) an individual under the supervision, as specified in subsection (s) of this section, of the authorized nuclear pharmacist in subparagraph (A) of this paragraph, or the physician or veterinarian who is an authorized user in subparagraph (B) of this paragraph; or

(3) [~~is~~] obtained from and prepared by an NRC or agreement state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an IND protocol accepted by the FDA; or

(4) [~~is~~] prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by the FDA.

(ii) Permissible molybdenum-99, strontium-82, and strontium-85 concentrations.

(1) The licensee may not administer to humans a radiopharmaceutical containing [~~that contains~~]:

(A) more than 0.15 Ci of molybdenum-99 per mCi of technetium-99m (0.15 kilobecquerel (kBq) of molybdenum-99 per MBq of technetium-99m); or

(B) more than 0.02 Ci of strontium-82 per mCi of rubidium-82 chloride (0.02 kBq of strontium-82 per MBq of rubidium-82 chloride) injection; or

(C) more than 0.2 Ci of strontium-85 per mCi of rubidium-82 (0.2 kBq of strontium-85 per MBq of rubidium-82 chloride) injection.

(2) The licensee using [~~who uses~~] molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical must [~~shall~~] measure the molybdenum-99 concentration in each eluate from a generator to demonstrate compliance with paragraph (1) of this subsection.

(3) The licensee using [~~who uses~~] a strontium-82/rubidium-82 generator for preparing a rubidium-82 radiopharmaceutical must [~~shall~~], before the first patient use of the day, measure the concentration of radionuclides strontium-82 and strontium-85 to demonstrate compliance with paragraph (1) of this subsection.

(4) If the licensee is required to measure the molybdenum-99 or strontium-82 and strontium-85 concentrations, the licensee must [~~shall~~] retain a record of each measurement as specified in [~~accordance with~~] subsection (xxx) [~~(www)~~] of this section for inspection by the department. The record must [~~shall~~] include [~~the following~~]:

(A) for each measured elution of technetium-99m:

(i) the ratio of the measures expressed as Ci of molybdenum-99 per mCi of technetium-99m (kBq of molybdenum-99 per MBq of technetium-99m);

(ii) time and date of the measurement; and

(iii) name of the individual who made the measurement.

(B) for each measured elution of rubidium-82:

(i) the ratio of the measures expressed as Ci of strontium-82 per mCi of rubidium (kBq of strontium-82 per MBq of rubidium-82);

(ii) the ratio of the measures expressed as Ci of strontium-85 per mCi of rubidium (kBq of strontium-85 per MBq of rubidium-82);

(iii) time and date of the measurement; and

(iv) name of the individual who made the measurement.

(5) The licensee must [~~shall~~] report any measurement that exceeds the limits in paragraph (1) of this subsection at the time of generator elution, as specified in [~~accordance with~~] subsection (www) [~~(xxx)~~] of this section.

(jj) Training for imaging and localization studies. Except as provided in subsection (l) of this section, the licensee must [~~shall~~] require an authorized user of unsealed radioactive material for the uses authorized in subsection (hh) of this section to be [~~a physician who~~]:

(1) a physician [~~is~~] certified by a medical specialty board whose certification process is [~~has been~~] recognized by the department, the NRC, or an agreement state. The names of board certifications [~~that have been~~] recognized by the department, the NRC, or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board must [~~shall~~] require all candidates for certification to:

(A) complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for imaging and localization studies as described in paragraph (3) of this subsection; and

(B) pass an examination, administered by diplomates of the specialty board, assessing [~~that assesses~~] knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(2) [~~is~~] an authorized user as specified in [~~accordance with~~] subsection (nn) of this section and who meets the requirements of paragraph (3)(A)(ii)(VII) of this subsection or equivalent NRC or agreement state requirements; or

(3) a physician or veterinarian who: [~~has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies.~~]

(A) completes 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical or veterinary use of unsealed radioactive material for imaging and localization studies. The training and experience must [~~shall~~] include [~~the following~~]:

(i) classroom and laboratory training in [~~the following areas~~]:

(I) radiation physics and instrumentation;

(II) radiation protection;

(III) mathematics pertaining to the use and measurement of radioactivity;

(IV) chemistry of radioactive material for medical or veterinary use; and

(V) radiation biology; and

(ii) work experience under the supervision of an authorized user who meets the requirements in subsection (l) of this section, this subsection, or paragraph (3)(A)(ii)(VII) of this section, and subsection (nn) of this section, or equivalent NRC or agreement state requirements. An authorized nuclear pharmacist who meets the requirements in subsections (k) or (l) of this section may provide the supervised work experience for subclause (VII) of this clause. Work experience must involve [~~the following~~]:

(I) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(II) performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(III) calculating, measuring, and safely preparing patient or human or animal research subject dosages;

(IV) using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(V) using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

(VI) administering dosages of radioactive drugs to patients or human or animal research subjects; and

(VII) eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclide purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(B) obtains [~~has obtained~~] written attestation [~~that~~] the individual has satisfactorily completed the requirements in this paragraph and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical or veterinary uses authorized under subsections (ff) and (hh) of this section. The attestation must be obtained from either:

(i) a preceptor authorized user meeting [~~who meets~~] the requirements of subsection (l) of this section, this subsection, or paragraph (3)(A)(ii)(VII) of this subsection, and subsection (nn) of this section, or equivalent NRC or agreement state requirements; or

(ii) a residency program director affirming [~~who affirms~~] in writing [~~that~~] the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user meeting [~~who meets~~] the requirements in subsections (l), [~~or~~] (jj), or (nn) of this section and paragraph (3)(A)(ii)(VII) of this subsection, or equivalent NRC or agreement state requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, [~~or~~] the Royal College of Physicians and Surgeons of Canada, or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in this paragraph.

(kk) Use of unsealed radioactive material requiring [~~that requires~~] a written directive. A licensee may use any unsealed radioactive material identified in subsection (nn)(2)(A)(ii)(VI) of this section prepared for medical or veterinary use requiring [~~that requires~~] a written directive [~~that meets the following~~]:

(1) [~~is~~] obtained from:

(A) a manufacturer or preparer licensed as specified in [~~accordance with~~] §289.252(r) of this subchapter [~~title~~] or equivalent NRC or agreement state requirements;

(B) a PET radioactive drug producer licensed as specified in [~~accordance with~~] §289.252(kk) of this subchapter [~~title~~] or equivalent NRC or agreement state requirements; or

(2) excluding production of PET radionuclides[,] prepared by:

(A) an authorized nuclear pharmacist; or

(B) a physician or veterinarian who is an authorized user and [who] meets the requirements specified in subsections (jj) or (nn) of this section; or

(C) an individual under the supervision, as specified in subsection (s) of this section, of the authorized nuclear pharmacist in subparagraph (A) of this paragraph, or the physician or veterinarian who is an authorized user in subparagraph (B) of this paragraph; or

(3) [is] obtained from and prepared by an NRC or agreement state licensee for use in research in accordance with an IND protocol accepted by the FDA; or

(4) [is] prepared by the licensee for use in research in accordance with an IND protocol accepted by the FDA.

(ll) Safety instruction to personnel.

(1) The licensee must [shall] provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human or animal research subjects who cannot be released as specified in [accordance with] subsection (cc) of this section. The instruction must [shall] be appropriate to the personnel's assigned duties and include [the following]:

(A) patient or human or animal research subject control; and

(B) visitor control, including [to include the following]:

(i) routine visitation to hospitalized individuals or animals as specified in [accordance with] §289.202(n) of this chapter [title];

(ii) contamination control;

(iii) waste control; and

(iv) notification of the RSO, or his or her designee, and an authorized user if the patient or the human or animal research subject has a medical emergency or dies.

(2) The licensee must [shall] maintain a record for inspection by the department, as specified in [accordance with] subsection (xxx) of this section, of individuals receiving instruction. The record must [shall] include [the following]:

(A) list of the topics covered;

(B) date of the instruction or training;

(C) names [name(s)] of the attendees [attendee(s)]; and

(D) names [name(s)] of the personnel [individual(s)] who provided the instruction.

(mm) Safety precautions. For each human patient or human research subject who cannot be released as specified in [accordance with] subsection (cc) of this section, the licensee must [shall do the following]:

(1) provide a private room with a private sanitary facility; or

(2) provide a room with a private sanitary facility with another individual who also has received therapy with an unsealed radioactive material and who also cannot be released as specified in [accordance with] subsection (cc) of this section;

(3) post the patient's or the research subject's room with a "Radioactive Materials" sign and note on the door and in the patient's or research subject's chart where and how long visitors may stay in the patient's or the research subject's room; and

(4) either monitor material and items removed from the patient's or the research subject's room to determine [that] their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or, handle such material and items as radioactive waste; and

(5) notify the RSO, or his or her designee, and the authorized user immediately if the patient or research subject has a medical emergency or dies.

(nn) Training for use of unsealed radioactive material requiring [that requires] a written directive. Except as provided in subsection (l) of this section, the licensee must [shall] require an authorized user of unsealed radioactive material for the uses authorized in subsection (kk) of this section to be [a physician who]:

(1) a physician [is] certified by a medical specialty board whose certification process is [has been] recognized by the department, the NRC, or an agreement state and who meets the requirements in paragraph (2)(A)(ii)(VI) of this subsection. The names of board certifications [that have been] recognized by the department, the NRC, or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page. To be recognized, a specialty board must [shall] require all candidates for certification to:

(A) successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must [shall] include 700 hours of training and experience as described in paragraph (2)(A)(i) - (2)(A)(ii)(V) of this subsection. Eligible training programs must [shall] be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Council on Postdoctoral [Committee on Post-Graduate] Training of the American Osteopathic Association; and

(B) pass an examination, administered by diplomates of the specialty board assessing[, which tests] knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed radioactive material for which a written directive is required; or

(2) a physician or veterinarian who: [has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive.]

(A) completes 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical or veterinary use of unsealed radioactive material requiring a written directive. The training and experience must [shall] include: [the following.]

(i) classroom and laboratory training in [the following areas]:

(I) radiation physics and instrumentation;

(II) radiation protection;

(III) mathematics pertaining to the use and measurement of radioactivity;

(IV) chemistry of radioactive material for medical or veterinary use; and

(V) radiation biology; and

(ii) work experience, under the supervision of an authorized user meeting [~~who meets~~] the requirements of subsection (l) of this section, this subsection, or equivalent NRC or agreement state requirements. A supervising authorized user meeting[~~, who meets~~] the requirements of this paragraph must [~~shall also~~] have experience in administering dosages in the same dosage category or categories (i.e., subclause (VI) of this clause) as the individual requesting authorized user status. The work experience must [~~shall~~] involve [~~the following~~]:

(I) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(II) performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(III) calculating, measuring, and safely preparing patient or human or animal research subject dosages;

(IV) using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(V) using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(VI) administering dosages of radioactive drugs to patients or human or animal research subjects from the three categories in the following items. Radioactive drugs containing radionuclides in categories not included in this paragraph are regulated under subsection (q) of this section. For each category in which the individual is requesting authorized user status, the [~~This~~] work experience must involve a minimum of three cases in [~~each of the following categories for which the individual is requesting authorized user status~~]:

(-a-) oral administration of less than or equal to 33 mCi (1.22 GBq) of sodium iodide I-131, for which a written directive is required;

(-b-) oral administration of greater than 33 mCi (1.22 GBq) of sodium iodide I-131 (experience with at least three cases in this item also satisfies the requirement of item (-a-) of this subclause); and

(-c-) parenteral administration of any radioactive drug that contains a radionuclide [~~that is~~] primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 kiloelectron volts (keV) for which a written directive is required; and

(B) obtains [~~has obtained~~] written attestation [~~that~~] the individual has satisfactorily completed the requirements of paragraph (2)(A) of this subsection[~~,~~] and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical or veterinary uses authorized under subsection (kk) of this section for which the individual is requesting authorized user status. The attestation must be obtained from either:

(i) a preceptor authorized user meeting [~~who meets~~] the requirements of subsection (l) of this section, this subsection, or equivalent NRC or agreement state requirements and has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status; or

(ii) a [~~A~~] residency program director affirming [~~who affirms~~] in writing [~~that~~] the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user meeting [~~who meets~~] the requirements in subsections (l) or (nn) of this section, or equivalent NRC or agreement state requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurring [~~concurs~~] with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, [~~or~~] the Royal College of Physicians and Surgeons of Canada, or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in this paragraph.

(oo) Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 33 mCi (1.22 GBq). Except as provided in subsection (l) of this section, the licensee must [~~shall~~] require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 33 mCi (1.22 GBq) to be [~~a physician who~~]:

(1) a physician [~~is~~] certified by a medical specialty board whose certification process includes all [~~of~~] the requirements of paragraph (3)(A) of this subsection and whose certification is [~~has been~~] recognized by the department, the NRC, or an agreement state[~~. The~~] (names of board certifications [~~that have been~~] recognized by the department, the NRC, or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page); or

(2) [~~is~~] an authorized user as specified in [~~accordance with~~] subsection (nn) of this section for uses listed in subsection (nn)(2)(A)(ii)(VI)(-a-) or (-b-) of this section, or subsection (pp) of this section, or equivalent NRC or agreement state requirements; or

(3) a physician or veterinarian who: [~~has successfully completed 80 hours of classroom and laboratory training and work experience applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive.~~]

(A) successfully completes 80 hours of classroom and laboratory training and work experience applicable to the medical or veterinary use of sodium iodide I-131 for procedures requiring a written directive. The training and experience must [~~shall~~] include: [~~the following.~~]

(i) classroom and laboratory training, including [~~shall include the following~~]:

(I) radiation physics and instrumentation;

(II) radiation protection;

(III) mathematics pertaining to the use and measurement of radioactivity;

(IV) chemistry of radioactive material for medical or veterinary use; and

(V) radiation biology; and

(ii) work experience, under the supervision of an authorized user meeting [~~who meets~~] the requirements of subsection (l) of this section, this subsection, subsection (nn) or subsection (pp) of this section, or equivalent NRC or agreement state requirements. A supervising authorized user meeting [~~who meets~~] the requirements in subsection (nn)(2) of this section must[~~, shall~~] also have experience in administering dosages as specified in subsection (nn)(2)(A)(ii)(VI)(-a-) or (-b-) of this section. The work experience must [~~shall~~] involve [~~the following~~]:

(I) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(II) performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(III) calculating, measuring, and safely preparing patient or human or animal research subject dosages;

(IV) using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(V) using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(VI) administering dosages of radioactive drugs to patients or human or animal research subjects that includes at least three cases involving the oral administration of less than or equal to 33mCi (1.22 GBq) of sodium iodide I-131; and

(B) obtains [~~has obtained~~] written attestation [~~that~~] the individual has satisfactorily completed the requirements of paragraph (3)(A) of this subsection[~~,~~] and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of less than or equal to 33 mCi (1.22 GBq) of sodium iodide I-131 for medical or veterinary uses authorized under subsection (kk) of this section. The attestation must be obtained from either:

(i) a preceptor authorized user meeting [~~who meets~~] the requirements of subsection (l) of this section, this subsection, subsection (nn) or subsection (pp) of this section, or equivalent NRC or agreement state requirements and has experience in administering dosages as specified in subsection (nn)(2)(A)(ii)(VI)(-a-) or (-b-) of this section; or

(ii) a residency program director affirming [~~who affirms~~] in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user meeting [~~who meets~~] the requirements in subsections (l), (nn), (oo), or (pp) of this section, or equivalent NRC or agreement state requirements, has experience in administering dosages as specified in subsection (nn)(2)(A)(ii)(VI)(-a-) or (-b-), and concurring [~~concurs~~] with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, [~~or~~] the Royal College of Physicians and Surgeons of Canada, or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in this paragraph.

(pp) Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 33 mCi (1.22 GBq). Except as provided in subsection (l) of this section, the licensee must [~~shall~~] require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 33 mCi (1.22 GBq) to be [~~a physician who~~]:

(1) a physician [~~is~~] certified by a medical specialty board whose certification process includes all [~~of~~] the requirements in paragraph (3)(A) of this subsection and whose certification is [~~has been~~] recognized by the department, the NRC, or an agreement state[~~. The~~] (names of board certifications [~~that have been~~] recognized by the department, the NRC, or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page); or

(2) [~~is~~] an authorized user as specified in [~~accordance with~~] subsection (nn) of this section or equivalent NRC or agreement state requirements for uses listed in subsection (nn)(2)(A)(ii)(VI)(-b-) of this section; or

(3) a physician or veterinarian who: [~~has training and experience including, successful completion of 80 hours of classroom and laboratory training applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive.~~]

(A) successfully completes 80 hours of classroom and laboratory training applicable to the medical or veterinary use of sodium iodide I-131 for procedures requiring a written directive. The training and experience must [~~shall~~] include: [~~the following.~~]

(i) classroom and laboratory training, including [~~shall include the following~~]:

(I) radiation physics and instrumentation;

(II) radiation protection;

(III) mathematics pertaining to the use and measurement of radioactivity;

(IV) chemistry of radioactive material for medical or veterinary use; and

(V) radiation biology; and

(ii) work experience, under the supervision of an authorized user meeting [~~who meets~~] the requirements of subsection (l) of this section, subsections (nn) or (pp) of this section, or equivalent NRC or agreement state requirements. A supervising authorized user meeting [~~who meets~~] the requirements of subsection (nn)(2) of this section must[~~, shall~~] also have experience in administering dosages as specified in subsection (nn)(2)(A)(ii)(VI)(-b-) of this section. The work experience must [~~shall~~] involve [~~the following~~]:

(I) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(II) performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(III) calculating, measuring, and safely preparing patient or human or animal research subject dosages;

(IV) using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(V) using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(VI) administering dosages of radioactive drugs to patients or human or animal research subjects that includes at least three cases involving the oral administration of greater than 33 mCi (1.22 GBq) of sodium iodide I-131; and

(B) obtains [~~has obtained~~] written attestation [~~that~~] the individual has satisfactorily completed the requirements of paragraph (3)(A) of this subsection[~~,~~] and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of greater than 33 mCi (1.22 GBq) of sodium iodide I-131 for medical or veterinary uses authorized under subsection (kk) of this section. The attestation must be obtained from either:

(i) a preceptor authorized user meeting [~~who meets~~] the requirements in subsections (l) or (nn) of this section, this subsection, or equivalent NRC or agreement state requirements[~~,~~] and has experience in administering dosages as specified in subsection (nn)(2)(A)(ii)(VI)(-b-) of this section; or

(ii) a residency program director affirming [~~who affirms~~] in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user meeting [~~who meets~~] the requirements in subsections (l), (nn), or (pp) of this section, or equivalent NRC[~~,~~] or agreement state requirements, has experience in administering dosages as speci-

fied in subsection (nn)(2)(A)(ii)(VI)(-b-) of this section, and concurring [~~concurs~~] with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, [~~or~~] the Royal College of Physicians and Surgeons of Canada, or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in this paragraph.

(qq) Training for the parenteral administration of unsealed radioactive material requiring a written directive.

(1) Except as provided in subsection (l) of this section, the licensee must [~~shall~~] require an authorized user for the parenteral administration of unsealed radioactive materials requiring a written directive to be [~~a physician who~~]:

(A) [~~is~~] an authorized user as specified in [~~accordance with~~] subsection (nn) of this section for uses listed in subsection (nn)(2)(A)(ii)(VI)(-c-) of this section or equivalent NRC or agreement state requirements; or

(B) [~~is~~] an authorized user under subsections (zz) or (ttt) of this section or equivalent NRC or agreement state requirements and meeting [~~who meets~~] the requirements of paragraph (2) of this subsection; or

(C) a physician [~~is~~] certified by a medical specialty board whose certification process is [~~has been~~] recognized by the department, the NRC, or an agreement state as specified in [~~accordance with~~] subsections (zz) or (ttt) of this section, and [~~who~~] meets the requirements of paragraph (2) of this subsection.

(2) The physician or veterinarian must also [~~meet the following requirements~~]:

(A) [~~has~~] successfully complete [~~completed~~] 80 hours of classroom and laboratory training applicable to parenteral administrations listed in subsection (nn)(2)(A)(ii)(VI)(-c-) of this section.

(B) complete [~~has the~~] training and experience to [~~that shall~~] include [~~the following~~]:

(i) classroom and laboratory training, including [~~shall include the following~~]:

(I) radiation physics and instrumentation;

(II) radiation protection;

(III) mathematics pertaining to the use and measurement of radioactivity;

(IV) chemistry of radioactive material for medical use; and

(V) radiation biology; and

(ii) work experience, under the supervision of an authorized user meeting [~~who meets~~] the requirements of subsection (l) of this section, this subsection, or subsection (nn) of this section, or equivalent NRC or agreement state requirements in the parenteral administration listed in subsection (nn)(2)(A)(ii)(VI)(-c-) of this section. A supervising authorized user meeting [~~who meets~~] the requirements of subsection (nn) of this section, this subsection, or equivalent NRC or agreement state requirements must [~~shall~~] have experience in administering dosages in the same category or categories as the individual requesting authorized user status. The work experience must [~~shall~~] involve [~~the following~~]:

(I) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(II) performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(III) calculating, measuring, and safely preparing patient or human or animal research subject dosages;

(IV) using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(V) using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(VI) administering dosages to patients or human or animal research subjects that include at least three cases involving the parenteral administration specified in subsection (nn)(2)(A)(ii)(VI)(-c-) of this section; and

(C) obtain [~~has obtained~~] written attestation [~~that~~] the individual has satisfactorily completed the requirements of paragraph (2)(A) and (B) of this subsection[~~,~~] and is able to independently fulfill the radiation safety-related duties as an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive. The attestation must be obtained from either:

(i) a preceptor authorized user meeting [~~who meets~~] the requirements of subsection (l) of this section, subsection (nn) of this section, or this subsection, or equivalent NRC or agreement state requirements. A preceptor authorized user meeting [~~who meets~~] the requirements in subsection (nn) of this section, this section, or equivalent agreement state [~~Agreement State~~] requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status; or[~~, and shall have experience in administering dosages in the same category or categories as the individual requesting authorized user status; or~~]

(ii) a [~~A~~] residency program director affirming [~~who affirms~~] in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user meeting [~~who meets~~] the requirements in subsections (l), (nn), or (qq) of this section, or equivalent NRC or agreement state requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurring [~~concurs~~] with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, [~~or~~] the Royal College of Physicians and Surgeons of Canada, or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in this paragraph.

(rr) Use of sealed sources for manual brachytherapy. The licensee must [~~shall~~] use only brachytherapy sources as follows:

(1) as approved in the Sealed Source and Device Registry for manual brachytherapy medical or veterinary use. The manual brachytherapy sources may be used for manual brachytherapy uses [~~that are~~] not explicitly listed in the Sealed Source and Device Registry, but must be used according to [~~in accordance with~~] the radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

(2) in research to deliver therapeutic doses for medical or veterinary use in accordance with an active Investigational Device Exemption application accepted by the FDA provided the requirements of subsection (u)(1) of this section are met.

(ss) Surveys after sealed source implants and removal.

(1) Immediately after implanting sealed sources in a patient or a human or animal research subject, the licensee must [~~shall~~] perform a survey to locate and account for all sealed sources [~~that have~~] not [~~been~~] implanted.

(2) Immediately after removing the last temporary implant sealed source from a patient or a human or animal research subject, the licensee must [~~shall~~] perform a survey of the patient or the human or animal research subject with a radiation detection survey instrument to confirm [~~that~~] all sealed sources are [~~have been~~] removed.

(3) A record of each survey must [~~shall~~] be retained, for inspection by the department, as specified in [~~accordance with~~] subsection (xxx) of this section. The record must [~~shall~~] include [~~the following~~]:

(A) date of the survey;

(B) results of the survey;

(C) manufacturer's name and model and serial number of the instrument used to make the survey; and

(D) name of the individual who performed the survey.

(tt) Brachytherapy sealed sources accountability.

(1) The licensee must [~~shall~~] maintain accountability at all times for all brachytherapy sealed sources in storage or use.

(2) Promptly after removing sealed sources from a patient or a human or animal research subject, the licensee must [~~shall~~] return brachytherapy sealed sources to a secure storage area.

(3) The licensee must [~~shall~~] maintain a record of the brachytherapy sealed source accountability as specified in [~~accordance with~~] subsection (xxx) of this section for inspection by the department.

(A) When removing temporary implants from storage, the licensee must [~~shall~~] record the number and activity of sources, time and date the sources were removed, the name of the individual who removed the sources, and the location of use. When temporary implants are returned to storage, the licensee must record the number and activity of sources, the time and date, and the name of the individual who returned them.

(B) When removing permanent implants from storage, the licensee must [~~shall~~] record the number and activity of sources, the date, the name of the individual who removed the sources, and the number and activity of sources permanently implanted in the patient or human or animal research subject. The licensee must record [~~Record~~] the number and activity of sources not implanted and returned to storage, the date they were returned to storage, and the name of the individual who returned them to storage.

(uu) Safety instruction to personnel. The licensee must [~~shall~~] provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human or animal research subjects [~~who are~~] receiving brachytherapy and who cannot be released as specified in [~~accordance with~~] subsection (cc) of this section or animals that are confined.

(1) The instruction must [~~shall~~] be appropriate to the personnel's assigned duties and include [~~the following~~]:

(A) size and appearance of brachytherapy sources;

(B) safe handling and shielding instructions;

(C) patient or human or animal research subject control;

(D) visitor control, including [~~to include~~] visitation to hospitalized patients [~~individuals~~] as specified in [~~accordance with~~] §289.202(n) of this chapter [~~title~~]; and

(E) notification of the RSO, or his or her designee, and an authorized user if the patient or the human or animal research subject has a medical emergency or dies.

(2) A licensee must [~~shall~~] maintain a record, for inspection by the department, as specified in [~~accordance with~~] subsection (xxx) of this section, of individuals receiving instruction. The record must [~~shall~~] include [~~the following~~]:

(A) list of the topics covered;

(B) date of the instruction or training;

(C) names [~~name(s)~~] of the attendees [~~attendee(s)~~]; and

(D) names [~~name(s)~~] of the personnel [~~individual(s)~~] who provided the instruction.

(vv) Safety precautions for the use of brachytherapy.

(1) For each patient or human research subject [~~who is~~] receiving brachytherapy and who cannot be released as specified in [~~accordance with~~] subsection (cc) of this section the licensee must [~~shall~~]:

(A) provide a private room with a private sanitary facility;

(B) post the patient's or the research subject's room with a "Radioactive Materials" sign and note on the door or in the patient's or research subject's chart where and how long visitors may stay in the patient's or the research subject's room; and

(C) have available near each treatment room, applicable emergency response equipment to respond to a sealed source [~~that is~~] inadvertently dislodged from the patient or inadvertently lodged within the patient following removal of the sealed source applicators.

(2) The RSO, or his or her designee, and the authorized user must [~~shall~~] be notified if the patient or research subject has a medical emergency, and[~~,~~] immediately[~~,~~] if the patient dies.

(ww) Calibration measurements of brachytherapy sealed sources.

(1) Before the first medical or veterinary use of a brachytherapy sealed source [~~on or after October 1,~~ 2000], the licensee must [~~shall do the following~~]:

(A) determine the sealed source output or activity using a dosimetry system meeting [~~that meets~~] the requirements of subsection (iii)(1) of this section;

(B) determine sealed source positioning accuracy within applicators; and

(C) use published protocols accepted by nationally recognized bodies to meet the requirements of subparagraphs (A) and (B) of this paragraph.

(2) Instead of the licensee making its own measurements as required in paragraph (1) of this subsection, the licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine [~~that are~~] made as specified in [~~accordance with~~] paragraph (1) of this subsection.

(3) The licensee must [~~shall~~] mathematically correct the outputs or activities determined in paragraph (1) of this subsection for physical decay at intervals consistent with one percent physical decay.

(4) The licensee must [~~shall~~] retain a record of each calibration as specified in [~~accordance with~~] subsection (xxx) of this section for inspection by the department. The record must [~~shall~~] include [~~the following~~]:

(A) complete date of the calibration including the month, day, and year;

(B) manufacturer's name and model and serial number for the sealed source and instruments used to calibrate the sealed source;

(C) sealed source output or activity;

(D) sealed source positioning accuracy within applicators; and

(E) name of the individual, the source manufacturer, or the calibration laboratory that performed the calibration.

(xx) Strontium-90 sources for ophthalmic treatments.

(1) A licensee using [~~who uses~~] strontium-90 for ophthalmic treatments must ensure [~~that~~] certain activities as specified in paragraph (2) of this subsection are performed by either:

(A) an authorized medical physicist; or

(B) an individual who:

(i) is identified as an ophthalmic physicist on a specific medical use license issued by the department, the NRC, or an agreement state; permit issued by the department, the NRC, or an agreement state broad scope medical use licensee; medical use permit issued by an NRC master material licensee; or permit issued by an NRC master material licensee broad scope medical use permittee; and

(ii) holds a master's or doctoral [~~doctor's~~] degree in physics, medical physics, other physical sciences, engineering, or applied mathematics from an accredited college or university; and

(iii) has successfully completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of a medical physicist; and

(iv) has documented training in:

(I) the creation, modification, and completion of written directives;

(II) procedures for administrations requiring a written directive; and

(III) performing the calibration measurements of brachytherapy sources as detailed in subsection (ww) of this section.

(2) The individual [~~who is~~] identified in paragraph (1) of this subsection must:

(A) calculate the activity of each strontium-90 source [~~that is~~] used to determine the treatment times for ophthalmic treatments, and the decay must be based on the activity determined under subsection (ww) of this section; and

(B) assist the licensee in developing, implementing, and maintaining written procedures to provide high confidence [~~that~~] the administration is in accordance with the written directive. These procedures must include the frequencies [~~that~~] the individual meeting the requirements in paragraph (1) of this subsection will:

(i) observe treatments;[~~,~~]

(ii) review the treatment methodology;[~~,~~]

(iii) calculate treatment time for the prescribed dose;[~~,~~] and

(iv) review records to verify [~~that~~] the administrations were in accordance with the written directives.

(3) A licensee must [~~shall~~] maintain a record of the activity of a strontium-90 source as specified in [~~accordance with~~] subsection (xxx) of this section for inspection by the department. The record must [~~shall~~] include [~~the following~~]:

(A) date and initial activity of the source as determined under subsection (ww) of this section; and

(B) for each decay calculation, the date and the source activity as determined under this subsection.

(yy) Therapy-related computer systems for manual brachytherapy. The licensee must [~~shall~~] perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must [~~shall~~] include, as applicable, verification of [~~the following~~]:

(1) the sealed source-specific input parameters required by the dose calculation algorithm;

(2) the accuracy of dose, dwell time, and treatment time calculations at representative points;

(3) the accuracy of isodose plots and graphic displays; and

(4) the accuracy of the software used to determine radioactive sealed source positions from radiographic images.

(zz) Training for use of manual brachytherapy sealed sources. Except as provided in subsection (l) of this section, the licensee must [~~shall~~] require an authorized user of a manual brachytherapy source for the uses authorized in subsection (rr) of this section to be a physician or veterinarian who:

(1) is certified by a medical specialty board whose certification process is [~~has been~~] recognized by the department, the NRC, or an agreement state. The names of board certifications [~~that have been~~] recognized by the department, the NRC, or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification recognized, a specialty board must [~~shall~~] require all candidates for certification to:

(A) successfully complete a minimum of three years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Council on Postdoctoral [~~Committee on Post-Graduate~~] Training of the American Osteopathic Association; and

(B) pass an examination[~~,~~] administered by diplomates of the specialty board assessing [~~, that assesses~~] knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or

(2) has [~~completed~~]:

(A) completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources, including [~~the following~~]:

(i) 200 hours of classroom and laboratory training in [~~the following areas~~]:

(I) radiation physics and instrumentation;

(II) radiation protection;

(III) mathematics pertaining to the use and measurement of radioactivity; and

(IV) radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user meeting [~~who meets~~] the requirements of subsection (l) of this section, this subsection, or equivalent NRC or agreement state requirements at a medical facility authorized to use radioactive material under subsection (rr) of this section, involving [~~the following~~]:

(I) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(II) checking survey meters for proper operation;

(III) preparing, implanting, and removing brachytherapy sources;

(IV) maintaining running inventories of material on hand;

(V) using administrative controls to prevent a medical event involving the use of radioactive material; and

(VI) using emergency procedures to control radioactive material; and

(B) three years of supervised clinical experience in radiation oncology, under an authorized user meeting [~~who meets~~] the requirements of subsection (l) of this section, this subsection, or equivalent NRC or agreement state requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Council [~~Committee~~] on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by subparagraph (A)(ii) of this paragraph; and

(C) [~~(3)~~] [~~has~~] obtained written attestation [~~that~~] the individual has satisfactorily completed the requirements in paragraph (2) of this subsection and is able to independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy sources for the medical or veterinary uses authorized under subsection (rr) of this section. The attestation must be obtained from either:

(i) [~~(A)~~] a preceptor authorized user meeting [~~who meets~~] the requirements of subsection (l) of this section, this subsection, or equivalent NRC or agreement state requirements; or

(ii) [~~(B)~~] a residency program director affirming [~~who affirms~~] in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user meeting [~~who meets~~] the requirements in subsection (l) of this section, this subsection, or equivalent NRC or agreement state requirements, and concurring [~~concurs~~] with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, [~~or~~] the Royal College of Physicians and Surgeons of Canada, or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraph (2) of this subsection.

(aaa) Training for ophthalmic use of strontium-90. Except as provided in subsection (l) of this section, the licensee must [~~shall~~] require an authorized user of strontium-90 for ophthalmic radiotherapy to be a physician or veterinarian who:

(1) is an authorized user under subsection (zz) of this section or equivalent NRC or agreement state requirements; or

(2) has completed 24 hours of classroom and laboratory training applicable to the medical or veterinary use of strontium-90 for ophthalmic radiotherapy.

(A) The training must [~~shall~~] include: [~~the following.~~]

(i) classroom training in [~~shall include the following~~]:

(I) radiation physics and instrumentation;

(II) radiation protection;

(III) mathematics pertaining to the use and measurement of radioactivity; and

(IV) radiation biology; and

(ii) supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five patients [~~individuals~~]. This supervised clinical training must [~~shall~~] involve:

(I) examination of each patient [~~individual~~] to be treated;

(II) calculation of the dose to be administered;

(III) administration of the dose; and

(IV) follow-up and review of each patient's [~~individual's~~] case history; and

(3) has obtained written attestation, signed by a preceptor authorized user meeting [~~who meets~~] the requirements of subsection (l) of this section, subsection (zz) of this section, or this subsection, or equivalent NRC or agreement state requirements, that the individual has satisfactorily completed the requirements of paragraph (2)(A) of this subsection and is able to independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.

(bbb) Use of sealed sources and medical devices for diagnosis.

(1) The licensee must [~~shall~~] use only sealed sources [~~that are~~] not in medical devices for diagnostic medical uses if the sealed sources are approved in the Sealed Source and Device Registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses [~~that are~~] not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

(2) The licensee must only use medical devices containing sealed sources for diagnostic medical uses if both the sealed sources and medical devices are approved in the Sealed Source and Device Registry for diagnostic medical uses. The diagnostic medical devices may be used for diagnostic medical uses [~~that are~~] not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

(3) Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of subsection (u)(1) of this section are met.

(4) The licensee must [~~shall~~] ensure [~~that~~] installation or exchange of sealed sources [~~source(s)~~] in medical imaging equipment is performed only by the manufacturer or persons specifically autho-

rized to perform these services by the department, the NRC, or another agreement state. The licensee must [~~shall~~] maintain a record for each installation or exchange for inspection by the department as specified in [~~accordance with~~] subsection (xxx) of this section. The record must [~~shall~~] include the date, the installer's radioactive material license number, and the regulatory agency that issued the license to the installer.

(ccc) Training for use of sealed sources for diagnosis. Except as provided in subsection (l) of this section, the licensee must [~~shall~~] require the authorized user of a diagnostic sealed source or a device authorized as specified in [~~accordance with~~] subsection (bbb) of this section to be a physician, dentist, [~~or~~] podiatrist, or veterinarian who:

(1) is certified by a specialty board whose certification process includes all [~~of~~] the requirements of paragraphs (3) and (4) of this subsection and whose certification is [~~has been~~] recognized by the department, the NRC, or an agreement state[~~. The~~] (names of board certifications [~~that have been~~] recognized by the department, the NRC, or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page); or

(2) is an authorized user for uses listed in subsection (hh) of this section or equivalent NRC or agreement state requirements; or

(3) has completed eight hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must [~~shall~~] include:

(A) radiation physics and instrumentation;

(B) radiation protection;

(C) mathematics pertaining to the use and measurement of radioactivity; and

(D) radiation biology; and

(4) has completed training in the use of the device for the uses requested.

(ddd) Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.

(1) The licensee must [~~shall~~] only use sealed sources:

(A) as approved and as provided for in the Sealed Source and Device Registry in photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units to deliver therapeutic doses for medical uses; or

(B) in research involving photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units in accordance with an active IDE application accepted by the FDA, provided the requirements of subsection (u)(1) of this section are met.

(2) A licensee must [~~shall~~] use photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units:

(A) approved in the Sealed Source and Device Registry to deliver a therapeutic dose for medical use. These devices may be used for therapeutic medical treatments [~~that are~~] not explicitly provided for in the Sealed Source and Device Registry, but must be used in accordance with radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

(B) in research in accordance with an active IDE application accepted by the FDA, provided the requirements of subsection (u)(1) of this section are met.

(eee) Surveys of patients and human research subjects treated with a remote afterloader unit.

(1) Before releasing a patient or a human research subject from licensee control, the licensee must [~~shall~~] perform a survey of the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm [~~that~~] the sealed source or sources have [~~source(s) has~~] been removed from the patient or human research subject and returned to the safe shielded position.

(2) The licensee must [~~shall~~] maintain a record of the surveys as specified in [~~accordance with~~] subsection (xxx) of this section for inspection by the department. The record must [~~shall~~] include [~~the following~~]:

(A) date of the survey;

(B) results of the survey;

(C) manufacturer's name, model, and serial number of the survey instrument used; and

(D) name of the individual who made the survey.

(fff) Installation, maintenance, adjustment, and repair.

(1) Only a person specifically licensed by the department, the NRC, or an agreement state may [~~shall~~] install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the sealed source [~~source(s)~~] shielding, the sealed source [~~source(s)~~] driving unit, or other electronic or mechanical component that could expose the sealed source or sources [~~source(s)~~], reduce the shielding around the sealed source or sources [~~source(s)~~], or compromise the radiation safety of the unit or the sealed source or sources [~~source(s)~~].

(2) Except for low dose-rate remote afterloader units, only a person specifically licensed by the department, the NRC, or an agreement state may [~~shall~~] install, replace, relocate, or remove a sealed source or sealed source contained in other remote afterloader units, teletherapy units, or gamma stereotactic units.

(3) For a low dose-rate remote afterloader unit, only a person specifically licensed by the department, the NRC, an agreement state, or an authorized medical physicist may [~~shall~~] install, replace, relocate, or remove a sealed source [~~source(s)~~] contained in the unit.

(4) The licensee must [~~shall~~] maintain a record of the installation, maintenance, adjustment, and repair done on remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as specified in [~~accordance with~~] subsection (xxx) of this section for inspection by the department. For each installation, maintenance, adjustment, and repair, the record must [~~shall~~] include the date, description of the service, and names [~~name(s)~~] of the individuals [~~individual(s)~~] who performed the work.

(ggg) Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

(1) A licensee must [~~shall do the following~~]:

(A) secure the unit, the console, the console keys, and the treatment room when not in use or unattended;

(B) permit only individuals approved by the authorized user, RSO, or authorized medical physicist to be present in the treatment room during treatment with the sealed source or sources [~~source(s)~~];

(C) prevent dual operation of more than one radiation producing device in a treatment room, if applicable; and

(D) develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the sealed source or sources [~~source(s)~~] in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. The procedures must [~~shall~~] include [~~the following~~]:

(i) instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

(ii) the process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

(iii) the names and telephone numbers of the authorized users, the authorized medical physicist, and the RSO to be contacted if the unit or console operates abnormally;

(2) A copy of the procedures required by paragraph (1)(D) of this subsection must be physically located at the unit console.

(3) The licensee must [~~shall~~] post instructions at the unit console to inform the operator of [~~the following~~]:

(A) the location of the procedures required by paragraph (1)(D) of this subsection; and

(B) the names and telephone numbers of the authorized users, the authorized medical physicist, and the RSO to be contacted if the unit or console operates abnormally.

(4) Before the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade affecting [~~that affects~~] the operation and safety of the unit:

(A) a licensee must [~~shall~~] ensure [~~that~~] vendor operational and safety training is provided to all individuals who will operate the unit. The vendor operational and safety training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training.

(B) a licensee must [~~shall~~] provide operational and safety instructions initially and at least annually [~~,~~] to all individuals who operate the unit at the facility, as appropriate to the individual's assigned duties, to include:

(i) procedures identified in paragraph (1)(D) of this subsection; and

(ii) operating procedures for the unit.

(5) A licensee must [~~shall~~] ensure [~~that~~] operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually. [~~; and~~]

(6) A licensee must [~~shall~~] maintain records of the procedures required by paragraphs (1)(D) and (4)(B)(ii) of this subsection as specified in [~~accordance with~~] subsection (xxx) of this section for inspection by the department.

(7) A licensee must [~~shall~~] maintain records of individuals receiving instruction and participating in drills required by paragraphs (4) and (5) of this subsection as specified in [~~accordance with~~] subsection (xxx) of this section for inspection by the department. The record must [~~shall~~] include [~~the following~~]:

(A) a list of the topics covered;

(B) date of the instruction or drill;

(C) names [~~name(s)~~] of the attendees [~~attendee(s)~~]; and

(D) names [~~name(s)~~] of the personnel [~~individual(s)~~] who provided the instruction.

(hhh) Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. The licensee must [~~shall do the following~~]:

(1) control access to the treatment room by a door at each entrance;

(2) equip each entrance to the treatment room with an electrical interlock system that will [~~do the following~~]:

(A) prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

(B) cause the sealed source or sources [~~source(s)~~] to be shielded promptly when an entrance door is opened; and

(C) prevent the sealed source or sources [~~source(s)~~] from being exposed following an interlock interruption until all treatment room entrance doors are closed and the sealed source [~~source(s)~~] "on-off" control is reset at the console;

(3) require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, [~~that~~] radiation levels have returned to ambient levels;

(4) except for low-dose remote afterloader units, construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation;

(5) for licensed activities when [~~where~~] sealed sources are placed within the patient's or human research subject's body, only conduct treatments allowing [~~that allow for~~] expeditious removal of a decoupled or jammed sealed source;

(6) in addition to the requirements specified in paragraphs (1) - (5) of this subsection, require [~~the following~~]:

(A) for low dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units:

(i) an authorized medical physicist [~~,~~] and either an authorized user or a physician, under the supervision of an authorized user, [~~who has been~~] trained in the operation and emergency response for the unit, be physically present during the initiation of all patient treatments involving the unit; and

(ii) an authorized medical physicist [~~,~~] and either an authorized user or an individual, under the supervision of an authorized user, [~~who has been~~] trained to remove the sealed source applicator [~~applicator(s)~~] in the event of an emergency involving the unit, be immediately available during continuation of all patient treatments involving the unit;

(B) for high dose-rate remote afterloader units:

(i) an authorized user and an authorized medical physicist be physically present during the initiation of all patient treatments involving the unit; and

(ii) an authorized medical physicist [~~,~~] and either an authorized user or a physician, under the supervision of an authorized user, [~~who has been~~] trained in the operation and emergency response for the unit, be physically present during continuation of all patient treatments involving the unit;

(C) for gamma stereotactic radiosurgery units and teletherapy units, require [~~that~~] an authorized user and an authorized medical physicist be physically present throughout all patient treatments [~~involving gamma stereotactic radiosurgery units and teletherapy units~~]; and

(D) notify the RSO, or his or her designee, and an authorized user as soon as possible [,] if the patient or human research subject has a medical emergency or dies; and

(7) have applicable emergency response equipment available near each treatment room to respond to a sealed source that remains in the unshielded position or lodges within the patient following completion of the treatment.

(iii) Dosimetry equipment.

(1) Except for low dose-rate remote afterloader sealed sources where the sealed source output or activity is determined by the manufacturer, the licensee must [~~shall~~] have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions are required [~~shall be met~~]:

(A) the system was [~~shall have been~~] calibrated using a system or sealed source traceable to the National Institute of Standards and Technology (NIST) and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration was [~~shall have been~~] performed within the previous two years and after any servicing that may have affected system calibration; or

(B) the system was [~~shall have been~~] calibrated within the previous four years. Eighteen to 30 months after that calibration, the system was [~~shall have been~~] intercompared with another dosimetry system [~~that was~~] calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison must have indicated [~~shall have indicated that~~] the calibration factor of the licensee's system had not changed by more than two percent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems [~~to be~~] used for calibrating sealed sources for therapeutic units [~~unit~~], the licensee must [~~shall~~] use a comparable unit with beam attenuators or collimators, as applicable, and sealed sources of the same radionuclide as the sealed source used at the licensee's facility.

(2) The licensee must [~~shall~~] have available for use a dosimetry system for spot check output measurements, if such measurements are required by this section. To satisfy this requirement, the system may be compared with a system [~~that has been~~] calibrated as specified in [~~accordance with~~] paragraph (1) of this subsection. This comparison must [~~shall~~] have been performed within the previous year and after each servicing that may have affected system calibration. The spot check system may be the same system used to meet the requirements of paragraph (1) of this subsection.

(3) The licensee must [~~shall~~] retain a record of each calibration, intercomparison, and comparison of dosimetry equipment as specified in [~~accordance with~~] subsection (xxx) of this section for inspection by the department. The record must [~~shall~~] include [~~the following~~]:

(A) complete date of the calibration including the month, day, and year;

(B) manufacturer's model and serial numbers of the instruments that were calibrated, intercompared, or compared;

(C) the correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and

(D) the names of the individuals who performed the calibration, intercomparison, or comparison.

(jjj) Full calibration measurements on teletherapy units.

(1) A licensee authorized to use a teletherapy unit for medical use must [~~shall~~] perform full calibration measurements on each teletherapy unit as follows:

(A) before the first medical use of the unit; and

(B) before medical use under any of the following conditions:

(i) whenever spot check measurements indicate [~~that~~] the output differs by more than five percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) following replacement of the sealed source or following reinstallation of the teletherapy unit in a new location;

(iii) following any repair of the teletherapy unit that includes removal of the sealed source or major repair of the components associated with the sealed source exposure assembly; and

(C) at intervals not to exceed one year.

(2) Full calibration measurements must [~~shall~~] include determination of [~~the following~~]:

(A) the output within plus or minus three percent for the range of field sizes and for the distance or range of distances used for medical use;

(B) the coincidence of the radiation field and the field indicated by the light beam localizing device;

(C) uniformity of the radiation field and its dependence on the orientation of the useful beam;

(D) timer accuracy and linearity over the range of use;

(E) "on-off" error; and

(F) the accuracy of all distance measuring and localization devices in medical use.

(3) The licensee must [~~shall~~] use the dosimetry system described in subsection (iii)(1) of this section to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph (2)(A) of this subsection may be made using a dosimetry system indicating [~~that indicates~~] relative dose rates.

(4) The licensee must [~~shall~~] make full calibration measurements required by paragraph (1) of this subsection in accordance with published protocols accepted by nationally recognized bodies.

(5) The licensee must [~~shall~~] mathematically correct the outputs determined in paragraph (2)(A) of this subsection for physical decay at intervals not to exceed one month for cobalt-60, six months for cesium-137, or at intervals consistent with one percent decay for all other nuclides.

(6) Full calibration measurements required by paragraph (1) of this subsection and physical decay corrections required by paragraph (5) of this subsection must [~~shall~~] be performed by an authorized medical physicist.

(7) The licensee must [~~shall~~] retain a record of each calibration as specified in [~~accordance with~~] subsection (xxx) of this section for inspection by the department. The record must [~~shall~~] include [~~the following~~]:

(A) complete date of the calibration including the month, day, and year;

(B) manufacturer's name, model number, and serial number of the teletherapy unit's sealed source and the instruments used to calibrate the unit;

(C) results and an assessment of the full calibrations; and

(D) name and signature of the authorized medical physicist who performed the full calibration.

(kkk) Full calibration measurements on remote afterloader units.

(1) A licensee authorized to use a remote afterloader for medical use must [~~shall~~] perform full calibration measurements on each unit [~~as follows~~]:

(A) before the first medical use of the unit;

(B) before medical use under any of the following conditions:

(i) following replacement of the sealed source;

(ii) following reinstallation of the unit in a new location outside the facility; and

(iii) following any repair of the unit that includes removal of the sealed source or major repair of the components associated with the sealed source exposure assembly;

(C) at intervals not to exceed three months for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sealed sources whose half-life exceeds 75 days; and

(D) at intervals not to exceed one year for low dose-rate afterloader units.

(2) Full calibration measurements must [~~shall~~] include, as applicable, determination of [~~the following~~]:

(A) the output within plus or minus five percent;

(B) sealed source positioning accuracy to within plus or minus 1 millimeter (mm);

(C) sealed source retraction with backup battery upon power failure;

(D) length of the sealed source transfer tubes;

(E) timer accuracy and linearity over the typical range of use;

(F) length of the applicators; and

(G) function of the sealed source transfer tubes, applicators, and transfer tube-applicator interfaces.

(3) A licensee must [~~shall~~] use the dosimetry system described in subsection (iii)(1) of this section to measure the output.

(4) A licensee must [~~shall~~] make full calibration measurements required by paragraph (1) of this subsection in accordance with published protocols accepted by nationally recognized bodies.

(5) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in paragraph (2) of this subsection, a licensee must [~~shall~~] perform an autoradiograph of the sealed source or sources [~~source(s)~~] to verify inventory and sealed source [~~source(s)~~] arrangement at intervals not to exceed three months.

(6) For low dose-rate remote afterloader units, a licensee may use measurements provided by the sealed source manufacturer that are made as specified in [~~accordance with~~] paragraphs (1) - (5) of this subsection.

(7) The licensee must [~~shall~~] mathematically correct the outputs determined in paragraph (2)(A) of this subsection for physical decay at intervals consistent with one percent physical decay.

(8) Full calibration measurements required by paragraph (1) of this subsection and physical decay corrections required by paragraph (7) of this subsection must [~~shall~~] be performed by an authorized medical physicist.

(9) The licensee must [~~shall~~] retain a record of each calibration as specified in [~~accordance with~~] subsection (xxx) of this section for inspection by the department. The record must [~~shall~~] include [~~the following~~]:

(A) complete date of the calibration including the month, day, and year;

(B) manufacturer's name, model number, and serial number of the remote afterloader unit's sealed source, and the instruments used to calibrate the unit;

(C) results and an assessment of the full calibrations;

(D) name and signature of the authorized medical physicist who performed the full calibration [~~of this section~~]; and

(E) results of the autoradiograph required for low dose-rate remote afterloader unit.

(lll) Full calibration measurements on gamma stereotactic radiosurgery units.

(1) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use must [~~shall~~] perform full calibration measurements on each gamma stereotactic radiosurgery unit [~~as follows~~]:

(A) before the first medical use of the unit;

(B) before medical use under the following conditions:

(i) whenever spot check measurements indicate [~~that~~] the output differs by more than five percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) following replacement of the sealed sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and

(iii) following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sealed sources or major repair of the components associated with the sealed source exposure assembly; and

(C) at intervals not to exceed one year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

(2) Full calibration measurements must [~~shall~~] include determination of [~~the following~~]:

(A) the output within plus or minus three percent;

(B) relative helmet factors;

(C) isocenter coincidence;

(D) timer accuracy and linearity over the range of use;

(E) "on-off" error;

(F) trunnion centricity;

(G) treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit "off";

(H) helmet microswitches;

(I) emergency timing circuits; and

(J) stereotactic frames and localizing devices (trunnions).

(3) The licensee must [~~shall~~] use the dosimetry system described in subsection (iii)(1) of this section to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph (2)(A) of this subsection may be made using a dosimetry system indicating [~~that indicates~~] relative dose rates.

(4) The licensee must [~~shall~~] make full calibration measurements required by paragraph (1) of this subsection in accordance with published protocols accepted by nationally recognized bodies.

(5) The licensee must [~~shall~~] mathematically correct the outputs determined in paragraph (2)(A) of this subsection at intervals not to exceed one month for cobalt-60 and at intervals consistent with one percent physical decay for all other radionuclides.

(6) Full calibration measurements required by paragraph (1) of this subsection and physical decay corrections required by paragraph (5) of this subsection must [~~shall~~] be performed by an authorized medical physicist.

(7) The licensee must [~~shall~~] retain a record of each calibration as specified in [~~accordance with~~] subsection (xxx) of this section for inspection by the department. The record must [~~shall~~] include [~~the following~~]:

(A) complete date of the calibration including the month, day, and year;

(B) manufacturer's name, model number, and serial number for the unit and the unit's sealed source and the instruments used to calibrate the unit;

(C) results and an assessment of the full calibration; and

(D) name and signature of the authorized medical physicist who performed the full calibration.

(mmm) Periodic spot checks for teletherapy units.

(1) A licensee authorized to use teletherapy units for medical use must [~~shall~~] perform output spot checks on each teletherapy unit once in each calendar month, including [~~that include~~] determination of [~~the following~~]:

(A) timer constancy and linearity over the range of use;

(B) "on-off" error;

(C) the coincidence of the radiation field and the field indicated by the light beam localizing device;

(D) the accuracy of all distance measuring and localization devices used for medical use;

(E) the output for one typical set of operating conditions measured with the dosimetry system described in subsection (iii)(2) of this section; and

(F) the difference between the measurement made in subparagraph (E) of this paragraph and the anticipated output, expressed as a percentage of the anticipated output, the value obtained at last full calibration corrected mathematically for physical decay.

(2) The licensee must [~~shall~~] perform measurements required by paragraph (1) of this subsection in accordance with written procedures established by an authorized medical physicist. That authorized medical physicist need not actually perform the spot check measurements. The licensee must [~~shall~~] maintain a copy of the written procedures as specified in [~~accordance with~~] subsection (xxx) of this section for inspection by the department.

(3) The licensee authorized to use a teletherapy unit for medical use must [~~shall~~] perform safety spot checks of each teletherapy facility once in each calendar month and after each sealed source installation to assure proper operation of [~~the following~~]:

(A) electrical interlocks at each teletherapy room entrance;

(B) electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of sealed source housing angulation or elevation, carriage or stand travel, and operation of the beam "on-off" mechanism);

(C) sealed source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;

(D) viewing and intercom systems;

(E) treatment room doors from inside and outside the treatment room; and

(F) electrically assisted treatment room doors with the teletherapy unit electrical power turned "off." [~~"off".~~]

(4) The licensee must [~~shall~~] have an authorized medical physicist review the results of each spot check and submit a written report to the licensee within 15 days of the spot check.

(5) If the results of the checks required in paragraph (3) of this subsection indicate the malfunction of any system, the licensee must [~~shall~~] lock the control console in the "off" position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(6) The licensee must [~~shall~~] retain a record of each spot check required by paragraphs (1) and (3) of this subsection, as specified in [~~accordance with~~] subsection (xxx) of this section for inspection by the department. The record must [~~shall~~] include [~~the following~~]:

(A) date of the spot-check;

(B) manufacturer's name and model and serial number for the teletherapy unit, and sealed source and instrument used to measure the output of the teletherapy unit;

(C) assessment of timer linearity and constancy;

(D) calculated "on-off" error;

(E) determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

(F) the determined accuracy of each distance measuring and localization device;

(G) the difference between the anticipated output and the measured output;

(H) notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each sealed source exposure indicator light, and the viewing and intercom system and doors;

(I) name of the individual who performed the periodic spot-check; and

(J) the name and signature of the authorized medical physicist who reviewed the record of the spot check.

(nnn) Periodic spot checks for remote afterloader units.

(1) A licensee authorized to use a remote afterloader unit for medical use must [~~shall~~] perform spot checks of each remote afterloader facility and on each unit [~~as follows~~]:

(A) before the first use each day [~~of use~~] of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit;

(B) before each patient treatment with a low dose-rate remote afterloader unit; and

(C) after each sealed source installation.

(2) The licensee must [~~shall~~] perform the measurements required by paragraph (1) of this subsection in accordance with written procedures established by an authorized medical physicist. That individual need not actually perform the spot check measurements. The licensee must [~~shall~~] maintain a copy of the written procedures as specified in [~~accordance with~~] subsection (xxx) of this section for inspection by the department.

(3) The licensee must [~~shall~~] have an authorized medical physicist review the results of each spot check and submit a written report to the licensee within 15 days of the spot check.

(4) To satisfy the requirements of paragraph (1) of this subsection, spot checks must [~~shall~~], at a minimum, assure proper operation of [~~the following~~]:

(A) electrical interlocks at each remote afterloader unit room entrance;

(B) sealed source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(C) viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;

(D) emergency response equipment;

(E) radiation monitors used to indicate the sealed source position;

(F) timer accuracy;

(G) clock (date and time) in the unit's computer; and

(H) decayed sealed source [~~source(s)~~] activity in the unit's computer.

(5) If the results of the checks required in paragraph (4) of this subsection indicate the malfunction of any system, the licensee must [~~shall~~] lock the control console in the "off" position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(6) The licensee must [~~shall~~] maintain a record, as specified in [~~accordance with~~] subsection (xxx) of this section for inspection by the department, of each check required by paragraph (4) of this subsection. The record must [~~shall~~] include [~~the following~~], as applicable:

(A) date of the spot-check;

(B) manufacturer's name and model and serial number for the remote afterloader unit and sealed source;

(C) an assessment of timer accuracy;

(D) notations indicating the operability of each entrance door electrical interlock, radiation monitors, sealed source exposure indicator lights, viewing and intercom systems, clock, and decayed sealed source activity in the unit's computer;

(E) name of the individual who performed the periodic spot-check; and

(F) the signature of an authorized medical physicist who reviewed the record of the spot-check.

(ooo) Periodic spot checks for gamma stereotactic radiosurgery units.

(1) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use must [~~shall~~] perform spot checks of each gamma stereotactic radiosurgery facility and on each unit [~~as follows~~]:

(A) monthly;

(B) before the first use of the unit on each day of use; and

(C) after each source installation.

(2) The licensee must [~~shall~~] perform the measurements required by paragraph (1) of this subsection in accordance with written procedures established by an authorized medical physicist with a specialty in therapeutic radiological physics. That individual need not actually perform the spot check measurements. The licensee must [~~shall~~] maintain a copy of the written procedures as specified in [~~accordance with~~] subsection (xxx) of this section for inspection by the department.

(3) The licensee must [~~shall~~] have an authorized medical physicist review the results of each spot check and submit a written report to the licensee within 15 days of the spot check.

(4) To satisfy the requirements of paragraph (1)(A) of this subsection, spot checks must [~~shall~~], at a minimum, achieve [~~the following by~~]:

(A) assurance of proper operation of these items:

(i) treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit "off;"

(ii) helmet microswitches;

(iii) emergency timing circuits; and

(iv) stereotactic frames and localizing devices (trunnions); and

(B) determination of [~~the following~~]:

(i) the output for one typical set of operating conditions measured with the dosimetry system described in subsection (iii)(2) of this section;

(ii) the difference between the measurement made in clause (i) of this subparagraph and the anticipated output, expressed as a percentage of the anticipated output, (i.e., the value obtained at last full calibration corrected mathematically for physical decay);

(iii) sealed source output against computer calculation;

(iv) timer accuracy and linearity over the range of use;

(v) "on-off" error; and

(vi) trunnion centricity.

(5) To satisfy the requirements of paragraph (1)(B) and (C) of this subsection, spot checks must [~~shall~~] assure proper operation of [~~the following~~]:

(A) electrical interlocks at each gamma stereotactic radiosurgery room entrance;

(B) sealed source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;

(C) viewing and intercom systems;

(D) timer termination;

(E) radiation monitors used to indicate room exposures; and

(F) emergency "off" buttons.

(6) The licensee must [~~shall~~] arrange for prompt repair of any system identified in paragraph (4) of this subsection [~~that is~~] not operating properly.

(7) If the results of the checks required in paragraph (5) of this subsection indicate the malfunction of any system, the licensee must [~~shall~~] lock the control console in the "off" position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(8) The licensee must [~~shall~~] retain a record of each check required by paragraphs (4) and (5) of this subsection as specified in [~~accordance with~~] subsection (xxx) of this section for inspection by the department. The record must [~~shall~~] include [~~the following~~]:

(A) date of the spot check;

(B) manufacturer's name, and model and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;

(C) an assessment of timer linearity and accuracy;

(D) the calculated "on-off" error;

(E) a determination of trunnion centricity;

(F) the difference between the anticipated output and the measured output;

(G) an assessment of sealed source output against computer calculations;

(H) notation [~~notations~~] indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency "off" buttons, electrical interlocks, sealed source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions);

(I) the name of the individual who performed the periodic spot check; and

(J) the name and signature of an authorized medical physicist who reviewed the record of the spot check.

(ppp) Additional technical requirements for mobile remote afterloader units.

(1) A licensee providing mobile remote afterloader service must [~~shall do the following~~]:

(A) check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and

(B) account for all sealed sources before departure from a client's address of use.

(2) In addition to the periodic spot checks required by subsection (nnn) of this section, a licensee authorized to use remote afterloaders for medical use must [~~shall~~] perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must [~~shall~~] be made to verify the operation of [~~the following~~]:

(A) electrical interlocks on treatment area access points;

(B) sealed source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(C) viewing and intercom systems;

(D) applicators, sealed source transfer tubes, and transfer tube-applicator interfaces;

(E) radiation monitors used to indicate room exposures;

(F) sealed source positioning (accuracy); and

(G) radiation monitors used to indicate whether the sealed source has returned to a safe shielded position.

(3) In addition to the requirements for checks in paragraph (2) of this subsection, the licensee must [~~shall~~] ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

(4) If the results of the checks required in paragraph (2) of this subsection indicate the malfunction of any system, the licensee must [~~shall~~] lock the control console in the "off" position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(5) The licensee must [~~shall~~] maintain a record for inspection by the department, as specified in [~~accordance with~~] subsection (xxx) of this section, of each check required by paragraph (2) of this subsection. The record must [~~shall~~] include [~~the following~~]:

(A) date of the check;

(B) manufacturer's name, model number, and serial number of the remote afterloader unit;

(C) notations accounting for all sealed sources before the licensee departs from a facility;

(D) notations indicating the operability of each entrance door electrical interlock, radiation monitors, sealed source exposure indicator lights, viewing and intercom system, applicators and sealed source transfer tubes, and sealed source positioning accuracy; and

(E) the name and signature of the individual who performed the check.

(qqq) Radiation surveys.

(1) In addition to the survey requirements of §289.202(p) of this chapter [~~title~~], a person licensed to use sealed sources in this section must [~~shall~~] make surveys to ensure [~~that~~] the maximum radiation levels and average radiation levels, from the surface of the main sealed source safe with the sealed source or sources [~~source(s)~~] in the shielded position, do not exceed the levels stated in the Sealed Source and Device Registry.

(2) The licensee must [~~shall~~] make the survey required by paragraph (1) of this subsection at installation of a new sealed source and following repairs to the sealed source [~~source(s)~~] shielding, the sealed source [~~source(s)~~] driving unit, or other electronic or mechanical component that could expose the sealed source or sources, reduce the shielding around the sealed source or sources [~~source(s)~~], or compromise the radiation safety of the unit or the sealed source or sources [~~source(s)~~].

(3) The licensee must [~~shall~~] maintain a record for inspection by the department, as specified in [~~accordance with~~] subsection

(xxx) of this section, of the radiation surveys required by paragraph (1) of this subsection. The record must [~~shall~~] include:

(A) date of the measurements;

(B) manufacturer's name, model number, and serial number of the treatment unit, sealed source, and instrument used to measure radiation levels;

(C) each dose rate measured around the sealed source while the unit is in the "off" position and the average of all measurements; and

(D) the name and signature of the individual who performed the test.

(rrr) Full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units.

(1) The licensee must [~~shall~~] have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during each sealed source replacement to ensure proper functioning of the sealed source exposure mechanism and other safety components. The interval between each full-inspection servicing must [~~shall~~] not exceed five years for each teletherapy unit and must [~~shall~~] not exceed seven years for each gamma stereotactic radiosurgery unit.

(2) This inspection and servicing must [~~may~~] only be performed by persons specifically licensed to do so by the department, the NRC, or an agreement state.

(3) The licensee must [~~shall~~] maintain a record of the inspection and servicing as specified in [~~accordance with~~] subsection (xxx) of this section for inspection by the department. The record must [~~shall~~] include [~~the following~~]:

(A) date of inspection;

(B) manufacturer's name, [~~and~~] model, and serial number of both the treatment unit and the sealed source;

(C) a list of components inspected and serviced, and the type of service;

(D) the inspector's radioactive material license number; and

(E) the name and signature of the inspector.

(sss) Therapy-related computer systems for photon-emitting remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. The licensee must [~~shall~~] perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must [~~shall~~] include, as applicable, verification of [~~the following~~]:

(1) the sealed source-specific input parameters required by the dose calculation algorithm;

(2) the accuracy of dose, dwell time, and treatment time calculations at representative points;

(3) the accuracy of isodose plots and graphic displays;

(4) the accuracy of the software used to determine sealed source positions from radiographic images; and

(5) the accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

(ttt) Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. Except as provided in subsection (l) of this section, the licensee must [~~shall~~] require an authorized user of a sealed source for a use authorized in subsection (ddd) of this section to be [~~for~~]:

(1) a physician who is certified by a medical specialty board whose certification process is [~~has been~~] recognized by the department, the NRC, or an agreement state and who meets the requirements of paragraph (3) of this subsection. The names of board certifications [~~that have been~~] recognized by the department, the NRC, or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification recognized, a specialty board must [~~shall~~] require all candidates for certification to:

(A) successfully complete a minimum of three years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Council on Postdoctoral [~~Committee on Post-Graduate~~] Training of the American Osteopathic Association; and

(B) pass an examination, administered by diplomates of the specialty board, assessing [~~that assesses~~] knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders, and external beam therapy; or

(2) a [~~the~~] physician who [~~must meet the following requirements~~]:

(A) has completed a structured educational program in basic radionuclide handling techniques applicable to the use of a sealed source in a therapeutic medical unit, including [~~the following~~]:

(i) 200 hours of classroom and laboratory training in [~~the following areas~~]:

(I) radiation physics and instrumentation;

(II) radiation protection;

(III) mathematics pertaining to the use and measurement of radioactivity; and

(IV) radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user meeting [~~who meets~~] the requirements of subsection (l) of this section, this subsection, or equivalent NRC or agreement state requirements at a medical facility [~~that is~~] authorized to use radioactive material in subsection (ddd) of this section involving [~~the following~~]:

(I) reviewing full calibration measurements and periodic spot checks;

(II) preparing treatment plans and calculating treatment times;

(III) using administrative controls to prevent a medical event involving the use of radioactive material;

(IV) implementing emergency procedures to be followed in the event of the abnormal operation of a medical unit or console;

(V) checking and using survey meters; and

(VI) selecting the proper dose and how it is to be administered; and

(iii) completion of three years of supervised clinical experience in radiation therapy, under an authorized user meeting [~~who meets~~] the requirements of subsection (l) of this section, this subsec-

tion, or equivalent NRC or agreement state requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Council [~~Committee~~] on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by clause (ii) of this subparagraph; and

(B) has obtained written attestation [~~that~~] the individual has satisfactorily completed the requirements of paragraphs (2)(A) and (3) of this subsection[~~,~~] and is able to independently fulfill the radiation safety-related duties as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The attestation must be obtained from either:

(i) a preceptor authorized user meeting [~~who meets~~] the requirements in subsection (l) of this section, this subsection, or equivalent NRC or agreement state requirements for the types [~~type(s)~~] of therapeutic medical units [~~unit~~] for which the individual is requesting authorized user status; or

(ii) a residency program director affirming [~~who affirms~~] in writing [~~that~~] the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user meeting [~~who meets~~] the requirements in subsection (l) of this section, this subsection, or equivalent NRC or agreement state requirements, for the types [~~type(s)~~] of therapeutic medical units [~~unit~~] for which the individual is requesting authorized user status, and concurring [~~concurs~~] with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, [~~or~~] the Royal College of Physicians and Surgeons of Canada, or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subparagraph (A) of this paragraph; and

(3) a [~~the~~] physician who has received training in device operation, safety procedures, and clinical use for the types [~~type(s)~~] of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, [~~who is~~] authorized for the types [~~type(s)~~] of use for which the individual is seeking authorization.

(uuu) Report and notification of a medical event.

(1) The licensee must [~~shall~~] report any event as a medical event, except for an event resulting [~~that results~~] from patient intervention, in which the administration of radioactive material, or radiation from radioactive material, except permanent implant brachytherapy, results in [~~the following~~]:

(A) a dose differing [~~that differs~~] from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 5 rem (0.05 sievert [~~Sievert~~] (Sv)) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin; and

(i) the total dose delivered differs from the prescribed dose by 20 percent or more;

(ii) the total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

(iii) the fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more;

(B) a dose that exceeds 5 rem (0.05 Sv) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin from [~~any of the following~~]:

(i) an administration of a wrong radioactive drug containing radioactive material or the wrong radionuclide for a brachytherapy procedure;

(ii) an administration of a radioactive drug containing radioactive material by the wrong route of administration;

(iii) an administration of a dose or dosage to the wrong individual or human research subject;

(iv) an administration of a dose or dosage delivered by the wrong mode of treatment; or

(v) a leaking sealed source; or

(C) a dose to the skin or an organ or tissue other than the treatment site that is more than: [~~exceeds by~~]

(i) 50 rem (0.5 Sv) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and

(ii) 50 percent or more of the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.

(2) For permanent implant brachytherapy, the licensee must [~~shall~~] report the administration of radioactive material or radiation from radioactive material (excluding sources that were implanted in the correct site but migrated outside the treatment site) resulting [~~that results~~] in:

(A) the total source strength administered differing by 20 percent or more from the total source strength documented in the post-implantation portion of the written directive;

(B) the total source strength administered outside of the treatment site exceeding 20 percent of the total source strength documented in the post-implantation portion of the written directive; or

(C) an administration, including [~~that includes any of the following~~]:

(i) the wrong radionuclide;

(ii) the wrong individual or human research subject;

(iii) sealed source or sources [~~source(s)~~] implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the written directive; or

(iv) a leaking sealed source resulting in a dose that exceeds 50 rem (0.5 Sv) to an organ or tissue.

(3) The licensee must [~~shall~~] report any event resulting from patient intervention in which the administration of radioactive material, or radiation from radioactive material, results or will result in an unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

(4) The licensee must [~~shall~~] notify the department by telephone no later than the next calendar day after discovery of the medical event.

(5) The licensee must [~~shall~~] submit a written report to the department within 15 calendar days after discovery of the medical event. The written report must [~~shall~~] include [~~the following~~], exclud-

ing the individual's name or any other information that could lead to identification of the individual:

(A) the licensee's name and radioactive material license number;

(B) a description of the licensed source of radiation involved, including, for radioactive material, the kind, quantity, chemical and physical form, source and device manufacturer, model number, and serial number, if applicable;

(C) the name of the prescribing physician;

(D) a brief description of the medical event;

(E) why the event occurred;

(F) the effect, if any, on the individual [~~individual(s)~~] who received the administration;

(G) actions, if any, [~~that have been~~] taken[,] or [~~are~~] planned[,] to prevent recurrence; and

(H) certification [~~that~~] the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

(6) The licensee must [~~shall~~] notify the referring physician and [~~also notify~~] the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or [~~that~~], based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee must [~~shall~~] notify the individual as soon as possible thereafter. The licensee may [~~shall~~] not delay any appropriate medical care for the individual, including any necessary remedial care resulting from [~~as a result of~~] the medical event, due to a [~~because of any~~] delay in notification. To meet the requirements of this subsection, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee must [~~shall~~] inform the individual or appropriate responsible relative or guardian[,] that a written description of the event can be obtained from the licensee upon request. The licensee must [~~shall~~] provide the written description if requested.

(7) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.

(8) The licensee must [~~shall~~] annotate a copy of the report provided to the department with [~~the following information~~]:

(A) the name of the individual who is the subject of the event; and

(B) an identification number or if no other identification number is available, the social security number of the individual who is the subject of the event.

(9) The licensee must [~~shall~~] provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 calendar days after the discovery of the event.

(10) The licensee must [~~shall~~] retain a copy of the annotated report of the medical event as specified in [~~accordance with~~] subsection (xxx) of this section for inspection by the department.

(vvv) Report and notification of a dose to an embryo/fetus or nursing child.

(1) The licensee must [~~shall~~] report any dose to an embryo/fetus [~~that is~~] greater than 5 rem (50 mSv) dose equivalent resulting from [~~that is a result of~~] an administration of radioactive material or radiation from radioactive material to a woman [~~pregnant individual~~], unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

(2) The licensee must [~~shall~~] report any dose to a nursing child resulting from [~~that is a result of~~] an administration of radioactive material to a breast-feeding woman [~~individual that~~]:

(A) [~~is~~] greater than 5 rem (50 mSv) TEDE; or

(B) resulting [~~has resulted~~] in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

(3) The licensee must [~~shall~~] notify the department by telephone no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child requiring [~~that requires~~] a report as specified in [~~accordance with~~] paragraphs (1) or (2) of this subsection.

(4) The licensee must [~~shall~~] submit a written report to the department no later than 15 calendar days after discovery of a dose to the embryo/fetus or nursing child that requires a report as specified in [~~accordance with~~] paragraphs (1) or (2) of this subsection. The written report must [~~shall~~] include [~~the following~~], excluding the individual's or child's name or any other information that could lead to identification of the individual or child:

(A) the licensee's name and radioactive material license number;

(B) a description of the licensed source of radiation involved, including, for radioactive material, the kind, quantity, chemical and physical form, source and [~~and/or~~] device manufacturer, model number, and serial number, if applicable;

(C) the name of the prescribing physician;

(D) a brief description of the event;

(E) why the event occurred;

(F) the effect, if any, on the embryo/fetus or the nursing child;

(G) actions, if any, [~~that have been~~] taken[,] or [~~are~~] planned[,] to prevent recurrence; and

(H) certification that the licensee notified the pregnant woman [~~individual or mother~~] (or the pregnant woman's [~~mother's~~] or child's responsible relative or guardian), and if not, why not.

(5) The licensee must [~~shall~~] notify the referring physician and also notify the pregnant woman [~~individual or mother~~], [~~both~~] hereafter referred to as the mother, no later than 24 hours after discovery of an event requiring [~~that would require~~] reporting as specified in [~~accordance with~~] paragraphs (1) or (2) of this subsection, unless the referring physician personally informs the licensee either that he or she will inform the mother or [~~that~~], based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee must [~~shall~~] make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care resulting from [~~as a result of~~] the event, due to a [~~because of any~~] delay in notification. To meet the requirements of this subsection, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother, when appropri-

ate. If a verbal notification is made, the licensee must [~~shall~~] inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee must [~~shall~~] provide such a written description if requested.

(6) The licensee must [~~shall~~] annotate a copy of the report provided to the department with [~~the following information~~]:

(A) the name of the individual or the nursing child who is the subject of the event; and

(B) an identification number or if no other identification number is available, the social security number of the individual who is the subject of the event.

(7) The licensee must [~~shall~~] provide a copy of the annotated report as described in paragraph (6) of this subsection to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

(8) The licensee must [~~shall~~] retain a copy of the annotated report as described in paragraph (6) of this subsection of a dose to an embryo/fetus or a nursing child as specified in [~~accordance with~~] subsection (xxx) of this section for inspection by the department.

(www) Report and notification for an eluate exceeding permissible molybdenum-99, strontium-82, and strontium-85 concentrations.

(1) The licensee must [~~shall~~] notify [~~by telephone~~] the department by telephone at (512) 458-7460 and the distributor of the generator within seven calendar days after discovery that an eluate exceeded the permissible concentration listed in subsection (ii) of this section at the time of generator elution. The telephone report to the department must include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects;[~~,~~] when the distributor was notified;[~~,~~] and the action taken.

(2) The licensee must [~~shall~~] submit a written report to the department within 30 calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report must include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; [~~and~~] the probable cause and an assessment of failure in the licensee's equipment, procedures, or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination; and the information in the telephone report as required by paragraph (1) of this subsection.

(xxx) Records/documents for department inspection. Each licensee must [~~shall~~] maintain copies of the following records/documents at each authorized use site and make them available to the department for inspection, upon reasonable notice.
Figure: 25 TAC §289.256(xxx)
[~~Figure: 25 TAC §289.256(xxx)~~]

§289.257. Packaging and Transportation of Radioactive Material.

(a) Purpose.

(1) This section establishes requirements for packaging, preparation for shipment, and transportation of radioactive material including radioactive waste.

(2) In addition to the requirements of this section, the [~~The~~] packaging and transport of radioactive material are [~~also~~] subject to the requirements of:

(A) §289.201 of this chapter [~~title~~] (relating to General Provisions for Radioactive Material);[~~,~~]

(B) §289.202 of this chapter [~~title~~] (relating to Standards for Protection Against Radiation from Radioactive Materials);[~~,~~]

(C) §289.203 of this chapter [~~title~~] (relating to Notices, Instructions, and Reports to Workers; Inspections);[~~,~~]

(D) §289.204 of this chapter [~~title~~] (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services) ;[~~,~~]

(E) §289.205 of this chapter [~~title~~] (relating to Hearing and Enforcement Procedures);[~~,~~]

(F) §289.251 of this subchapter [~~title~~] (relating to Exemptions, General Licenses, and General License Acknowledgements);[~~,~~]

(G) §289.252 of this subchapter [~~title~~] (relating to Licensing of Radioactive Material);[~~,~~]

(H) §289.256 of this subchapter [~~title~~] (relating to Medical and Veterinary Use of Radioactive Material);[~~,~~] and

(I) [~~to~~] the regulations of other agencies (e.g., the United States Department of Transportation (DOT) and the United States Postal Service) having jurisdiction over means of transport. [~~The requirements of this section are in addition to, and not in substitution for, other requirements.~~]

(b) Scope.

(1) The requirements of this section apply to any licensee authorized by a specific or general license issued by the department to receive, possess, use, or transfer radioactive material, if the licensee delivers [~~that~~] material to a carrier for transport, transports the material outside the site of usage, as specified in the department license, or transports [~~that~~] material on public highways. No provision of this section authorizes possession of radioactive material.

(2) Exemptions from the requirements for a license in subsection (c) of this section are specified in subsection (f) of this section. The general license in subsection (i)(2), (3), and (4) of this section requires that a United States Nuclear Regulatory Commission (NRC) certificate of compliance or other package approval be issued for the package [~~to be~~] used as specified in [~~accordance with~~] the general license. A licensee transporting radioactive material, or delivering radioactive material to a carrier for transport, must [~~shall~~] comply with the operating control requirements of subsections (l) - (q) of this section; the quality assurance (QA) requirements of subsections (s) - (u) and (w) - (bb) of this section; and the general provisions of subsections (a) - (e) of this section, including DOT regulations referenced in subsection (e) of this section.

(c) Requirement for license. Except as authorized in a general or specific license issued by the department, or as exempted as specified in [~~accordance with~~] this section, no licensee may transport radioactive material or deliver radioactive material to a carrier for transport.

(d) Definitions. The following words and terms when used in this section [~~shall~~] have the following meaning [~~,~~] unless the context clearly indicates otherwise. To ensure compatibility with international transportation standards, all limits in this section are given in terms of dual units: The International System of Units (SI) followed or preceded by United States (U.S.) standard or customary units. The U.S. customary units are not exact equivalents, but are rounded to a convenient value, providing a functionally equivalent unit. In [~~For the purpose of~~] this section, SI units are [~~shall be~~] used.

(1) A_1-- The maximum activity of special form radioactive material permitted in a Type A package. This value is either listed in Table 257-3 of subsection (ee)(6) of this section, or may be derived as specified in [~~accordance with~~] the procedure prescribed in subsection (ee) of this section.

(2) A_2--The maximum activity of radioactive material, other than special form, low specific activity (LSA), and surface contaminated object (SCO) material, permitted in a Type A package. This value is either listed in Table 257-3 of subsection (ee)(6) of this section, or may be derived as specified in [~~accordance with~~] the procedure prescribed in subsection (ee) of this section.

(3) Carrier--A person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier, or by civil aircraft.

(4) Certificate holder--A person who has been issued a certificate of compliance or other package approval by the department.

(5) Certificate of compliance (CoC)--The certificate issued by the NRC that approves the design of a package for the transportation of radioactive materials.

(6) Chelating agent--Amine polycarboxylic acids (e.g., ethylenediaminetetraacetic acid (EDTA) and diethylenetriaminepentaacetic acid (DTPA)) [~~(e.g., EDTA, DTPA)~~], hydroxy-carboxylic acids, and polycarboxylic acids (e.g., citric acid, carbolic acid, and glucinic acid).

(7) Chemical description--A description of the principal chemical characteristics of low-level radioactive waste (LLRW).

(8) Consignee--The designated receiver of the shipment of low-level radioactive waste.

(9) Consignment--Each shipment of a package or groups of packages or load of radioactive material offered by a shipper for transport.

(10) Containment system--The assembly of components of the packaging intended to retain the radioactive material during transport.

(11) Contamination--The presence of a radioactive substance on a surface in quantities more than [~~in excess of~~] 0.4 becquerel per square centimeter (Bq/cm^2) [~~(Bq/cm^2)~~] (10^{-5}microcurie per square centimeter (Ci/cm^2) [~~(Ci/cm^2)~~]) for beta and gamma emitters and low toxicity alpha emitters, or 0.04 Bq/cm^2(10^{-6} Ci/cm^2) [~~(10^{-6} Ci/cm^2)~~] for all other alpha emitters.

(A) Fixed contamination means contamination that cannot be removed from a surface during normal conditions of transport.

(B) Non-fixed contamination means contamination that can be removed from a surface during normal conditions of transport.

(12) Conveyance--For transport on:

(A) public highway or rail by transport vehicle or large freight container;

(B) water by vessel, or any hold, compartment, or defined deck area of a vessel including any transport vehicle on board the vessel; and

(C) aircraft.

(13) Criticality Safety Index (CSI)--The dimensionless number (rounded up to the next tenth) assigned to and placed on the label of a fissile material package[,] to designate the degree of control of accumulation of packages, overpacks, or freight containers containing fissile material during transportation. Determination of the criticality safety index is described in subsection (i) of this section and 10 Code of Federal Regulations (CFR) §§71.22, 71.23, and 71.59 [~~Title 10, Code of Federal Regulations (CFR), §71.22, §71.23, and §71.59~~]. The criticality safety index for an overpack, freight container, consignment, or conveyance containing fissile material packages is the arithmetic sum of the criticality safety indices of all the fissile material packages contained within the overpack, freight container, consignment, or conveyance.

(14) Decontamination facility--A facility operating under [~~in accordance with~~] an NRC, agreement state, or department license whose principal purpose is decontamination of equipment or materials to accomplish recycle, reuse, or other waste management objectives, and, for purposes of this section, is not considered to be a consignee for LLRW shipments.

(15) Deuterium--In [~~For the purposes of~~] this section, this means deuterium and any deuterium compound, including heavy water, in which the ratio of deuterium atoms to hydrogen atoms is greater than [~~exceeds~~] 1:5000.

(16) Disposal container--A transport container principally used to confine LLRW during disposal operations at a land disposal facility (also see definition for high integrity container). Note that for some shipments, the disposal container may be the transport package.

(17) Environmental Protection Agency (EPA) identification number--The number received by a transporter following application to the administrator of EPA as required by 40 CFR [~~Title 40, CFR,~~] Part 263.

(18) Exclusive use--The sole use by a single consignor of a conveyance for which all initial, intermediate, and final loading and unloading are carried out as specified in [~~accordance with~~] the direction of the consignor or consignee. The consignor and the carrier must [~~shall~~] ensure [~~that~~] any loading or unloading is performed by personnel having radiological training and resources appropriate for safe handling of the consignment. The consignor issues [~~shall issue~~] specific instructions, in writing, for maintenance of exclusive use shipment controls, and includes [~~include~~] them with the shipping paper information provided to the carrier by the consignor.

(19) Fissile material--The radionuclides plutonium-239, plutonium-241, uranium-233, uranium-235, or any combination of these radionuclides. Fissile material means the fissile nuclides themselves, not material containing fissile nuclides. Unirradiated natural uranium and depleted uranium, and natural uranium or depleted uranium [~~that has been~~] irradiated in thermal reactors only, are not included in this definition. The department's [~~Agency~~] jurisdiction extends only to special nuclear material in quantities not sufficient to form a "critical mass" as defined in §289.201(b) of this chapter [~~title~~]. Certain exclusions from fissile material controls are provided in subsection (h) of this section.

(20) Freight forwarder--A person or entity holding [~~which holds~~] itself out to the general public to provide transportation of property for compensation and in the ordinary course of its business:

(A) assembles and consolidates, or provides for assembling and consolidating, shipments and performs break-bulk and distribution operations of the shipments;

(B) assumes responsibility for the transportation from the place of receipt to the place of destination; and

(C) uses for any part of the transportation a rail, motor, or water carrier subject to the jurisdiction of either the Federal Motor Carrier Safety Administration or the Surface Transportation Board.

(21) Generator--A licensee operating under a department [in accordance with an agency], NRC, or agreement state license who:

(A) is a waste generator as defined in this section; or

(B) is the licensee to whom waste can be attributed within the context of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (e.g., waste generated from [as a result of] decontamination or recycle activities).

(22) Graphite--In [For the purposes of] this section, this means graphite with a boron equivalent content of less than 5 parts per million and density greater than 1.5 grams (g) per cubic centimeter.

(23) High integrity container (HIC)--A container commonly designed to meet the structural stability requirements of 10 CFR [Title 10, CFR,] §61.56, and to meet DOT requirements for a Type A package.

(24) Indian Tribe--An Indian or Alaska Native Tribe, band, nation, pueblo, village, or community that the Secretary of the Interior acknowledges to exist as an Indian Tribe pursuant to the Federally Recognized Indian Tribe List Act of 1994, 25 United States Code (U.S.C.) [U.S.C.] §479a.

(25) Low-level radioactive waste (LLRW)--Radioactive material that meets the following criteria:

(A) LLRW is radioactive material [that is]:

(i) discarded or unwanted and [is] not exempt by rule adopted as specified in [accordance with] the Texas Radiation Control Act (Act), Texas Health and Safety Code[,] §401.106;

(ii) waste, as that term is defined in 10 CFR [Title 10, CFR,] §61.2; and

(iii) subject to:

(I) concentration limits established in 10 CFR [Title 10, CFR,] §61.55, or compatible rules adopted by the department or the Texas Commission on Environmental Quality (TCEQ), as applicable; and

(II) disposal criteria established in 10 CFR [Title 10, CFR,] or established by the department or TCEQ, as applicable.

(B) LLRW does not include:

(i) high-level radioactive waste as defined in 10 CFR [Title 10, CFR,] §60.2;

(ii) spent nuclear fuel as defined in 10 CFR [Title 10, CFR,] §72.3;

(iii) byproduct material defined in the Act, Texas Health and Safety Code[,] §401.003(3)(B);

(iv) naturally occurring radioactive material (NORM) waste that is not oil and gas NORM waste;

(v) oil and gas NORM waste; or

(vi) transuranics greater than 100 nanocuries (3.7 kilobecquerels) per gram (g).

(26) Low specific activity (LSA) material--Radioactive material with limited specific activity that [which] is non-fissile [non fissile] or is excepted as specified in [accordance with] subsection (h) of this section, and [which] satisfies the following descriptions and limits set forth in this section. Shielding materials surrounding the LSA material is [may] not [be] considered in determining the estimated average specific activity of the package contents. LSA material is [shall be] in one of the following three groups:

(A) LSA-I.

(i) Uranium and thorium ores, concentrates of uranium and thorium ores, and other ores containing naturally occurring radionuclides [that are] intended to be processed for the use of these radionuclides; [or]

(ii) Natural uranium, depleted uranium, natural thorium, or their compounds or mixtures, provided they are unirradiated and in solid or liquid form; [or]

(iii) Radioactive material other than fissile material for which the A_2 value is unlimited; or

(iv) Other radioactive material (e.g., [:] mill tailings, contaminated earth, concrete, rubble, other debris, and activated material) in which the radioactivity is distributed throughout, and the estimated average specific activity is not more than [does not exceed] 30 times the value for exempt material activity concentration determined in accordance with subsection (ee) of this section.

(B) LSA-II.

(i) Water with tritium concentration up to 0.8 terabecquerel per liter (TBq/l) (20.0 curies per liter (Ci/l)); or

(ii) Other material in which the radioactivity is distributed throughout, and the average specific activity is not greater than [does not exceed] 10^{-4} A_2/g [A_2/g] for solids and gases[,] and 10^{-5} A_2/g [A_2/g] for liquids.

(C) LSA-III. Solids (e.g., consolidated wastes, activated materials), excluding powders, satisfying [that satisfy] the requirements of 10 CFR [Title 10, CFR,] §71.77 in which:

(i) the radioactive material is distributed throughout a solid or a collection of solid objects, or is essentially uniformly distributed in a solid compact binding agent (such as concrete, bitumen, ceramic, etc.); [and]

(ii) the radioactive material is relatively insoluble, or it is intrinsically contained in a relatively insoluble material, so that[,] even with a loss of packaging, the loss of radioactive material per package by leaching, when placed in water for seven [7] days, is not greater than [will not exceed] 0.1 A_2; [A_2;] and

(iii) the estimated average specific activity of the solid, excluding any shielding material, is not greater than [does not exceed] 2 x 10^{-3} A_2/g [A_2/g].

(27) Low toxicity alpha emitters--Natural uranium, depleted uranium, natural thorium; uranium-235, uranium-238, thorium-232, thorium-228, or thorium-230 when contained in ores or physical or chemical concentrates or tailings; or alpha emitters with a half-life of less than 10 days.

(28) Maximum normal operating pressure--The maximum gauge pressure that would develop in the containment system in a period of one [1] year under the heat condition specified in 10 CFR [Title 10, CFR,] §71.71(c)(1), in the absence of venting, external cooling by an ancillary system, or operational controls during transport.

(29) Natural thorium--Thorium with the naturally occurring distribution of thorium isotopes (essentially 100 weight percent thorium-232).

(30) Normal form radioactive material--Radioactive material [that has] not [been] demonstrated to qualify as special form radioactive material.

(31) NRC Forms 540, 540A, 541, 541A, 542, and 542A--Official NRC forms referenced in subsection (ff) of this section that

include [~~which includes~~] the information required by DOT in 49 CFR [~~Title 49, CFR,~~] Part 172. Licensees need not use originals of these forms if [~~as long as~~] any substitute forms contain the equivalent information. Licensees may include additional information deemed relevant to the licensee's shipment of low-level radioactive waste. Upon agreement between the shipper and consignee, NRC Forms 541 (and 541A) and NRC Forms 542 (and 542A) or equivalent documents may be completed, transmitted, and stored in electronic media. The electronic media must [~~shall~~] have the capability for producing legible, accurate, and complete records in the format of the uniform manifest.

(32) Package--The packaging together with its radioactive contents as presented for transport.

(A) Fissile material package, Type AF package, Type BF package, Type B(U)F package, or Type B(M)F package--A fissile material packaging together with its fissile material contents.

(B) Type A package--A Type A packaging together with its radioactive contents. A Type A package is defined and complies [~~shall comply~~] with [~~the~~] DOT regulations in 49 CFR [~~Title 49, CFR,~~] Part 173.

(C) Type B package--A Type B packaging together with its radioactive contents. On approval by the NRC, a Type B package design is designated by NRC as B(U) unless the package has a maximum normal operating pressure of more than 700 kilopascals (kPa) (100 pounds per square inch (lbs/in^2) [~~(lb/ in^2)~~]) gauge or a pressure relief device allowing [~~that would allow~~] the release of radioactive material to the environment under the tests specified in 10 CFR [~~Title 10, CFR,~~] §71.73 (hypothetical accident conditions), in which case it will receive a designation B(M). B(U) refers to the need for unilateral approval of international shipments; B(M) refers to the need for multilateral approval of international shipments. There is no distinction made in how packages with these designations may be used in domestic transportation. To determine their distinction for international transportation, see DOT regulations in 49 CFR [~~Title 49, CFR,~~] Part 173. A Type B package approved before September 6, 1983, was designated only as Type B. Limitations on its use are specified in 10 CFR [~~Title 10, CFR,~~] §71.19.

(33) Packaging--The assembly of components necessary to ensure compliance with the packaging requirements of this section. It may consist of one or more receptacles, absorbent materials, spacing structures, thermal insulation, radiation shielding, and devices for cooling or absorbing mechanical shocks. The vehicle, tie-down system, and auxiliary equipment may be designated as part of the packaging.

(34) Physical description--The items called for on NRC Form 541 to describe an [~~a~~] LLRW.

(35) Registered freight forwarder--A freight forwarder having [~~that has~~] an emergency plan approved as specified in [~~accordance with~~] subsection (r) of this section and [~~has been~~] issued a registration letter.

(36) Registered shipper--A shipper having [~~that has~~] an emergency plan approved as specified in [~~accordance with~~] subsection (r) of this section[~~,~~] and shipping containers approved as specified in [~~accordance with~~] subsection(cc)(8) of this section and [~~been~~] issued a registration letter.

(37) Registered transporter--A transporter having [~~that has~~] an emergency plan approved as specified in [~~accordance with~~] subsection (r) of this section[~~,~~] and proof of financial responsibility submitted and approved as specified in [~~accordance with~~] subsection(e)(4) of this section and [~~has been~~] issued a registration letter.

(38) Residual waste--LLRW resulting from processing or decontamination activities that cannot be easily separated into distinct batches attributable to specific waste generators. This waste is attributable to the processor or decontamination facility, as applicable.

(39) Shipper--The licensed entity (i.e., the waste generator, waste collector, or waste processor) offering [~~who offers~~] LLRW for transportation, typically consigning this type of waste to a licensed waste collector, waste processor, or land disposal facility operator. This definition applies only to shipments of LLRW shipped to a Texas LLRW disposal facility.

(40) Site of usage--The licensee's facility, including all buildings and structures between which radioactive material is transported and all roadways [~~that are~~] not within the public domain on which radioactive material can be transported.

(41) Special form radioactive material--Radioactive material satisfying [~~that satisfies~~] the following conditions:

(A) [~~it is~~] either a single solid piece or [~~is~~] contained in a sealed capsule that can be opened only by destroying the capsule;

(B) the piece or capsule has at least one dimension not less than 5 [~~five~~] millimeters (0.2 inches (in)) [~~(0.2 in)~~]; and

(C) [~~it~~] satisfies the requirements of 10 CFR [~~Title 10, CFR,~~] §71.75. A special form encapsulation designed as specified in [~~accordance with~~] the requirements of this subsection in effect on or after June 30, 1983 (see 10 CFR [~~Title 10, CFR,~~] Part 71, revised as of January 1, 1983), and constructed before July 1, 1985; a special form encapsulation designed as specified in [~~accordance with~~] the requirements of this subsection in effect on or after March 31, 1996 (see 10 CFR [~~Title 10, CFR,~~] Part 71, revised as of January 1, 1996), and constructed before April 1, 1998; and

(D) special form material [~~that was~~] successfully tested before September 10, 2015, as specified in [~~accordance with~~] the requirements of 10 CFR [~~Title 10, CFR,~~] §71.75(d) in effect before September 10, 2015, may continue to be used. Any other special form encapsulation must meet the specifications of this definition.

(42) Specific activity of a radionuclide--The radioactivity of the radionuclide per unit mass of that nuclide. The specific activity of a material in which the radionuclide is essentially uniformly distributed is the radioactivity per unit mass of the material.

(43) Spent nuclear fuel or spent fuel--Fuel [~~that has been~~] withdrawn from a nuclear reactor following irradiation, [~~has~~] undergone at least one year's decay since being used as a source of energy in a power reactor, and [~~has~~] not [~~been~~] chemically separated into its constituent elements by reprocessing. Spent fuel includes the special nuclear material, byproduct material, source material, and other radioactive materials associated with fuel assemblies.

(44) Surface contaminated object (SCO)--A solid object [~~that is~~] not itself classed as radioactive material, but which has radioactive material distributed on any of its surfaces. An [~~A~~] SCO must [~~shall~~] be in one of the following two groups with surface activity not greater than [~~exceeding~~] the following limits:

(A) SCO-I--A solid object on which:

(i) the non-fixed contamination on the accessible surface averaged over 300 square centimeters (cm^2) [~~(cm^2)~~] (or the area of the surface if less than 300 cm^2) [~~cm^2)~~] is not greater than [~~does not exceed~~] 4 Bq/cm^2 [~~becquerels per square centimeter (Bq/cm^2)~~] (10^{-4}Ci/cm^2 [~~microcurie per square centimeter (Ci/cm^2)~~]) for beta and gamma and low toxicity alpha emitters, or 4 x 10^{-1} Bq/cm^2 [~~Bq/cm2~~] (10^{-5}Ci/cm^2) [~~Ci/cm^2)~~] for all other alpha emitters;

(ii) the fixed contamination on the accessible surface averaged over 300 cm^2(or the area of the surface if less than 300 cm^2) [~~cm^2~~)] is not greater than [~~does not exceed~~] 4 x 10^4 Bq/cm^2 (1 Ci/cm^2) [~~Ci/cm^2~~)] for beta and gamma and low toxicity alpha emitters, or 4 x 10^3 Bq/cm^2 ($10^{-1}$$Ci/cm^2$) [~~$Ci/cm^2$~~)] for all other alpha emitters; and

(iii) the non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2(or the area of the surface if less than 300 cm^2) [~~cm^2~~)] is not greater than [~~does not exceed~~] 4 x 10^4 Bq/cm^2 (1 Ci/cm^2) [~~Ci/cm^2~~)] for beta and gamma and low toxicity alpha emitters, or 4 x 10^3Bq/cm^2 ($10^{-1}$$Ci/cm^2$) [~~$Ci/cm^2$~~)] for all other alpha emitters.

(B) SCO-II--A solid object on which the limits for SCO-I are exceeded and on which the following limits are not exceeded:

(i) the non-fixed contamination on the accessible surface averaged over 300 cm^2(or the area of the surface if less than 300 cm^2) [~~cm^2~~)] is not greater than [~~does not exceed~~] 400 Bq/cm^2 ($10^{-2}$$Ci/cm^2$) [~~$Ci/cm^2$~~)] for beta and gamma and low toxicity alpha emitters, or 40 Bq/cm^2 (10^{-3} Ci/cm^2) [~~Ci/cm^2~~)] for all other alpha emitters;

(ii) the fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) [~~cm^2~~)] is not greater than [~~does not exceed~~] 8 x 10^5 Bq/cm^2 (20Ci/cm^2) [~~Ci/cm^2~~)] for beta and gamma and low toxicity alpha emitters, or 8 x 10^4 Bq/cm^2 (2 Ci/cm^2) [~~Ci/cm^2~~)] for all other alpha emitters; and

(iii) the non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) [~~cm^2~~)] is not greater than [~~does not exceed~~] 8 x 10^5 Bq/cm^2 (20 Ci/cm^2) [~~Ci/cm^2~~)] for beta and gamma and low toxicity alpha emitters, or 8 x 10^4 Bq/cm^2 (2 Ci/cm^2) [~~Ci/cm^2~~)] for all other alpha emitters.

(45) Transporter--A carrier who transports radioactive material.

(46) Tribal official--The highest ranking individual representing [~~that represents~~] Tribal leadership, such as the Chief, President, or Tribal Council leadership.

(47) Uniform Low-Level Radioactive Waste Manifest or uniform manifest--The combination of NRC Forms 540, 541, and, if necessary, 542, and their respective continuation sheets as needed, or equivalent.

(48) Unirradiated uranium--Uranium containing not more than 2 x 10^3 Bq (0.054 Ci) of plutonium per gram of uranium-235, not more than 9 x 10^6 Bq (243 Ci) of fission products per gram of uranium-235, and not more than 5 x 10^{-3} g of uranium-236 per gram of uranium-235.

(49) Uranium--Natural, depleted, enriched:

(A) Natural uranium--Uranium that [(~~which~~] may be chemically separated[)] with the naturally occurring distribution of uranium isotopes (approximately 0.711 weight percent uranium-235, and the remainder by weight essentially uranium-238).

(B) Depleted uranium--Uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes.

(C) Enriched uranium--Uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes.

(50) Waste collector--An entity, operating under [~~in accordance with~~] a department [~~an agency~~], NRC, or agreement state license, whose principal purpose is to collect and consolidate waste generated by others, and to transfer this waste, without processing or repackaging the collected waste, to another licensed waste collector, licensed waste processor, or licensed land disposal facility.

(51) Waste description--The physical, chemical, and radiological description of an [~~a~~] LLRW as called for on NRC Form 541.

(52) Waste generator--An entity, operating under [~~in accordance with~~] a department [~~an agency~~], NRC, or agreement state license, who:

(A) possesses any material or component that contains radioactivity or is radioactively contaminated for which the licensee foresees no further use; and

(B) transfers this material or component to a licensed land disposal facility or to a licensed waste collector or processor for handling or treatment before disposal. A licensee performing processing or decontamination services may be a waste generator if the transfer of LLRW from its facility is defined as residual waste.

(53) Waste processor--An entity, operating under [~~in accordance with~~] an NRC or agreement state license, whose principal purpose is to process, repackage, or otherwise treat LLRW or waste generated by others before eventual transfer of waste to a licensed LLRW land disposal facility.

(54) Waste type--A waste within a disposal container having a unique physical description (i.e., a specific waste descriptor code or description; or a waste sorbed on or solidified in a specifically defined [~~specifically-defined~~] media).

(e) Transportation of radioactive material.

(1) Each licensee transporting [~~who transports~~] radioactive material outside the site of usage as specified in the department license, transporting [~~transports~~] on public highways, or delivering [~~delivers~~] radioactive material to a carrier for transport must[~~, shall~~] comply with the applicable requirements of [~~the~~] DOT regulations in 49 CFR [~~Title 49, CFR,~~] Part 107, Parts 171 - 180, and Parts 390 - 397 appropriate to the mode of transport. The licensee must [~~shall~~] particularly note DOT regulations in the following areas:

(A) Packaging - 49 CFR [~~Title 49, CFR,~~] Part 173: Subparts A, B, and I.

(B) Marking and labeling - 49 CFR [~~Title 49, CFR,~~] Part 172: Subpart D, and §§172.400 - 172.407 and §§172.436 - 172.441 of Subpart E.

(C) Placarding - 49 CFR [~~Title 49, CFR,~~] Part 172: Subpart F, especially §§172.500 - 172.519 and §172.556, and Appendices B and C.

(D) Accident reporting - 49 CFR [~~Title 49, CFR,~~] Part 171: §171.15 and §171.16.

(E) Shipping papers and emergency information - 49 CFR [~~Title 49, CFR,~~] Part 172: Subparts C and G.

(F) Hazardous material employee training - 49 CFR [~~Title 49, CFR,~~] Part 172: Subpart H.

(G) Hazardous material shipper/carrier registration - 49 CFR [~~Title 49, CFR,~~] Part 107: Subpart G.

(H) Security Plans - 49 CFR [~~Title 49, CFR,~~] Part 172: Subpart I.

(2) The licensee must comply with [~~shall also note~~] DOT regulations pertaining to the following modes of transportation:

(A) Rail: 49 CFR [~~Title 49, CFR~~] Part 174: Subparts A through D and K.

(B) Air: 49 CFR [~~Title 49, CFR~~] Part 175.

(C) Vessel: 49 CFR [~~Title 49, CFR~~] Part 176: Subparts A through F and M.

(D) Public Highway: 49 CFR [~~Title 49, CFR~~] Part 177 and Parts 390 through 397.

(3) If DOT regulations are not applicable to a shipment of radioactive material (i.e., DOT does not have jurisdiction), the licensee must [~~shall~~] conform to DOT standards and requirements specified in paragraph (1) of this subsection to the same extent as if the shipment or transportation were subject to DOT regulations. A request for modification, waiver, or exemption from those requirements must [~~shall~~] be filed and approved by the department. Any notification referred to in those requirements must[~~, shall~~] be submitted to the department.

(4) Transporter proof of financial responsibility.

(A) Transporters of LLRW [~~low-level radioactive waste~~] to a Texas LLRW [~~low-level radioactive waste~~] disposal site must [~~shall~~] submit proof of financial responsibility required by 49 CFR [~~Title 49, CFR,~~] §387.7 and §387.9[~~,~~] to the department and receive a registration letter from the department before initial shipment.

(B) The transporter registration expires on the expiration date of the proof of financial responsibility or in 10 years[~~,~~] if the proof of financial responsibility does not have an expiration date.

(C) To renew a transporter's registration, the transporter must [~~shall~~] submit to the department new proof of financial responsibility.

(D) The transporter must [~~shall~~] submit to the department new proof of financial responsibility any time the amount of liability coverage is reduced or a new policy is purchased.

(5) The department must [~~shall~~] review and determine alternate routes for the transportation and routing of radioactive material as specified in [~~accordance with~~] 49 CFR[~~,~~] §397.103.

(f) Exemption for low-level radioactive materials.

(1) A licensee is exempt from all requirements of this section with respect to shipment or carriage of the following low-level materials:

(A) Natural material and ores containing naturally occurring radionuclides [~~that are~~] either in their natural state, or [~~have~~] only [~~been~~] processed for purposes other than for the extraction of the radionuclides, and [~~which are~~] not intended to be processed for use of these radionuclides, provided the activity concentration of the material is not greater than [~~does not exceed~~] 10 times the applicable radionuclide activity concentration values specified in subsection (ee), (ee)(7), and (ee)(8) of this section.

(B) Materials for which the activity concentration is not greater than the activity concentration values specified in subsection (ee), (ee)(7), and (ee)(8) of this section, or for which the consignment activity is not greater than the limit for an exempt consignment found in subsection (ee), (ee)(7), and (ee)(8) of this section.

(C) Non-radioactive solid objects with radioactive substances present on any surfaces in quantities not over [~~in excess of~~] the levels cited in the definition of contamination in subsection (d) of this section.

(2) Common and contract carriers, freight forwarders, warehousemen, and the United States Postal Service are exempt from the regulations in this subchapter to the extent [~~that~~] they transport or store radioactive material in the regular course of their carriage for another, or storage incident thereto.

(3) Persons who discard licensed material as specified in [~~accordance with~~] §289.202(fff) of this chapter [~~title~~] are exempt from all requirements of this section.

(g) Exemption of physicians and veterinarians. Any physician or veterinarian licensed by a state [~~State~~] to dispense drugs in the practice of medicine or veterinary medicine is exempt from subsection (e) of this section with respect to transport by the physician or veterinarian of licensed material for use in the practice of medicine or veterinary medicine. However, any physician or veterinarian operating under this exemption must [~~shall~~] be licensed under [~~in accordance with~~] §289.256 of this subchapter [~~title~~] or the equivalent NRC or agreement state regulations.

(h) Exemption from classification as fissile material. Fissile materials meeting the requirements of at least one of [~~the~~] paragraphs (1) through (6) of this subsection are exempt from classification as fissile material and from the fissile material package standards of 10 CFR [~~Title 10, CFR~~] §71.55 and §71.59, but are subject to all other requirements of this section, except as noted.

(1) An individual package containing 2 g [~~grams~~] or less fissile material.

(2) Individual or bulk packaging containing 15 g [~~grams~~] or less of fissile material provided the package has at least 200 g [~~grams~~] of solid non-fissile [~~nonfissile~~] material for every gram of fissile material. Lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but must [~~shall~~] not be included in determining the required mass for solid non-fissile [~~nonfissile~~] material.

(3) Solid fissile material commingled with solid non-fissile material.

(A) Low concentrations of solid fissile material commingled with solid non-fissile [~~nonfissile~~] material provided:

(i) [~~that~~] there is at least 2000 g [~~grams~~] of solid non-fissile [~~nonfissile~~] material for every gram of fissile material; and

(ii) there is no more than 180 g [~~grams~~] of fissile material distributed within 360 kilograms (kg) [~~kg~~] of contiguous non-fissile material.

(B) Lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but must [~~shall~~] not be included in determining the required mass of solid non-fissile [~~nonfissile~~] material.

(4) Uranium enriched in uranium-235 to a maximum of one percent by weight, and with total plutonium and uranium-233 content of up to one percent of the mass of uranium-235, provided [~~that~~] the mass of any beryllium, graphite, and hydrogenous material enriched in deuterium constitutes less than five percent of the uranium mass, and [~~that~~] the fissile material is distributed homogeneously and does not form a lattice arrangement within the package.

(5) Liquid solutions of uranyl nitrate enriched in uranium-235 to a maximum of two percent by mass, with a total plutonium and uranium-233 content not greater than [~~exceeding~~] 0.002 percent of the mass of uranium, and with a minimum nitrogen to uranium atomic ratio (N/U) of 2. The material must [~~shall~~] be contained in at least a DOT Type A package.

(6) Packages containing, individually, a total plutonium mass of not more than 1000 g [~~grams~~], of which not more than 20

percent by mass may consist of plutonium-239, plutonium-241, or any combination of these radionuclides.

(i) General license.

(1) NRC-approved package.

(A) A general license is issued to any licensee of the department to transport, or to deliver to a carrier for transport, radioactive material in a package for which a license, CoC [~~certificate of compliance (CoC)~~], or other approval has been issued by the NRC.

(B) This general license applies only to a licensee who has a QA [~~quality assurance~~] program approved by the NRC as satisfying the provisions of 10 CFR [~~Title 10, CFR,~~] Part 71:[~~,~~] Subpart H.

(C) This general license applies only to a licensee who [~~meets the following requirements~~]:

(i) has a copy of the CoC or other approval by the NRC of the package, and has the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken before shipment; and

(ii) complies with the terms and conditions of the specific license, certificate, or other approval by the NRC, as applicable, and the applicable requirements in 10 CFR [~~of Title 10, CFR,~~] Part 71:[~~,~~] Subparts A, G, and H; and

(iii) before the licensee's first use of the package, submits in writing to: ATTN: Document Control Desk, Director, Division of Fuel Management, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 using an appropriate method listed in 10 CFR [~~Title 10, CFR,~~] Part 71, the licensee's name and license number and the package identification number specified in the package approval.

(D) This general license applies only when the package approval authorizes use of the package as specified in [~~accordance with~~] this general license.

(E) For a Type B or fissile material package, the design of which was approved by NRC before April 1, 1996, the general license is subject to the additional restrictions of paragraph (2) of this subsection.

(F) For radiography containers, a program for transport container inspection and maintenance limited to radiographic exposure devices, source changers, or packages transporting these devices and meeting the requirements of §289.255(m)(2)(B) of this chapter [~~title~~] (relating to Radiation Safety Requirements and Licensing and Registration Procedures for Industrial Radiography), is deemed to satisfy the requirements of subparagraph (B) of this paragraph.

(2) Use of foreign approved package.

(A) A general license is issued to any licensee to transport, or to deliver to a carrier for transport, licensed material in a package the design of which has been approved in a foreign national competent authority certificate [~~that has been~~] revalidated by the DOT as meeting the applicable requirements of 49 CFR [~~Title 49, CFR,~~] §171.23.

(B) Except as otherwise provided by this section, the general license applies only to a licensee having [~~who has~~] a QA [~~quality assurance~~] program approved by the department as satisfying the applicable provisions of subsection (s) - (u) and (w) - (bb) of this section.

(C) This general license applies only to shipments made to or from locations outside the United States.

(D) Each licensee issued a general license under subparagraph (A) of this paragraph must [~~shall~~]:

(i) maintain a copy of the applicable certificate, the revalidation, and the drawings and other documents referenced in the certificate relating to the use and maintenance of the packaging and [~~to~~] the actions [~~to be~~] taken before shipment; and

(ii) comply with the terms and conditions of the certificate and revalidation, and with the applicable requirements of §289.205(j) and (k) of this chapter [~~title~~] and subsections (a) - (e), (j) - (q), (s) - (u), and (w) - (bb) of this section.

(3) Fissile material.

(A) A general license is issued to any licensee to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped as specified in [~~accordance with~~] this section. The fissile material need not be contained in a package meeting [~~that meets~~] the standards of this section. The[~~; however, the~~] material must [~~shall~~] be contained in a Type A package. The Type A package must [~~shall~~] also meet [~~the~~] DOT requirements in 49 CFR [~~of Title 49, CFR,~~] §173.417(a).

(B) The general license applies only to a licensee having [~~who has~~] a QA [~~quality assurance~~] program approved by the NRC as satisfying the provisions of 10 CFR [~~Title 10, CFR,~~] Part 71.

(C) The general license applies only when a package's contents:

(i) contain no more than a Type A quantity of radioactive material; and

(ii) contain less than 500 total grams of beryllium, graphite, or hydrogenous material enriched in deuterium.

(D) The general license applies only to packages containing fissile material [~~that are~~] labeled with a CSI [~~that~~]:

(i) [~~has been~~] determined as specified in [~~accordance with~~] paragraph (E) of this subsection;

(ii) with [~~has~~] a value less than or equal to 10.0; and

(iii) for a shipment of multiple packages containing fissile material, with a [~~the~~] sum of the CSIs [~~shall be~~] less than or equal to 50.0 [~~(~~]for shipment on a nonexclusive use conveyance[~~)~~] and less than or equal to 100.0 [~~(~~]for shipment on an exclusive use conveyance[~~)~~].

(E) The CSI must [~~shall~~] be as follows:

(i) the value for the CSI is [~~shall be~~] greater than or equal to the number calculated by the following equation:
Figure: 25 TAC §289.257(i)(3)(E)(i) (No change.)

(ii) the calculated CSI is [~~shall be~~] rounded up to the first decimal place;

(iii) the values of X, Y, and Z used in the CSI equation is [~~shall be~~] taken from Tables 257-1 or 257-2 of this clause, as appropriate;
Figure: 25 TAC §289.257(i)(3)(E)(iii) (No change.)

(iv) if Table 257-2 of clause (iii) of this subparagraph is used to obtain the value of X, then the values for the terms in the equation for uranium-233 and plutonium must [~~shall~~] be assumed to be zero; and

(v) Table 257-1 values of clause (iii) of this subparagraph for X, Y, and Z are [~~shall be~~] used to determine the CSI if:

(I) uranium-233 is present in the package;

(II) the mass of plutonium is greater than [~~exceeds~~] one percent of the mass of uranium-235;

(III) the uranium is of unknown uranium-235 enrichment, or greater than 24 weight percent enrichment; or

(IV) substances having a moderating effectiveness (i.e., an average hydrogen density greater than H_2O [~~H_2O~~]) (e.g., certain hydrocarbon oils or plastics) are present in any form, except as polyethylene used for packing or wrapping.

(4) Plutonium-beryllium special form material.

(A) A general license is issued to any licensee to transport fissile material in the form of plutonium-beryllium (Pu-Be) special form sealed sources, or to deliver Pu-Be sealed sources to a carrier for transport, if the material is shipped as specified in [~~accordance with~~] this section. This material need not be contained in a package meeting [~~that meets~~] the standards of 10 CFR [~~Title 10, CFR,~~] Part 71;[~~,~~] however, the material must [~~shall~~] be contained in a Type A package. The Type A package must [~~shall~~] also meet [~~the~~] DOT requirements in 49 CFR [~~of Title 49, CFR,~~] §173.417(a).

(B) The general license applies only to a licensee having [~~who has~~] a QA [~~quality assurance~~] program approved by the NRC as satisfying the provisions of 10 CFR [~~Title 10, CFR,~~] Part 71.

(C) The general license applies only when a package's contents:

(i) contain no more than a Type A quantity of material; and

(ii) contain less than 1000 g [~~1000g~~] of plutonium, provided [~~that~~] plutonium-239, plutonium-241, or any combination of these radionuclides, constitutes less than 240 g of the total quantity of plutonium in the package.

(D) The general license applies only to packages labeled with a CSI [~~that~~]:

(i) [~~has been~~] determined as specified in [~~accordance with~~] subparagraph (E) of this paragraph;

(ii) with [~~has~~] a value less than or equal to 100.0; and

(iii) for a shipment of multiple packages containing Pu-Be sealed sources, with a [~~the~~] sum of the CSIs [~~shall be~~] less than or equal to 50.0 [~~(~~]for shipment on a nonexclusive use conveyance[~~)~~] and less than or equal to 100.0 [~~(~~]for shipment on or exclusive use conveyance[~~)~~].

(E) The value for the CSI must [~~shall be as follows~~]:

(i) [~~the CSI shall~~] be greater than or equal to the number calculated by the following equation:
Figure: 25 TAC §289.257(i)(4)(E)(i) (No change.)

(ii) [~~the calculated CSI shall~~] be rounded up to the first decimal place once calculated.

(j) Assumptions as to unknown properties. When the isotopic abundance, mass, concentration, degree of irradiation, degree of moderation, or other pertinent property of fissile material in any package is not known, the licensee must [~~shall~~] package the fissile material as if the unknown properties have credible values causing [~~that will cause~~] the maximum neutron multiplication.

(k) Preliminary determinations. Before the first use of any packaging for the shipment of licensed material, the licensee must [~~shall~~] ascertain [~~that~~] the determinations were [~~have been~~] made as specified in 10 CFR [~~in accordance with Title 10, CFR,~~] §71.85.

(l) Routine determinations. Before each shipment of radioactive material, the licensee must [~~shall~~] ensure [~~that~~] the package with its contents satisfies the applicable requirements of this section and of the license. The licensee must [~~shall~~] determine [~~that~~]:

(1) the package is proper for the contents to be shipped;

(2) the package is in unimpaired physical condition except for superficial defects such as marks or dents;

(3) each closure device of the packaging, including any required gasket, is properly installed, secured, and free of defects;

(4) any system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid;

(5) any pressure relief device is operable and set as specified in [~~accordance with~~] written procedures;

(6) the package has been loaded and closed as specified in [~~accordance with~~] written procedures;

(7) for fissile material, any moderator or neutron absorber, if required, is present and in proper condition;

(8) any structural part of the package [~~that could be~~] used to lift or tie down the package during transport is rendered inoperable for that purpose, unless it satisfies the design requirements of 10 CFR [~~Title 10, CFR,~~] §71.45;

(9) the level of non-fixed (removable) radioactive contamination on the external surfaces of each package offered for shipment is as low as reasonably achievable (ALARA), and within the limits specified in DOT regulations 49 CFR [~~in Title 49, CFR,~~] §173.443;

(10) external radiation levels around the package and around the vehicle, if applicable, are not greater than [~~will not exceed~~] the following limits at any time during transportation:

(A) Except as provided in subparagraph (B) of this paragraph, each package of radioactive materials offered for transportation must [~~shall~~] be designed and prepared for shipment so, [~~that~~] under conditions normally incident to transportation, the radiation level is not greater than [~~does not exceed~~] 2 millisieverts per hour (mSv/hr) (200 millirem per hour (mrem/hr)) [~~mSv/hr (200 mrem/hr)~~] at any point on the external surface of the package, and the transport index is not greater than [~~does not exceed~~] 10.

(B) A package that exceeds the radiation level limits specified in subparagraph (A) of this paragraph must [~~shall~~] be transported by exclusive use shipment only, and the radiation levels for such shipment must [~~shall~~] not be greater than [~~exceed~~] the following during transportation:

(i) 2 mSv/hr (200 mrem/hr) on the external surface of the package, unless the following conditions are met, in which case the limit is 10 mSv/hr (1000 mrem/hr) [~~(1,000 mrem/hr)~~]:

(I) the shipment is made in a closed transport vehicle;

(II) the package is secured within the vehicle so [~~that~~] its position remains fixed during transportation; and

(III) there are no loading or unloading operations between the beginning and end of the transportation;

(ii) 2 mSv/hr (200 mrem/hr) at any point on the outer surface of the vehicle, including the top and underside of the vehicle; or in the case of a flat-bed style vehicle, at any point on the vertical planes projected from the outer edges of the vehicle, on the upper surface of

the load or enclosure, if used, and on the lower external surface of the vehicle; and

(iii) 0.1 mSv/hr (10 mrem/hr) at any point 2 meters (m) (6.6 feet (ft)) from the outer lateral surfaces of the vehicle (excluding the top and underside of the vehicle); or in the case of a flat-bed style vehicle, at any point 2 m (6.6 ft) from the vertical planes projected by the outer edges of the vehicle (excluding the top and underside of the vehicle); and

(iv) 0.02 mSv/hr (2 mrem/hr) in any normally occupied space, except [~~that~~] this provision does not apply to private carriers, if exposed personnel under their control wear radiation dosimetry devices in conformance with §289.202(q) of this chapter [~~title~~].

(C) For shipments made as specified in [~~accordance with~~] the provisions of subparagraph (B) of this paragraph, the shipper must [~~shall~~] provide specific written instructions to the carrier for maintenance of the exclusive use shipment controls. The instructions must [~~shall~~] be included with the shipping paper information.

(D) The written instructions required for exclusive use shipments must [~~shall~~] be sufficient so [~~that~~], when followed, they will cause the carrier to avoid actions [~~that will~~] unnecessarily delaying [~~delay~~] delivery or unnecessarily resulting [~~result~~] in increased radiation levels or radiation exposures to transport workers or members of the general public.

(m) Air transport of plutonium.

(1) Notwithstanding the provisions of any general licenses and notwithstanding any exemptions stated directly in this section or included in 49 CFR [~~indirectly by citation of Title 49, CFR,~~] Chapter I, as may be applicable, the licensee must [~~shall~~] assure [~~that~~] plutonium in any form, whether for import, export, or domestic shipment, is not transported by air or delivered to a carrier for air transport unless:

(A) the plutonium is contained in a medical device designed for individual human application; or

(B) the plutonium is contained in a material in which the specific activity is less than or equal to the activity concentration values for plutonium specified in Table 257-4 of subsection (ee)(7) of this section, and in which the radioactivity is essentially uniformly distributed; or

(C) the plutonium is shipped in a single package containing no more than an A_2 quantity of plutonium in any isotope or form, and is shipped as specified in [~~accordance with~~] subsection (e) of this section; or

(D) the plutonium is shipped in a package specifically authorized for the shipment of plutonium by air in the CoC [~~Certificate of Compliance~~] for that package issued by the NRC.

(2) Nothing in paragraph (1) of this subsection is [~~to be~~] interpreted as removing or diminishing the requirements of 10 CFR [~~Title 10, CFR,~~] §73.24.

(3) For a shipment of plutonium by air [~~which is~~] subject to paragraph (1) of this subsection, the licensee must [~~shall~~], through special arrangement with the carrier, require compliance with 49 CFR [~~Title 49, CFR,~~] §175.704, DOT regulations applicable to the air transport of plutonium.

(n) Opening instructions. Before delivery of a package to a carrier for transport, the licensee must [~~shall~~] ensure [~~that~~] any special instructions needed to safely open the package are [~~have been~~] sent to, or otherwise made available to, the consignee for the consignee's use as specified in [~~accordance with~~] §289.202(ee)(5) of this chapter [~~title~~].

(o) Records.

(1) For a period of three years after shipment, each licensee must [~~shall~~] maintain, for inspection by the department, a record of each shipment of radioactive material not exempt under subsection (f) of this section, including, [~~the following~~] where applicable:

(A) identification of the packaging by model number and serial number;

(B) verification [~~that~~] there are no significant defects in the packaging, as shipped;

(C) volume and identification of coolant;

(D) type and quantity of radioactive material in each package, and the total quantity of each shipment;

(E) for each item of irradiated fissile material:

(i) identification by model number and serial number;

(ii) irradiation and decay history to the extent appropriate to demonstrate [~~that~~] its nuclear and thermal characteristics comply with license conditions; and

(iii) any abnormal or unusual condition relevant to radiation safety;

(F) date of the shipment;

(G) for fissile packages and for Type B packages, any special controls exercised;

(H) name and address of the transferee;

(I) address to which the shipment was made; and

(J) results of the determinations required by subsection (l) of this section and by the conditions of the package approval.

(2) The licensee, certificate holder, and an applicant for a CoC must[~~, shall~~] make available to the department for inspection, upon reasonable notice, all records required by this section. Records are only valid if stamped, initialed, or signed and dated by authorized personnel, or otherwise authenticated.

(3) The licensee, certificate holder, and an applicant for a CoC must [~~shall~~] maintain sufficient written records to furnish evidence of the quality of packaging.

(A) The records [~~to be~~] maintained include:

(i) results of the determinations required by subsection (k) of this section;

(ii) design, fabrication, and assembly records;

(iii) results of reviews, inspections, tests, and audits;

(iv) results of monitoring work performance and materials analyses; and

(v) results of maintenance, modification, and repair activities.

(B) Inspection, test, and audit records must identify the:

(i) inspector or data recorder;

(ii) type of observation;

(iii) results;

(iv) acceptability; and

(v) action taken in connection with any deficiencies noted.

(C) These records must be retained for three years after the life of the packaging to which they apply.

(p) Reports. The transporter and shipper must [~~shall~~] immediately report by telephone all radioactive waste transportation accidents to the department, at (512) 458-7460, and the local emergency management officials in the county where the radioactive waste accident occurs. All other accidents involving radioactive material must [~~shall~~] be reported as specified in [~~accordance with~~] §289.202(xx) and (yy) of this chapter [~~title~~].

(q) Advance notification of transport of irradiated reactor fuel and certain radioactive waste.

(1) As specified in paragraphs (3) - (5) of this subsection, each licensee must [~~shall~~] provide advance notification to the governor of a state[~~,~~] or the governor's designee, of the shipment of radioactive waste[~~,~~] within or across the boundary of the state[~~,~~] before the transport[~~,~~] or delivery to a carrier, for transport[~~,~~] of radioactive waste outside the confines of the licensee's facility or other place of use or storage.

(2) As specified in paragraphs (3) - (5) of this subsection, after June 11, 2013, each licensee must [~~shall~~] provide advance notification to the Tribal official of participating Tribes referenced in paragraph (4)(C)(iii) of this subsection[~~,~~] or the official's designee, of the shipment of radioactive waste[~~,~~] within or across the boundary of the Tribe's reservation[~~,~~] before the transport[~~,~~] or delivery to a carrier, for transport[~~,~~] of radioactive waste outside the confines of the licensee's facility or other place of use or storage.

(3) Advanced notification is also required under this subsection for the shipment of licensed radioactive material, other than irradiated fuel, meeting the following three conditions:

(A) the radioactive waste is required by this section to be in Type B packaging for transportation;

(B) the radioactive waste is being transported to or across a state boundary en route to a disposal facility or to a collection point for transport to a disposal facility; and

(C) the quantity of radioactive waste in a single package is not greater than [~~exceeds~~] the least of [~~the following~~]:

(i) 3000 [~~3,000~~] times the A_1 value of the radionuclides as specified in subsection (ee) of this section for special form radioactive material;

(ii) 3000 [~~3,000~~] times the A_2 value of the radionuclides as specified in subsection (ee) of this section for normal form radioactive material; or

(iii) 1000 [~~1,000~~] terabecquerels (TBq) (27,000 curies (Ci)).

(4) Procedures [~~The following are procedures~~] for submitting advance notification:

(A) The notification must [~~shall~~] be made in writing, to:

(i) the office of each appropriate governor or governor's designee and to the department;

(ii) the office of each appropriate Tribal official or Tribal official's designee; and

(iii) the Director, Office of Nuclear Security and Incident Response.

(B) A notification delivered by mail must [~~shall~~] be postmarked at least seven days before the beginning of the seven-day period during which departure of the shipment is estimated to occur.

(C) A notification delivered by any means other [~~means~~] than mail must [~~shall~~] reach the office of the governor or of the governor's designee or the Tribal official or Tribal official's designee at least four days before the beginning of the seven-day period during which departure of the shipment is estimated to occur.

~~f(i)~~ ~~A list of the names and mailing addresses of the governors' designees receiving advance notification of transportation of radioactive waste was published in the *Federal Register* on June 30, 1995 (60 FR 34306).~~]

(i) [~~(ii)~~] Contact information for each state, including telephone and mailing addresses of governors and governors' designees, and participating Tribes, including telephone and mailing addresses of Tribal officials and Tribal official's designees, is available on the NRC website at: https://scp.nrc.gov/special/designee.pdf.

(ii) [~~(iii)~~] A list of the names and mailing addresses of the governors' designees and Tribal officials' designees of participating Tribes is available on request from the Director, Division of Materials Safety, Security, State, and Tribal Programs, Office of Nuclear Material Safety and Safeguards, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

(D) The licensee must [~~shall~~] retain a copy of the notification for inspection by the department [~~as a record~~] for three years.

(5) Each advance notification of shipment of irradiated reactor fuel or radioactive waste must [~~shall~~] contain [~~the following information~~]:

(A) the name, address, and telephone number of the shipper, carrier, and receiver of the irradiated reactor fuel or radioactive waste shipment;

(B) a description of the irradiated reactor fuel or radioactive waste contained in the shipment, as specified in the regulations of DOT in 49 CFR [~~Title 49, CFR,~~] §172.202 and §172.203(d);

(C) the point of origin of the shipment and the seven-day period during which departure of the shipment is estimated to occur;

(D) the seven-day period during which arrival of the shipment at state boundaries or Tribal reservation is estimated to occur;

(E) the destination of the shipment, and the seven-day period during which arrival of the shipment is estimated to occur; and

(F) a point of contact, with a telephone number, for current shipment information.

(6) A licensee who finds [~~that~~] schedule information previously furnished to a governor or governor's designee or a Tribal official or Tribal official's designee, as specified in [~~accordance with~~] this section, is [~~will~~] not [~~be~~] met, must [~~shall~~] telephone a responsible individual in the office of the governor of the state or of the governor's designee or the Tribal official or the Tribal official's designee and inform that individual of the extent of the delay beyond the schedule originally reported. The licensee must [~~shall~~] maintain a record of the name of the individual contacted for three years.

(7) Procedures [~~The following are procedures~~] for a cancellation notice.

(A) Each licensee canceling [~~who cancels~~] an irradiated reactor fuel or radioactive waste shipment for which advance notifica-

tion was [has been] sent must [shall] send a cancellation notice to the governor of each state or to the governor's designee previously notified, to each Tribal official or to the Tribal official's designee previously notified, [and] to the Director, Office of Nuclear Security and Incident Response, and to the department.

(B) The licensee must [shall] state in the notice [that] it is a cancellation and identify the advance notification [that is] being canceled. The licensee must [shall] retain a copy of the notice for inspection by the department [as a record] for three years.

(r) Emergency plan registration requirements.

(1) Each shipper and transporter of radioactive waste must [shall] submit an emergency plan to the department and receive a registration letter from the department before initial shipment.

(2) A freight forwarder must submit an emergency plan [in order] to become a registered freight forwarder.

(3) Each shipper, transporter, or freight forwarder applying for registration must [shall] submit a Business Information Form (RC 252-1).

(4) Shipper and freight forwarder registrations expire 10 years from the date of issuance. New documentation to renew the registration must be submitted at least 30 days before the expiration date.

(s) QA [quality assurance] requirements.

(1) Purpose. This subsection describes QA [quality assurance] requirements applying to the design, purchase, fabrication, handling, shipment [shipping], storage [storing], cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components of packaging that are important to safety.

(A) QA [Quality assurance] comprises all those planned and systematic actions necessary to provide adequate confidence [that] a system or component performs [will perform] satisfactorily in service.

(B) QA [quality assurance] includes quality control, which comprises those QA [quality assurance] actions related to control of the physical characteristics and quality of the material or component to predetermined requirements.

(C) The licensee, certificate holder, and applicant for a CoC are responsible for [the following]:

(i) the QA [quality assurance] requirements as they apply to the design, fabrication, testing, and modification of packaging; and

(ii) the QA [quality assurance] provision applicable to its use of a packaging for the shipment of licensed material under subsections (s) - (bb) and (ee) of this section.

(2) Establishment of program. Each licensee, certificate holder, and applicant for a CoC must [shall]:

(A) establish [Establish], maintain, and execute a QA [quality assurance] program satisfying each of the applicable criteria of this subsection, subsections (s) and (t) of this section, and 10 CFR [Title 10, CFR,] §§71.101 - [through] 71.137 and satisfying any specific provisions [that are] applicable to the licensee's activities including procurement of packaging; and

(B) execute [Execute] the applicable criteria in a graded approach to an extent [that is] commensurate with the QA [quality assurance] requirement's importance to safety.

(3) Approval of program. Before the use of any package for the shipment of licensed material subject to this subsection, each licensee must [shall]:

(A) obtain department approval of its QA [quality assurance] program; and

(B) file a description of its QA [quality assurance] program, including a discussion of which requirements of this subsection and subsections (t) and (u) are applicable and how they will be satisfied.

(4) Radiography containers. A program for transport container inspection and maintenance limited to radiographic exposure devices, source changers, or packages transporting these devices and meeting the requirements of §289.255(m) of this subchapter [title], is deemed to satisfy the requirements of subsection (i)(1)(B) of this section and paragraph (2) of this subsection.

(t) QA [quality assurance] organization. The licensee, certificate holder, and applicant for a CoC must [shall] (while the term "licensee" is used in these criteria, the requirements are applicable to the [whatever] design, fabrication [fabricating], assembly, and testing of the package [is] accomplished [with respect to a package] before the time a package approval is issued):

(1) be responsible for establishing and executing [the establishment and execution of] the QA [quality assurance] program. The licensee, certificate holder, and applicant for a CoC may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the QA [quality assurance] program, or any part of the QA [quality assurance] program, but must [shall] retain responsibility for the program; [and]

(2) clearly establish and delineate, in writing, the authority and duties of persons and organizations performing activities affecting the functions of structures, systems, and components [that are] important to safety. These activities include performing the functions associated with attaining quality objectives and the QA [quality assurance] functions; and [.]

(3) establish QA [quality assurance] functions as follows:

(A) assuring [that] an appropriate QA [quality assurance] program is established and effectively executed; and

(B) verifying, by procedures such as checking, auditing, and inspecting [inspection], [that] activities affecting the functions [that are] important to safety are [have been] correctly performed; and[.]

(4) assure [that] persons and organizations performing QA [quality assurance] functions have sufficient authority and organizational freedom to:

(A) identify quality problems;

(B) initiate, recommend, or provide solutions; and

(C) verify implementation of solutions.

(u) QA [quality assurance] program. A QA [quality assurance] program must [shall] be maintained as follows:

(1) The licensee, certificate holder, and applicant for a CoC must [shall]:

(A) establish, at the earliest practicable time consistent with the schedule for accomplishing the activities, a QA [quality assurance] program complying [that complies] with the requirements of this section and 10 CFR [Title 10, CFR,] §§71.101 - [through] 71.137;

(B) document the QA [~~quality assurance~~] program by written procedures or instructions and [~~shall~~] carry out the program as specified in [~~accordance with~~] those procedures throughout the period during which the packaging is used; and

(C) identify the material and components [~~to be~~] covered by the QA [~~quality assurance~~] program, the major organizations participating in the program, and the designated functions of these organizations.

(2) The licensee, certificate holder, and applicant for a CoC, through its QA [~~quality assurance~~] program, must [~~shall~~]:

(A) provide control over activities affecting the quality of the identified materials and components to an extent consistent with their importance to safety, and as necessary to assure conformance to the approved design of each individual package used for the shipment of radioactive material;

(B) assure [~~that~~] activities affecting quality are accomplished under suitable controlled conditions, including [~~which include~~]:

(i) the use of appropriate equipment;

(ii) suitable environmental conditions for accomplishing the activity, such as adequate cleanliness; and

(iii) all prerequisites for the given activity are [~~have been~~] satisfied; and

(C) consider [~~take into account~~] the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection and test.

(3) The licensee, certificate holder, and applicant for a CoC must [~~shall~~] base the requirements and procedures of its QA [~~quality assurance~~] program on [~~the following~~] considerations concerning the complexity and proposed use of the package and its components, including: [~~.~~]

(A) the [~~The~~] impact of malfunction or failure of the item to safety;

(B) the [~~The~~] design and fabrication complexity or uniqueness of the item;

(C) the [~~The~~] need for special controls and surveillance over processes and equipment;

(D) the [~~The~~] degree to which functional compliance can be demonstrated by inspection or test; and

(E) the [~~The~~] quality history and degree of standardization of the item.

(4) The licensee, certificate holder, and applicant for a CoC must [~~shall~~] provide for indoctrination and training of personnel performing activities affecting quality, as necessary to assure [~~that~~] suitable proficiency is achieved and maintained.

(5) The licensee, certificate holder, and applicant for a CoC must [~~shall~~] review the status and adequacy of the QA [~~quality assurance~~] program at established intervals. Management of other organizations participating in the QA [~~quality assurance~~] program must [~~shall~~] review regularly the status and adequacy of that part of the QA [~~quality assurance~~] program they are executing.

(6) Changes to QA [~~quality assurance~~] program.

(A) Each QA [~~quality assurance~~] program approval holder must [~~shall~~] submit, as specified in [~~accordance with~~] §289.201(k) of this chapter [~~title~~], a description of a proposed change to its department-approved QA [~~agency-approved quality assurance~~] program reducing [~~that will reduce~~] commitments in the program description as approved by the department. The QA [~~quality assurance~~] program approval holder must [~~shall~~] not implement the change before receiving [~~agency~~] approval from the department. The description of a proposed change to the department-approved QA [~~agency-approved quality assurance~~] program must identify the change, the reason for the change, and the basis for concluding [~~that~~] the revised program incorporating the change continues to satisfy the applicable requirements of subsections (s) - (bb) of this section.

(B) Each QA [~~quality assurance~~] program approval holder may change a previously approved QA [~~quality assurance~~] program without prior [~~agency~~] approval from the department[~~,~~] if the change does not reduce the commitments in the QA [~~quality assurance~~] program previously approved by the department. Changes to the QA [~~quality assurance~~] program that do not reduce the commitments must [~~shall~~] be submitted to the department every 24 months as specified in [~~accordance with~~] §289.201(k) of this chapter [~~title~~]. In addition to QA [~~quality assurance~~] program changes involving administrative improvements and clarifications, spelling corrections, and non-substantive changes to punctuation or editorial items, the following changes are not considered reductions in commitment:

(i) the use of a QA [~~quality assurance~~] standard approved by the department [~~that is~~] more recent than the QA [~~quality assurance~~] standard in the certificate holder's or applicant's current QA [~~quality assurance~~] program at the time of the change;

(ii) the use of generic organizational position titles [~~that~~] clearly denoting [~~denote~~] the position function, supplemented as necessary by descriptive text, rather than specific titles, provided [~~that~~] there is no substantive change to either the functions of the position or reporting responsibilities;

(iii) the use of generic organizational charts to indicate functional relationships, authorities, and responsibilities, or alternatively, the use of descriptive text, provided [~~that~~] there is no substantive change to the functional relationships, authorities, or responsibilities;

(iv) the elimination of QA [~~quality assurance~~] program information duplicating [~~that duplicates~~] language in QA [~~quality assurance~~] regulatory guides and [~~quality assurance~~] standards to which the QA [~~quality assurance~~] program approval holder has committed [~~to~~] on record; and

(v) organizational revisions ensuring [~~that ensure that~~] persons and organizations performing QA [~~quality assurance~~] functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations.

(vi) Quality control program. Each shipper must [~~shall~~] adopt a quality control program ensuring [~~to include verification of the following to ensure that~~] shipping containers are suitable for shipments to a licensed disposal facility by verifying:

(C) Each QA [~~quality assurance~~] program approval holder must [~~shall~~] maintain records of QA [~~quality assurance~~] program changes.

(v) Quality control program. Each shipper shall adopt a quality control program to include verification of the following to ensure that shipping containers are suitable for shipments to a licensed disposal facility:

(1) identification of appropriate containers [~~container(s)~~];

(2) container testing documentation is adequate;

(3) appropriate container used;

(4) container packaged appropriately;

(5) container labeled appropriately;

(6) manifest filled out appropriately; and

(7) documentation maintained of each step.

(w) Handling, storage, and shipping control. The licensee, certificate holder, and applicant for a CoC must [~~shall~~] establish measures to control, as specified in [~~accordance with~~] instructions, the handling, storing [~~storage~~], shipping, cleaning, and preserving [~~preservation~~] of materials and equipment [~~to be~~] used in packaging to prevent damage or deterioration. When necessary for particular products, special protective environments, such as inert gas atmosphere, and specific moisture content and temperature levels must [~~shall~~] be specified and provided.

(x) Inspection, test, and operating status. Measures to track inspection, test, and operating status must [~~shall~~] be established [~~as follows~~].

(1) The licensee, certificate holder, and applicant for a CoC must [~~shall~~] establish measures to indicate, using [~~by the use of~~] markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items of the packaging. These measures must [~~shall~~] provide for the identification of items having [~~that have~~] satisfactorily passed required inspections and tests[~~,~~] where necessary to preclude inadvertent bypassing of the inspections and tests; and

(2) The licensee must [~~, shall~~] establish measures to identify the operating status of components of the packaging, such as tagging valves and switches, to prevent inadvertent operation.

(y) Non-conforming [~~Non conforming~~] materials, parts, or components. The licensee, certificate holder, and applicant for a CoC must [~~shall~~] establish measures to control materials, parts, or components [~~that do~~] not conforming [~~conform~~] to the licensee's requirements to prevent their inadvertent use or installation. These measures must [~~shall~~] include [~~the following~~], as appropriate:

(1) procedures for identification, documentation, segregation, disposition, and notification to affected organizations; and

(2) non-conforming [~~nonconforming~~] items must [~~shall~~] be reviewed and accepted, rejected, repaired, or reworked as specified in [~~accordance with~~] documented procedures.

(z) Corrective action. The licensee, certificate holder, and applicant for a CoC must [~~shall~~] establish measures to assure [~~that~~] conditions adverse to quality, such as deficiencies, deviations, defective material and equipment, and non-conformances [~~nonconformances~~], are promptly identified and corrected.

(1) In the case of a significant condition adverse to quality, the measures must [~~shall~~] assure [~~that~~] the cause of the condition is determined and corrective action taken prevents [~~to preclude~~] repetition.

(2) The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken must [~~shall~~] be documented and reported to appropriate levels of management.

(aa) QA [~~quality assurance~~] records. The licensee, certificate holder, and applicant for a CoC must [~~shall~~] maintain written records sufficient to describe the activities affecting quality for inspection by the department for three years beyond the date when the licensee, certificate holder, and applicant for a CoC last engaged [~~engage~~] in the activity for which the QA [~~quality assurance~~] program was developed. If any portion of the written procedures or instructions is superseded, the licensee, certificate holder, and applicant for a CoC must [~~shall~~] retain the superseded material for three years after it is superseded. The records must include [~~the following~~]:

(1) instructions, procedures, and drawings to prescribe QA [~~quality assurance~~] activities, and closely related specifications such as required qualifications of personnel, procedures, and equipment;

(2) instructions or procedures establishing [~~which establish~~] a records retention program [~~that is~~] consistent with applicable regulations and designating [~~designates~~] factors such as duration, location, and assigned responsibility; and

(3) changes to the QA [~~quality assurance~~] program as required by subsection (u)(6) of this section.

(bb) Audits. The licensee, certificate holder, and applicant for a CoC must [~~shall~~] carry out a comprehensive system of planned and periodic audits, verifying [~~to verify~~] compliance with all aspects of the QA [~~quality assurance~~] program, and determining [~~to determine~~] the effectiveness of the program. The audit program must [~~shall~~] include:

(1) performance as specified in [~~accordance with~~] written procedures or checklists by appropriately trained personnel not having direct responsibilities in the area being audited;

(2) documented results [~~that are~~] reviewed by management having responsibility in the area audited; and

(3) follow-up action, including reaudit of deficient areas, [~~shall be~~] taken where indicated.

(cc) Transfer for disposal and manifests.

(1) The requirements of this section and subsection (ff) of this section are designed to:

(A) control transfers of LLRW by any waste generator, waste collector, or waste processor licensee, as defined in this section, shipping [~~who ships~~] LLRW either directly[~~,~~] or indirectly through a waste collector or waste processor[~~,~~] to a licensed LLRW land disposal facility, as defined in §289.201(b) of this chapter [~~title~~];

(B) establish a manifest tracking system; and

(C) supplement existing requirements concerning transfers and recordkeeping for those wastes.

(2) Beginning March 1, 1998, all affected licensees must [~~shall~~] use subsection (ff) of this section.

(3) Each shipment of LLRW intended for disposal at a licensed land disposal facility must [~~shall~~] be accompanied by a shipment manifest as specified in [~~accordance with~~] subsection (ff)(1) of this section.

(4) Any licensee shipping LLRW intended for ultimate disposal at a licensed land disposal facility must [~~shall~~] document the information required on the uniform manifest and transfer this recorded manifest information to the intended consignee as specified in [~~accordance with~~] subsection (ff) of this section.

(5) Each shipment manifest must [~~shall~~] include a certification by the waste generator as specified in subsection (ff)(10) of this section, as appropriate.

(6) Each person involved in the transfer for disposal and disposal of LLRW, including the waste generator, waste collector, waste processor, and disposal facility operator, must [~~shall~~] comply

with the requirements specified in subsection (ff) of this section, as appropriate.

(7) Any licensee shipping LLRW to a licensed Texas LLRW disposal facility must [~~shall~~] comply with the waste acceptance criteria in 30 Texas Administrative Code [~~Title 30, Texas Administrative Code, Part 1,~~] Chapter 336.

(8) Each shipper must [~~shall~~] submit a list for approval by the department of shipping containers [~~that~~] they intend to use to ship LLRW to the Texas LLRW site. If the shipper is licensed in Texas and is the holder of a CoC, the shipper must [~~shall~~] also submit written documentation of its program for QA [~~quality assurance~~] and control and handling, shipping, and control measures complying [~~that comply~~] with the requirements of subsections (s), (t), and (v) - (bb) of this section.

(dd) Fees.

(1) Each shipper is [~~shall be~~] assessed a fee for shipments of LLRW originating in Texas or originating out-of-state being shipped to a licensed Texas LLRW disposal facility and these fees are [~~shall~~]:

(A) [~~be~~] $10 per cubic foot of shipped LLRW;

(B) [~~be~~] collected by the department and deposited to the credit of the department's Radiation and Perpetual Care Account;

(C) [~~be~~] used by the department for emergency planning for and response to transportation accidents involving LLRW, including first responder training in counties through which transportation routes are designated as specified in [~~accordance with~~] this section; and

(D) not [~~be~~] collected on waste disposed of at a federal waste disposal facility.

(2) Fee assessments are suspended from imposition against a party state compact waste generator when the amount in the department's Radiation and Perpetual Care Account attributable to those fees reaches $500,000. If the amount in that account attributable to those fees is reduced to $350,000 or less, the fee is reinstated until the amount reaches $500,000.

(3) Money expended from the department's Radiation and Perpetual Care Account to respond to accidents involving LLRW are [~~shall be~~] reimbursed to the department's Radiation and Perpetual Care Account by the responsible shipper or transporter according to this section.

(4) For purposes of this subsection, "shipper" means a person who generates LLRW [~~low-level radioactive waste~~] and ships, or arranges with others to ship, [~~the~~] waste to a disposal site.

(5) This subsection does not relieve a generator from liability for a transportation accident involving LLRW.

(ee) Appendices for determination of A_1 and A_2.

(1) Values of A_1 and A_2. Values of A_1 and A_2 for individual radionuclides, which are the bases for many activity limits elsewhere in these rules, are given in Table 257-3 of paragraph (6) of this subsection. The Ci [~~curie (Ci)~~] values specified are obtained by converting from the TBq [~~terabecquerel (TBq)~~] value. The TBq values are the regulatory standard. The Ci [~~curie~~] values are for information only and are not intended to be the regulatory standard. Where values of A_1 or A_2 are unlimited, it is for radiation control purposes only. For nuclear criticality safety, some materials are subject to controls placed on fissile material.

(2) Values of radionuclides not listed.

(A) For individual radionuclides whose identities are known[~~,~~] but are not listed in Table 257-3 of paragraph (6) of this subsection, the A_1 and A_2 values contained in Table 257-5 of paragraph (8) of this subsection may be used. Otherwise, the licensee must [~~shall~~] obtain prior department or NRC approval of the A_1 and A_2 values for radionuclides not listed in Table 257-3 of paragraph (6) of this subsection[~~,~~] before shipping the material.

(B) For individual radionuclides whose identities are known[~~,~~] but [~~that are~~] not listed in Table 257-4 of paragraph (7) of this subsection, the exempt material activity concentration and exempt consignment activity values contained in Table 257-5 of paragraph (8) of this subsection may be used. Otherwise, the licensee must [~~shall~~] obtain prior department or NRC approval of the exempt material activity concentration and exempt consignment activity values[~~,~~] for radionuclides not listed in Table 257-4 of paragraph (7) of this subsection[~~,~~] before shipping the material.

(C) The licensee must [~~shall~~] submit requests for prior approval, described in subparagraphs (A) and (B) of this paragraph, to the department or the NRC.

(3) Calculations of A_1 and A_2 for a radionuclide not in Table 257-3 of paragraph (6) of this subsection. In the calculations of A_1 and A_2 for a radionuclide not in Table 257-3 of paragraph (6) of this subsection, a single radioactive decay chain[~~,~~] in which radionuclides are present in their naturally occurring proportions[~~,~~] and in which no daughter radionuclide has a half-life either longer than 10 days[~~,~~] or longer than [~~that of~~] the parent radionuclide, must [~~shall~~] be considered as a single radionuclide, and the activity to be taken into account and the A_1 and A_2 value to be applied must [~~shall~~] be those corresponding to the parent radionuclide of that chain. In the case of radioactive decay chains in which any daughter radionuclide has a half-life either longer than 10 days, or greater than [~~that of~~] the parent radionuclide, the parent and those daughter radionuclides must [~~shall~~] be considered as mixtures of different radionuclides.

(4) Determination for mixtures of radionuclides whose identities and respective activities are known. For mixtures of radionuclides whose identities and respective activities are known, the following conditions apply.

(A) For special form radioactive material, the maximum quantity transported in a Type A package is as follows:
Figure: 25 TAC §289.257(ee)(4)(A) (No change.)

(B) For normal form radioactive material, the maximum quantity transported in a Type A package is as follows:
Figure: 25 TAC §289.257(ee)(4)(B) (No change.)

(C) If the package contains both special and normal form radioactive material, the activity that may be transported in a Type A package is as follows:
Figure: 25 TAC §289.257(ee)(4)(C) (No change.)

(D) Alternatively, an A_1 value for mixtures of special form material may be determined as follows:
Figure: 25 TAC §289.257(ee)(4)(D) (No change.)

(E) Alternatively, an A_2 value for mixtures of normal form material may be determined as follows:
Figure: 25 TAC §289.257(ee)(4)(E) (No change.)

(F) The exempt activity concentration for mixtures of nuclides may be determined as follows:
Figure: 25 TAC §289.257(ee)(4)(F) (No change.)

(G) The activity limit for an exempt consignment for mixtures of radionuclides may be determined as follows:
Figure: 25 TAC §289.257(ee)(4)(G) (No change.)

(5) Determination when individual activities of some of the radionuclides are not known.

(A) When the identity of each radionuclide is known[,] but the individual activities of some of the radionuclides are not known, the radionuclides may be grouped and the lowest A_1 or A_2 value, as appropriate, for the radionuclides in each group may be used in applying the formulas in paragraph (4) of this subsection. Groups may be based on the total alpha activity and the total beta/gamma activity when these are known, using the lowest A_1 or A_2 values for the alpha emitters and beta/gamma emitters.

(B) When the identity of each radionuclide is known but the individual activities of some of the radionuclides are not known, the radionuclides may be grouped and the lowest [A] (activity concentration for exempt material) or A (activity limit for exempt consignment) value, as appropriate, for the radionuclides in each group may be used in applying the formulas in paragraph (4) of this subsection. Groups may be based on the total alpha activity and the total beta/gamma activity when these are known, using the lowest [A] or A values for the alpha emitters and beta/gamma emitters, respectively.

(6) A_1 and A_2 values for radionuclides. [The following] Table 257-3 contains A_1 and A_2 values for radionuclides.
Figure: 25 TAC §289.257(ee)(6)
[Figure: 25 TAC §289.257(ee)(6)]

(7) Exempt material activity concentrations and exempt consignment activity limits for radionuclides. [The following] Table 257-4 contains exempt material activity concentrations and exempt consignment activity limits for radionuclides:
Figure: 25 TAC §289.257(ee)(7) (No change.)

(8) General values for A_1 and A_2. [The following] Table 257-5 contains general values for A_1 and A_2:
Figure: 25 TAC §289.257(ee)(8) (No change.)

(9) Activity-mass relationships for uranium. [The following] Table 257-6 contains activity-mass relationships for uranium:
Figure: 25 TAC §289.257(ee)(9)
[Figure: 25 TAC §289.257(ee)(9)]

(ff) Appendices for the requirements for transfers of LLRW intended for disposal at licensed land disposal facilities and manifests.

(1) Manifest. A waste generator, collector, or processor who transports, or offers for transportation, LLRW intended for ultimate disposal at a licensed LLRW land disposal facility must [shall] prepare a manifest reflecting information requested on applicable NRC Forms 540 (Uniform Low-Level Radioactive Waste Manifest (Shipping Paper)) and 541 (Uniform Low-Level Radioactive Waste Manifest (Container and Waste Description)) and, if necessary, on an applicable NRC Form 542 (Uniform Low-Level Radioactive Waste Manifest (Manifest Index and Regional Compact Tabulation)) or their equivalent. NRC Forms 540 and 540A must [shall] be completed and [shall] physically accompany the pertinent LLRW shipment. Upon agreement between shipper and consignee, NRC Forms 541, 541A, [and] 542, and 542A may be completed, transmitted, and stored in electronic media with the capability for producing legible, accurate, and complete records on the respective forms. Licensees are not required by the department to comply with the manifesting requirements of this section when they ship:

(A) LLRW for processing and expect its return (i.e., for storage under [in accordance with] their license) before disposal at a licensed land disposal facility;

(B) LLRW [that is] being returned to the licensee who is the waste generator or generator, as defined in this section; or

(C) radioactively contaminated material to a waste processor that becomes the processor's residual waste.

(2) Form instructions. For guidance in completing these forms, refer to the instructions accompanying [that accompany] the forms. Copies of manifests required by this subsection may be legible carbon copies, photocopies, or computer printouts reproducing [that reproduce] the data in the format of the uniform manifest.

(3) Forms. NRC Forms 540, 540A, 541, 541A, 542, and 542A, and the accompanying instructions, in hard copy, may be obtained by writing or calling the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone (301) 415-5877; or by visiting the NRC's website [Web site] at http://www.nrc.gov and selecting forms from the index found on the NRC home page or at www.nrc.gov/reading-rm/doc-collections/forms/#NRC.

(4) Information requirements of the DOT. This subsection includes information requirements of the DOT, [as codified] in 49 CFR [Title 49, CFR,] Part 172. Information on hazardous, medical, or other waste[,] required to meet EPA regulations[, as codified] in 40 CFR [Title 40, CFR,] Parts 259 and 261 or elsewhere, are [is] not addressed in this section[,] and must [shall] be provided on the required EPA forms. The [However, the] required EPA forms must [shall] accompany the uniform manifest required by this section.

(5) General information. The shipper of the LLRW must include [, shall provide the following information] on the uniform manifest:

(A) the name, facility address, and telephone number of the licensee shipping the waste;

(B) an explicit declaration indicating whether the shipper is acting as a waste generator, collector, processor, or a combination of these identifiers for purposes of the manifested shipment; and

(C) the name, address, and telephone number, or the name and EPA identification number, for the carrier transporting the waste.

(6) Shipment information. The shipper of the LLRW must [shall] provide [the following] information regarding the waste shipment on the uniform manifest, including:

(A) the date of the waste shipment;

(B) the total number of packages/disposal containers;

(C) the total disposal volume and disposal weight in the shipment;

(D) the total radionuclide activity in the shipment;

(E) the activity of each of the radionuclides hydrogen-3, carbon-14, technetium-99, and iodine-129 contained in the shipment; and

(F) the total masses of uranium-233, uranium-235, and plutonium in special nuclear material, and the total mass of uranium and thorium in source material.

(7) Disposal container and waste information. The shipper of the LLRW must [shall] provide [the following] information on the uniform manifest regarding the waste and each disposal container of waste in the shipment, including:

(A) an alphabetic or numeric identification [that] uniquely identifying [identifies] each disposal container in the shipment;

(B) a physical description of the disposal container, including the manufacturer and model of any high integrity container;

(C) the volume displaced by the disposal container;

(D) the gross weight of the disposal container, including the waste;

(E) for waste consigned to a disposal facility, the maximum radiation level at the surface of each disposal container;

(F) a physical and chemical description of the waste;

(G) the total weight percentage of chelating agent for any waste containing more than 0.1 percent chelating agent by weight, plus the identity of the principal chelating agent;

(H) the approximate volume of waste within a container;

(I) the sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name;

(J) the identities and activities of individual radionuclides contained in each container, the masses of uranium-233, uranium-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material. For discrete waste types (i.e., activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification/stabilization media), the identities and activities of individual radionuclides associated with or contained on these waste types within a disposal container must [~~shall~~] be reported;

(K) the total radioactivity within each container; and

(L) for wastes consigned to a disposal facility, the classification of the waste as specified in [~~accordance with~~] §289.202(ggg)(4)(A) of this chapter [~~title~~]. Waste not meeting the structural stability requirements of §289.202(ggg)(4)(B)(ii) of this chapter must [~~title shall~~] be identified.

(8) Uncontainerized waste information. The shipper of the LLRW must [~~shall~~] provide [~~the following~~] information on the uniform manifest regarding a waste shipment delivered without a disposal container including:

(A) the approximate volume and weight of the waste;

(B) a physical and chemical description of the waste;

(C) the total weight percentage of chelating agent if the chelating agent is not greater than [~~exceeds~~] 0.1 percent by weight, plus the identity of the principal chelating agent;

(D) for waste consigned to a disposal facility, the classification of the waste as specified in [~~accordance with~~] §289.202(ggg)(4)(A) of this chapter [~~title~~]. Waste not meeting the structural stability requirements of §289.202(ggg)(4)(B)(ii) of this chapter must [~~title shall~~] be identified;

(E) the identities and activities of individual radionuclides contained in the waste, the masses of uranium-233, uranium-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material; and

(F) for wastes consigned to a disposal facility, the maximum radiation levels at the surface of the waste.

(9) Multi-generator disposal container information. This paragraph applies to disposal containers enclosing mixtures of waste originating from different generators. (Note: The origin of the LLRW resulting from a processor's activities may be attributable to one or more generators (including waste generators) as defined in this section). It also applies to mixtures of wastes shipped in an uncontainerized form, for which portions of the mixture within the shipment originate from different generators.

(A) For homogeneous mixtures of waste, such as incinerator ash, provide the waste description applicable to the mixture and the volume of the waste attributed to each generator.

(B) For heterogeneous mixtures of waste, such as the combined products from a large compactor, identify each generator contributing waste to the disposal container, and, for discrete waste types (i.e., activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification/stabilization media), the identities and activities of individual radionuclides contained on these waste types within the disposal container. For each generator, provide [~~the following~~]:

(i) the volume of waste within the disposal container;

(ii) a physical and chemical description of the waste, including the solidification agent, if any;

(iii) the total weight percentage of chelating agents for any disposal container containing more than 0.1 percent chelating agent by weight, plus the identity of the principal chelating agent;

(iv) the sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name if the media is claimed to meet stability requirements in §289.202(ggg)(4)(B)(ii) of this chapter [~~title~~]; and

(v) radionuclide identities and activities contained in the waste, the masses of uranium-233, uranium-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material if contained in the waste.

(10) Certification. An authorized representative of the waste generator, processor, or collector must [~~shall~~] certify by signing and dating the shipment manifest [~~that~~] the transported materials are properly classified, described, packaged, marked, and labeled and are in proper condition for transportation according to the applicable regulations of the DOT and the department. A collector in signing the certification is certifying [~~that~~] nothing has been done to the collected waste invalidating [~~that would invalidate~~] the waste generator's certification.

(11) Control and tracking.

(A) Any licensee transferring [~~who transfers~~] LLRW to a land disposal facility or a licensed waste collector must [~~shall~~] comply with the requirements in clauses (i) - (ix) of this subparagraph. Any licensee transferring [~~who transfers~~] waste to a licensed waste processor for waste treatment or repackaging must [~~shall~~] comply with the requirements of clauses (iv) - (ix) of this subparagraph. A licensee must [~~shall~~]:

(i) prepare all wastes so [~~that~~] the waste is classified according to §289.202(ggg)(4)(A) of this chapter [~~title~~] and meets the waste characteristic requirements in §289.202(ggg)(4)(B) of this chapter [~~title~~];

(ii) label each disposal container (or transport package if potential radiation hazards preclude labeling of the individual disposal container) of waste to identify whether it is Class A waste, Class B waste, Class C waste, or greater than Class C waste, as specified in [~~accordance with~~] §289.202(ggg)(4)(A) of this chapter [~~title~~];

(iii) conduct a QA [~~quality assurance~~] program to assure compliance with §289.202(ggg)(4)(A) and (B) of this chapter [~~title~~];

(iv) prepare the uniform manifest as required by this subsection;

(v) forward a copy or electronically transfer the uniform manifest to the intended consignee so that either:

(I) receipt of the manifest precedes the LLRW shipment; and

(II) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both subclauses (I) and (II) of this clause are also acceptable;

(vi) include the uniform manifest with the shipment regardless of the option chosen in clause (v) of this subparagraph;

(vii) receive acknowledgement of the receipt of the shipment in the form of a signed copy of the uniform manifest;

(viii) retain a copy of or electronically store the uniform manifest and documentation of acknowledgement of receipt as the record of transfer of radioactive material as required by §289.251 of this subchapter [~~title~~] and §289.252 of this subchapter [~~title~~]; and

(ix) for any shipments or any part of a shipment for which acknowledgement of receipt is [~~has~~] not [~~been~~] received within the times set forth in this subsection, conduct an investigation as specified in [~~accordance with~~] subparagraph (D) of this paragraph.

(B) Any waste collector licensee handling [~~who handles~~] only prepackaged waste must [~~shall~~]:

(i) acknowledge receipt of the waste from the shipper within one week of receipt by returning a signed copy of the uniform manifest;

(ii) prepare a new uniform manifest to reflect consolidated shipments meeting [~~that meet~~] the requirements of this subsection. The waste collector must [~~shall~~] ensure [~~that~~], for each container of waste in the shipment, the uniform manifest identifies the generator of that container of waste;

(iii) forward a copy or electronically transfer the uniform manifest to the intended consignee so [~~that~~] either:

(I) receipt of the uniform manifest precedes the LLRW shipment; or

(II) the uniform manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both subclauses (I) and (II) of this clause are also acceptable;

(iv) include the uniform manifest with the shipment regardless of the option chosen in clause (iii) of this subparagraph;

(v) receive acknowledgement of the receipt of the shipment in the form of a signed copy of the uniform manifest;

(vi) retain a copy of or electronically store the uniform manifest and documentation of acknowledgement of receipt as the record of transfer of radioactive material as required by §289.251 of this subchapter [~~title~~] and §289.252 of this subchapter [~~title~~];

(vii) conduct an investigation as specified in subparagraph (D) of this paragraph for any shipments or any part of a shipment for which acknowledgement of receipt is not [~~has not been~~] received within the times set forth as specified in [~~accordance with~~] this clause[~~, conduct an investigation in accordance with subparagraph (D) of this paragraph~~]; and

(viii) notify the shipper and the department when any shipment, or part of a shipment, does [~~has~~] not arrive [~~arrived~~] within 60 days after receipt of an advance uniform manifest, unless notified by the shipper [~~that~~] the shipment has been cancelled.

(C) Any licensed waste processor treating [~~who treats~~] or repackaging [~~repackages~~] waste must [~~shall~~]:

(i) acknowledge receipt of the waste from the shipper within one week of receipt by returning a signed copy of the uniform manifest;

(ii) prepare a new uniform manifest meeting [~~that meets~~] the requirements of this subsection. Preparation of the new uniform manifest reflects [~~that~~] the processor's responsibility [~~processor is responsible~~] for meeting these requirements. For each container of waste in the shipment, the manifest must [~~shall~~] identify the waste generators, the preprocessed waste volume, and the other information as required in clause (i) of this subparagraph;

(iii) prepare all wastes so [~~that~~] the waste is classified according to §289.202(ggg)(4)(A) of this chapter [~~title~~] and meets the waste characteristics requirements in §289.202(ggg)(4)(B) of this chapter [~~title~~];

(iv) label each package of waste to identify whether it is Class A waste, Class B waste, or Class C waste, as specified in [~~accordance with~~] §289.202(ggg)(4)(A) and (C) of this chapter [~~title~~];

(v) conduct a QA [~~quality assurance~~] program to assure compliance with §289.202(ggg)(4)(A) and (B) of this subchapter [~~title~~];

(vi) forward a copy or electronically transfer the uniform manifest to the intended consignee so [~~that~~] either:

(I) receipt of the uniform manifest precedes the LLRW shipment; or

(II) the uniform manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both subclause (I) of this clause and this subclause is also acceptable;

(vii) include the uniform manifest with the shipment regardless of the option chosen in clause (vi) of this subparagraph;

(viii) receive acknowledgement of the receipt of the shipment in the form of a signed copy of the uniform manifest;

(ix) retain a copy of or electronically store the uniform manifest and documentation of acknowledgement of receipt as the record of transfer of radioactive material as required by §289.251 of this subchapter [~~title~~] and §289.252 of this subchapter [~~title~~];

(x) conduct an investigation as specified in clause (v) of this subparagraph for any shipment or any part of a shipment for which acknowledgement of receipt is [~~has~~] not [~~been~~] received within the times set forth as specified in [~~accordance with~~] this clause[~~, conduct an investigation in accordance with clause (v) of this subparagraph~~]; and

(xi) notify the shipper and the department when any shipment, or part of a shipment, does [~~has~~] not arrive [~~arrived~~] within 60 days after receipt of an advance uniform manifest, unless notified by the shipper [~~that~~] the shipment has been cancelled.

(D) Any shipment or part of a shipment for which acknowledgement is not received within the times set forth as specified in [~~accordance with~~] this section must be [~~shall undergo the following~~]:

(i) [~~be~~] investigated by the shipper if the shipper has not received notification or receipt within 20 days after transfer; and

(ii) [~~be~~] traced and reported. The investigation must [~~shall~~] include tracing the shipment and filing a report with the department. Each licensee who conducts a trace investigation must [~~shall~~] file a written report with the department within two weeks of completion of the investigation.

§289.258. Licensing and Radiation Safety Requirements for Irradiators.

(a) Purpose. This section contains requirements for the issuance of a license authorizing the use of sealed sources containing radioactive material used in irradiating [~~irradiators that irradiate~~] objects or materials using gamma radiation. This section also contains radiation safety requirements for operating irradiators.

(b) Scope.

(1) In addition to the requirements of this section, all licensees, unless otherwise specified, are subject to the requirements of:

(A) §289.201 of this chapter [~~title~~] (relating to General Provisions for Radioactive Material);[~~,~~]

(B) §289.202 of this chapter [~~title~~] (relating to Standards for Protection Against Radiation from Radioactive Materials);[~~,~~]

(C) §289.203 of this chapter [~~title~~] (relating to Notices, Instructions, and Reports to Workers; Inspections);[~~,~~]

(D) §289.204 of this chapter [~~title~~] (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services);[~~,~~]

(E) §289.205 of this chapter [~~title~~] (relating to Hearing and Enforcement Procedures);[~~,~~]

(F) §289.252 of this subchapter [~~title~~] (relating to Licensing of Radioactive Material);[~~,~~] and

(G) §289.257 of this subchapter [~~title~~] (relating to Packaging and Transportation of Radioactive Material).

(2) Nothing in this section relieves the licensee from complying with other applicable federal, state, and local regulations governing the siting, zoning, land use, and building code requirements for industrial facilities.

(3) [~~(2)~~] The requirements in this section apply to panoramic irradiators having [~~that have~~] either dry or wet storage of [~~the~~] radioactive sealed sources and to underwater irradiators in which both the source and the product being irradiated are under water. Irradiators whose dose rates are greater than [~~exceed~~] 500 rads (5 grays) per hour at 1 meter (m) from the radioactive sealed sources in air or in water, as applicable for the irradiator type, are covered by this section.

(4) [~~(3)~~] The requirements in this section do not apply to self-contained, dry-source-storage irradiators (those in which both the source and the area subject to irradiation are contained within a device and are not accessible by personnel), medical radiology or teletherapy, radiography (the irradiation of materials for non-destructive [~~nondestructive~~] testing purposes), gauging, or open-field (agricultural) irradiations.

(c) Definitions. The following words and terms [~~,~~] when used in this section [~~, shall~~] have the following meanings [~~,~~] unless the context clearly indicates otherwise.

(1) Annually--At intervals not greater than [~~to exceed~~] 390 days.

(2) Doubly encapsulated sealed source--A sealed source in which the radioactive material is sealed within a capsule and that capsule is sealed within another capsule.

(3) Category I self-contained, dry-source irradiator--An irradiator in which the sealed source is completely contained in a dry container constructed of solid materials and [~~is~~] shielded at all times, and in which human access to the sealed source and the volume undergoing irradiation is not physically possible in its designed configuration.

(4) Irradiator--A facility using [~~that uses~~] radioactive sealed sources for the irradiation of objects or materials and in which radiation dose rates are greater than [~~exceeding~~] 500 rads (5 grays) per hour exist at 1 m from the sealed radioactive sources in air or water, as applicable for the irradiator type, but does not include irradiators in which both the sealed source and the area subject to irradiation are contained within a device and [~~are~~] not accessible to personnel.

(5) Irradiator operator--An individual who [~~has~~] successfully completed the training and testing described in subsection (s) of this section and is authorized by the terms of the license to operate the irradiator without the presence of a supervisor who [~~has~~] completed the requirements of subsection (s)(1) - (3) of this section.

(6) Onsite--A physical presence within the building housing the irradiator or on property controlled by the licensee [~~that is~~] contiguous with the building housing the irradiator.

(7) Panoramic dry-source-storage irradiator--An irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored in shields made of solid materials. The term includes beam-type dry-source-storage irradiators in which only a narrow beam of radiation is produced for performing irradiations.

(8) Panoramic irradiator--An irradiator in which the irradiations are done in air in areas potentially accessible to personnel. The term includes beam-type irradiators.

(9) Panoramic wet-source-storage irradiator--An irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored under water in a storage pool.

(10) Pool irradiator--Any irradiator in which the sources are stored or used in a pool of water, including panoramic wet-source-storage irradiators and underwater irradiators.

(11) Product conveyor system--A system for moving the product to be irradiated to, from, and within the area where irradiation takes place.

(12) Radiation room--A shielded room in which irradiations take place. Underwater irradiators do not have radiation rooms.

(13) Seismic area--Any area where the probability of horizontal acceleration in rock of more than 0.3 times the acceleration of gravity in 250 years is greater than 10 percent [~~10%~~], as designated by the United States Geological Survey.

(14) Underwater irradiator--An irradiator in which the sources always remain shielded under water and humans do not have access to the sealed sources or the space subject to irradiation without entering the pool.

(d) Application for a specific license. Applications for specific licenses must [~~shall~~] be filed as specified in [~~accordance with~~] §289.252(d) of this subchapter [~~title~~].

(e) Specific licenses for irradiators.

(1) The department approves [~~agency will approve~~] an application for a specific license for the use of licensed material in an irradiator if the applicant meets the requirements contained in this section.

(2) The applicant must [~~shall~~] satisfy the general requirements specified in §289.252 of this subchapter [~~title~~] and the requirements contained in this section.

(3) The application must [~~shall~~] describe the training provided to irradiator operators including:

(A) classroom training;

(B) on-the-job or simulator training;

(C) safety reviews;

(D) means employed by the applicant to test each operator's understanding of the department's [~~agency's~~] rules and licensing requirements and the irradiator operating, safety, and emergency procedures; and

(E) minimum training and experience of personnel providing [~~who may provide~~] training.

(4) The application must [~~shall~~] include a copy of the written operating, safety, and emergency procedures as outlined in subsection (t) of this section describing [~~that describes~~] the radiation safety aspects of the procedures.

(5) The application must [~~shall~~] describe the organizational structure for managing the irradiator, specifically the radiation safety responsibilities and authorities of the radiation safety officer (RSO) and those management personnel having [~~who have~~] radiation safety responsibilities or authorities. In particular, the application must [~~shall~~] specify who, within the management structure, has the authority to stop unsafe operations. The application must [~~shall~~] also describe the training and experience required for the position of RSO.

(6) The application must [~~shall~~] include a description of the access control systems required by subsection (i) of this section, the radiation monitors required by subsection (l) of this section, the method of detecting leaking sources required by subsection (w) of this section, including the sensitivity of the method, and a diagram of the facility showing [~~that shows~~] the locations of all required interlocks and radiation monitors.

(7) If the applicant intends to perform and analyze leak tests of dry-source-storage sealed sources, the applicant must [~~shall~~] establish procedures for leak testing and submit a description of these procedures to the department [~~agency~~]. The description must [~~shall~~] include at least [~~the following~~]:

(A) the instruments to be used;

(B) the methods of performing the analysis; and

(C) the pertinent experience of the individual analyzing [~~who analyzes~~] the samples.

(8) If licensee personnel are to load or unload sources, the applicant must [~~shall~~] describe the qualifications and training of the personnel and the procedures [~~to be~~] used. If the applicant intends to contract for source loading or unloading at its facility, the loading or unloading must [~~shall~~] be done by a person specifically authorized by the department [~~agency~~], the United States Nuclear Regulatory Commission (NRC), or an agreement state[~~, or a licensing state~~] to load or unload irradiator sources.

(9) The applicant must [~~shall~~] describe the inspection and maintenance checks, including the frequency of the checks required by subsection (x) of this section.

(f) Start of construction. The applicant must [~~may~~] not begin construction of a new irradiator before [~~prior to~~] the submission to the department [~~agency~~] of both an application for a license for the irradiator and the fee required by §289.204 of this chapter [~~title~~]. As used in this section, the term "construction" includes the construction of any portion of the permanent irradiator structure on the site but does not include[~~:~~] engineering and design work; purchase of a site; site surveys or soil testing; site preparation; site excavation; construction of warehouse or auxiliary structures; and other similar tasks. Any construction activities undertaken before [~~prior to~~] the issuance of a license are entirely at the risk of the applicant and have no bearing on the issuance of a license with respect to the requirements of the Texas Radiation Control Act (Act), rules, and orders issued as specified in [~~accordance with~~] the Act.

(g) Applications for exemptions. Any applications for a license or for amendment of a license authorizing use of a teletherapy-type unit for irradiation of materials or objects may include proposed alternatives for the requirements of this section. The department approves [~~agency will approve~~] the proposed alternatives if the applicant provides adequate rationale for the proposed alternatives and demonstrates [~~that~~] they are likely to provide an adequate level of safety for workers and the public.

(h) Performance criteria for sealed sources.

(1) Cesium-137 must [~~shall~~] not be used in any irradiator other than a Category I self-contained, dry-source irradiator as defined in subsection (c) of this section.

(2) Sealed sources. Sealed sources installed after August 1, 1996, must [~~shall meet the following requirements~~]:

(A) be [~~have been~~] evaluated as specified in [~~accordance with~~] §289.252(v) of this subchapter [~~title~~];

(B) be doubly encapsulated;

(C) use radioactive material [~~that is~~] as non-dispersible [~~nondispersible~~] as practical and [~~that is~~] as insoluble as practical if the source is used in a wet-source-storage or wet-source-change irradiator;

(D) be encapsulated in a material resistant to general corrosion and to localized corrosion, such as 316L stainless steel or other material with equivalent resistance if the sources are for use in irradiator pools; and

(E) be [~~have been~~] leak tested and found leak-free in prototype testing of the sealed source after each of the tests described in paragraphs (3) - (8) of this subsection.

(3) Temperature. The test source must [~~shall~~] be held at negative 40 [~~-40~~] degrees Celsius for 20 minutes, 600 degrees Celsius for one hour, and then [~~be~~] subjected to thermal shock test with a temperature drop from 600 degrees Celsius to 20 degrees Celsius within 15 seconds.

(4) Pressure. The test source must [~~shall~~] be [~~twice~~] subjected twice, for at least five minutes, to an external pressure (absolute) of 2 million newtons per square meter.

(5) Impact. A 2-kilogram steel weight, 2.5 centimeters (cm) in diameter, must [~~shall~~] be dropped from a height of 1 m onto the test source.

(6) Vibration. The test source must [~~shall~~] be subjected three times for ten minutes each to vibrations sweeping from 25 hertz

to 500 hertz with a peak amplitude of five times the acceleration of gravity. In addition, each test source must [~~shall~~] be vibrated for 30 minutes at each resonant frequency found.

(7) Puncture. A 50-gram weight and pin, 0.3-centimeter pin diameter, must [~~shall~~] be dropped from a height of 1 m onto the test source.

(8) Bend. If the length of the source is more than 15 times larger than the minimum cross-sectional dimension, the test source must [~~shall~~] be subjected to a force of 2,000 newtons at its center equidistant from two support cylinders, the distance between which is 10 times the minimum cross-sectional dimension of the source.

(i) Access control requirements in addition to the requirements of §289.202(u) of this chapter [~~title~~].

(1) Each entrance to a radiation room at a panoramic irradiator must [~~shall~~] have a door or other physical barrier to prevent inadvertent entry of personnel if the sources are not in the shielded position. Product conveyor systems may serve as barriers if [~~as long as~~] they reliably and consistently function as a barrier. It must [~~shall~~] not be possible to move the sources out of their shielded position if the door or barrier is open. Opening the door or barrier while the sources are exposed must [~~shall~~] cause the sources to return promptly to the shielded position. The personnel entrance door or barrier must [~~shall~~] have a lock [~~that is~~] operated by the same key used to move the sources. The doors and barriers must [~~shall~~] not prevent any individual in the radiation room from leaving.

(2) In addition, each entrance to a radiation room at a panoramic irradiator must [~~shall~~] have an independent backup access control to detect personnel entry while the sources are exposed. Detection of entry while the sources are exposed must [~~shall~~] cause the sources to return to their fully shielded position and must [~~shall~~] also activate a visible and audible alarm to make the individual entering the room aware of the hazard. The alarm must [~~shall~~] also make at least one other individual [~~who is~~] onsite aware of the entry. That individual must [~~shall~~] be trained on how to respond to the alarm and be prepared to promptly render or summon assistance.

(3) A radiation monitor must [~~shall~~] be provided to detect the presence of high radiation levels in the radiation room of a panoramic irradiator before personnel entry. The monitor must [~~shall~~] be integrated with personnel access door locks to prevent room access when radiation levels are high. Attempted personnel entry while the monitor measures high radiation levels must [~~shall~~] activate the alarm described in paragraph (2) of this subsection. The monitor may be located in the entrance (normally referred to as the maze) but not in the direct radiation beam.

(4) Before the sources move from their shielded position in a panoramic irradiator, the source control must [~~shall~~] automatically activate conspicuous visible and audible alarms to alert people in the radiation room that the sources will be moved from their shielded position. The alarms must [~~shall~~] give individuals enough time to leave the room and to operate the control described in paragraph (5) of this subsection before the sources leave the shielded position.

(5) Each radiation room at a panoramic irradiator must [~~shall~~] have a clearly visible and readily accessible control allowing [~~that allows~~] an individual in the room to return the sources to their fully shielded position.

(6) Each radiation room of a panoramic irradiator must [~~shall~~] contain a control preventing [~~that prevents~~] the sources from moving from the shielded position unless the control is [~~has been~~] activated and the door or barrier to the radiation room has been closed within a preset time after activation of the control.

(7) Each entrance to the radiation room of a panoramic irradiator and each entrance to the area within the personnel access barrier of an underwater irradiator must [~~shall~~] have a sign bearing the radiation symbol and the words, "CAUTION (or DANGER), RADIOACTIVE MATERIAL." Panoramic irradiators must [~~shall~~] also have a sign stating "CAUTION (or DANGER), HIGH RADIATION AREA," as defined in §289.201(b) of this chapter [~~title~~], or "GRAVE DANGER, VERY HIGH RADIATION AREA," as defined in §289.201(b) of this chapter [~~title~~], whichever is applicable, but the sign may be removed, covered, or otherwise made inoperative when the sources are fully shielded.

(8) If the radiation room of a panoramic irradiator has roof plugs or other movable shielding, it must [~~shall~~] not be possible to operate the irradiator unless the shielding is in its proper location. The requirement may be met by interlocks preventing [~~that prevent~~] operation if shielding is not placed properly or by an operating procedure requiring inspection of shielding before operating.

(9) Underwater irradiators must [~~shall~~] have a personnel access barrier around the pool [~~that shall be~~] locked to prevent access when the irradiator is not attended. Only operators and facility management may have access [~~to~~] keys to the personnel access barrier. There must [~~shall~~] be an intrusion alarm to detect unauthorized entry when the personnel access barrier is locked. Activation of the intrusion alarm must [~~shall~~] alert an individual (not necessarily onsite) [~~who is~~] prepared to respond or summon assistance.

(j) Shielding.

(1) The radiation dose rate in areas [~~that are~~] normally occupied during operation of a panoramic irradiator must [~~may~~] not be greater than [~~exceed~~] 2 millirem [~~millirems~~] (mrem) (0.02 millisievert (mSv)) per hour at any location 30 cm [~~centimeters (cm)~~] or more from the wall of the room when the sources are exposed. The dose rate must [~~shall~~] be averaged over an area not greater than [~~to exceed~~] 100 square centimeters (cm^2) [~~(cm^2)~~] having no linear dimension greater than 20 cm. Areas where the radiation dose rate is greater than [~~exceeds~~] 2 mrem (0.02 mSv) per hour must [~~shall~~] be locked, roped off, or posted.

(2) The radiation dose at 30 cm over the edge of the pool of a pool irradiator may not be greater than [~~exceed~~] 2 mrem (0.02 mSv) per hour when the sources are in the fully shielded position.

(3) The radiation dose rate at 1 m from the shield of a dry-source-storage panoramic irradiator when the source is shielded must [~~may~~] not be greater than [~~exceed~~] 2 mrem (0.02 mSv) per hour and at 5 cm from the shield, [~~may~~] not greater than [~~exceed~~] 20 mrem (0.2 mSv) per hour.

(k) Fire protection.

(1) The radiation room at a panoramic irradiator must [~~shall~~] have heat and smoke detectors. The detectors must [~~shall~~] activate an audible alarm. The alarm must [~~shall~~] be capable of alerting a person [~~who is~~] prepared to summon assistance promptly. The sources must [~~shall~~] automatically become fully shielded if a fire is detected.

(2) The radiation room at a panoramic irradiator must [~~shall~~] be equipped with a fire extinguishing system capable of extinguishing a fire without the entry of personnel into the room. If water is used, the system for the radiation room must [~~shall~~] have a shut-off valve to control flooding into unrestricted areas.

(l) Radiation monitors.

(1) Irradiators with automatic product conveyor systems must [~~shall~~] have a radiation monitor with an audible alarm located to detect loose radioactive sources [~~that are~~] carried toward the product exit. If the monitor detects a source, an alarm must [~~shall~~] sound

and product conveyors must [~~shall~~] stop automatically. The alarm must [~~shall~~] be capable of alerting an individual in the facility [~~who is~~] prepared to summon assistance. Underwater irradiators in which the product moves within an enclosed stationary tube are exempt from the requirements of this paragraph.

(2) Underwater irradiators [~~that are~~] not in a shielded radiation room must [~~shall~~] have a radiation monitor over the pool to detect abnormal radiation levels. The monitor must [~~shall~~] have an audible alarm and a visible indicator at entrances to the personnel access barrier around the pool. The audible alarm may have a manual shut-off. The alarm must [~~shall~~] be capable of alerting an individual [~~who is~~] prepared to respond promptly.

(m) Control of source movement.

(1) The mechanism moving [~~that moves~~] the sources of a panoramic irradiator must [~~shall~~] require a key to actuate. Actuation of the mechanism must [~~shall~~] cause an audible signal to indicate [~~that~~] the sources are leaving the shielded position. Only one key may be in use at any time[~~,~~] and only operators or facility management may possess it. The key must [~~shall~~] be attached to a portable radiation survey meter by a chain or cable. The lock for source control must [~~shall~~] be designed so [~~that~~] the key may not be removed if the sources are in an unshielded position. The door to the radiation room must [~~shall~~] require the same key.

(2) The console of a panoramic irradiator must [~~shall~~] have a source position indicator indicating [~~that indicates~~] when the sources are in the fully shielded position, when they are in transit, and when the sources are in the fully exposed position.

(3) The control console of a panoramic irradiator must [~~shall~~] have a control that, when activated, must [~~shall~~] return the source to its fully shielded position within its normal transit time.

(4) Each control for a panoramic irradiator must [~~shall~~] be clearly marked as to its function.

(n) Irradiator pools.

(1) For licenses initially issued after August 1, 1996, irradiator pools must [~~shall~~] either:

(A) have a water-tight stainless steel liner or a liner metallurgically compatible with other components in the pool; or

(B) be constructed so [~~that~~] there is a low likelihood of substantial leakage and have a surface designed to facilitate decontamination. In either case, the licensee must [~~shall~~] have a method to safely store the sources during repairs of the pool.

(2) For licenses initially issued after August 1, 1996, irradiator pools must [~~shall~~] have no outlets more than 0.5 m below the normal low water level that could allow water to drain out of the pool. Pipes having [~~that have~~] openings more than 0.5 m below the normal low water level and that could act as siphons must [~~shall~~] have siphon breakers to prevent the siphoning of pool water.

(3) A means must [~~shall~~] be provided to replenish water losses from the pool.

(4) A visible indicator must [~~shall~~] be provided in a clearly visible location to indicate if the pool water level is below the normal low water level or above the normal high water level.

(5) Irradiator pools must [~~shall~~] be equipped with a purification system designed to maintain [~~be capable of maintaining~~] the water during normal operation at a conductivity of 20 microsiemens per centimeter or less and with a clarity so [~~that~~] the sources can be seen clearly.

(6) A physical barrier, such as a railing or cover, must [~~shall~~] be used around or over irradiator pools during normal operation preventing [~~to prevent~~] personnel from accidentally falling into the pool. The barrier may be removed during maintenance, inspection, and service operations.

(7) If long-handled tools or poles are used in irradiator pools, the radiation dose rate on the handling areas of the tools may not be greater than [~~exceed~~] 2 mrem (0.02 mSv) per hour.

(o) Source rack protection. If the product to be irradiated moves on a product conveyor system, the source rack and the mechanism moving [~~that moves~~] the rack must [~~shall~~] be protected by a carrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism.

(p) Power failures.

(1) If electrical power at a panoramic irradiator is lost for longer than 10 seconds, the sources must [~~shall~~] automatically return to the shielded position.

(2) The lock on the door of the radiation room of a panoramic irradiator must [~~shall~~] not be deactivated by a power failure.

(3) During a power failure, the area of any irradiator where sources are located may be entered only when using an operable and calibrated radiation survey meter.

(q) Design requirements for irradiators. The following are design requirements for irradiators [~~that have construction~~] beginning construction after August 1, 1996.

(1) Shielding. For panoramic irradiators, the licensee must [~~shall~~] design shielding walls to meet generally accepted building code requirements for reinforced concrete and design the walls, wall penetrations, and entrance ways to meet the radiation shielding requirements of subsection (j) of this section. If the irradiator will use more than 5 million curies (2×10^{17} becquerels) of activity, the licensee must [~~shall~~] evaluate the effects of heating of the shielding walls by the irradiator sources.

(2) Foundations. For panoramic irradiators, the licensee must [~~shall~~] design the foundation, with consideration given to soil characteristics, ensuring [~~to ensure~~] it is adequate to support the weight of the facility shield walls.

(3) Pool integrity. For pool irradiators, the licensee must [~~shall~~] design the pool to assure [~~that~~] it is leak resistant, [~~that it is~~] strong enough to bear the weight of the pool water and shipping casks, [~~that~~] a dropped cask would not fall on sealed sources, [~~that~~] all outlets or pipes meet the requirements of subsection (n)(2) of this section, and [~~that~~] metal components are metallurgically compatible with other components in the pool.

(4) Water handling system. For pool irradiators, the licensee must [~~shall~~] verify [~~that~~] the design of the water purification system is adequate to meet the requirements of subsection (n)(5) of this section. The system must [~~shall~~] be designed so [~~that~~] water leaking from the system does not drain to unrestricted areas without being monitored.

(5) Radiation monitors. For all irradiators, the licensee must [~~shall~~] evaluate the location and sensitivity of the monitor to detect sources carried by the product conveyor system as required by subsection (l)(1) of this section. The licensee must [~~shall~~] verify [~~that~~] the product conveyor is designed to stop before a source on the product conveyor would cause a radiation overexposure to any person. For pool irradiators, if the licensee uses radiation monitors to detect contamination as specified in [~~accordance with~~] subsection

(w)(2) of this section, the licensee must [~~shall~~] verify [~~that~~] the design of radiation monitoring systems to detect pool contamination includes sensitive detectors located close to where contamination is likely to concentrate.

(6) Source rack. For pool irradiators, the licensee must [~~shall~~] verify [~~that~~] there are no crevices on the source or between the source and source holder that would promote corrosion on a critical area of the source. For panoramic irradiators, the licensee must [~~shall~~] determine [~~that~~] source rack drops due to loss of power will not damage the source rack and [~~that~~] source rack drops due to failure of cables (or alternate means of support) do [~~will~~] not cause loss of integrity of sealed sources. For panoramic irradiators, the licensee must [~~shall~~] review the design of the mechanism that moves the sources to assure that the likelihood of a stuck source is low and that, if the rack sticks, a means exists to free it with minimal risk to personnel.

(7) Access control. For panoramic irradiators, the licensee must [~~shall~~] verify from the design and logic diagram [~~that~~] the access control system meets [~~will meet~~] the requirements of subsection (i) of this section.

(8) Fire protection. For panoramic irradiators, the licensee must [~~shall~~] verify [~~that~~] the number, locations, and spacing of the smoke and heat detectors are appropriate to detect fires and [~~that~~] the detectors are protected from mechanical and radiation damage. The licensee must [~~shall~~] verify [~~that~~] the design of the fire extinguishing system provides the necessary discharge patterns, densities, and flow characteristics for complete coverage of the radiation room and [~~that~~] the system is protected from mechanical and radiation damage.

(9) Source return. For panoramic irradiators, the licensee must [~~shall~~] verify [~~that~~] the source rack will automatically return to the fully shielded position if power is lost for more than 10 seconds.

(10) Seismic. For panoramic irradiators to be built in seismic areas, the licensee must [~~shall~~] design the reinforced concrete radiation shields to retain their integrity in the event of an earthquake by designing to the seismic requirements of an appropriate source such as American Concrete Institute Standard ACI 318-89, "Building Code Requirements for Reinforced Concrete," Chapter 21, "Special Provisions for Seismic Design," or local building codes, if current.

(11) Wiring. For panoramic irradiators, the licensee must [~~shall~~] verify [~~that~~] electrical wiring and electrical equipment in the radiation room are selected to minimize failures due to prolonged exposure to radiation.

(r) Construction monitoring and acceptance testing requirements. The requirements for [~~following are~~] construction monitoring and acceptance testing must be [~~requirements to be~~] met before [~~prior to~~] loading sources in irradiators that began [~~have begun~~] construction after August 1, 1996.

(1) Shielding. For panoramic irradiators, the licensee must [~~shall~~] monitor the construction of the shielding to verify [~~that~~] its construction meets design specifications and generally accepted building code requirements for reinforced concrete.

(2) Foundations. For panoramic irradiators, the licensee must [~~shall~~] monitor the construction of the foundations to verify [~~that~~] the foundation construction meets design specifications.

(3) Pool integrity. For pool irradiators, the licensee must [~~shall~~] verify [~~that~~] the pool meets design specifications and must [~~shall~~] test the integrity of the pool. The licensee must [~~shall~~] verify [~~that~~] outlets and pipes meet the requirements of subsection (n)(2) of this section.

(4) Water handling system. For pool irradiators, the licensee must [~~shall~~] verify [~~that~~] the water purification system, the conductivity meter, and the water level indicators operate properly.

(5) Radiation monitors. For all irradiators, the licensee must [~~shall~~] verify the proper operation of the monitor to detect sources carried on the product conveyor system and the related alarms and interlocks required by subsection (l)(1) of this section. For pool irradiators, the licensee must [~~shall~~] verify the proper operation of the radiation monitors and the related alarm if used to meet subsection (w)(2) of this section. For underwater irradiators, the licensee must [~~shall~~] verify the proper operation of the over-the-pool monitor, alarms, and interlocks required by subsection (l)(2) of this section.

(6) Source rack. For panoramic irradiators, the licensee must [~~shall~~] test the movement of the source racks for proper operation before [~~prior to~~] source loading. Testing must [~~shall~~] include source rack lowering due to simulated loss of power. For all irradiators with product conveyor systems, the licensee must [~~shall~~] observe and test the operation of the conveyor system to assure [~~that~~] the requirements in subsection (o) of this section are met for protection of the source rack and the mechanism moving [~~that moves~~] the rack. Testing must [~~shall~~] include tests of any limit switches and interlocks protecting [~~used to protect~~] the source rack and mechanism moving [~~that moves~~] that rack from moving product carriers.

(7) Access control. For panoramic irradiators, the licensee must [~~shall~~] test the completed access control system to assure [~~that~~] it functions as designed and [~~that~~] all alarms, controls, and interlocks work properly.

(8) Fire protection. For panoramic irradiators, the licensee must [~~shall~~] test the ability of the heat and smoke detectors to detect a fire, [~~to~~] activate alarms, and [~~to~~] cause the source rack to automatically become fully shielded. The licensee must [~~shall~~] test the operability of the fire extinguishing system.

(9) Source return. For panoramic irradiators, the licensee must [~~shall~~] demonstrate [~~that~~] the source racks can be returned to their fully shielded positions without power.

(10) Computer systems. For panoramic irradiators using [~~that use~~] a computer system to control the access control system, the licensee must [~~shall~~] verify [~~that~~] the access control system operates [~~will operate~~] properly if power is lost and must [~~shall~~] verify [~~that~~] the computer has security features preventing [~~that prevent~~] an irradiator operator from commanding the computer to override the access control system when it is required to be operable.

(11) Wiring. For panoramic irradiators, the licensee must [~~shall~~] verify [~~that~~] the electrical wiring and electrical equipment [~~that were~~] installed meet the design specifications.

(s) Training.

(1) Before an individual is permitted to operate an irradiator without a supervisor present[~~,~~] who has completed the requirements of this paragraph and paragraphs (2) and (3) of this subsection, the individual must [~~shall~~] be instructed in:

(A) the fundamentals of radiation protection applied to irradiators (including the differences between external radiation and radioactive contamination, units of radiation dose, dose limits, why large radiation doses must [~~shall~~] be avoided, how shielding and access controls prevent large doses, how an irradiator is designed to prevent contamination, the proper use of survey meters and individual monitoring devices, other radiation safety features of an irradiator, and the basic function of the irradiator);

(B) the requirements of this section and §289.203 of this chapter [~~title that are~~] relevant to the irradiator;

(C) the operation of the irradiator;

(D) those operating, safety, and emergency procedures listed in subsection (t) of this section [~~that~~] the individual is responsible for performing; and

(E) case histories of accidents or problems involving irradiators.

(2) Before an individual is permitted to operate an irradiator without a supervisor present[~~,~~] who has completed the requirements of this paragraph and paragraphs (1) and (3) of this subsection, the individual must [~~shall~~] pass a written test on the instruction received consisting primarily of questions based on the licensee's operating, safety, and emergency procedures [~~that~~] the individual is responsible for performing and other operations necessary to safely operate the irradiator without supervision.

(3) Before an individual is permitted to operate an irradiator without a supervisor present[~~,~~] who has completed the requirements of this paragraph and paragraphs (1) and (2) of this subsection, the individual must [~~shall~~] have received on-the-job training or simulator training in the use of the irradiator as described in the license application. The individual must [~~shall~~] also demonstrate the ability to perform those portions of the operating, safety, and emergency procedures [~~that~~] he or she is to perform.

(4) The licensee must [~~shall~~] conduct safety reviews for irradiator operators at least annually. The licensee must [~~shall~~] give each operator a brief written test on the information. Each safety review must [~~shall~~] include, to the extent appropriate[~~, each of the following~~]:

(A) changes in operating, safety, and emergency procedures since the last review, if any;

(B) changes in rules and license conditions since the last review, if any;

(C) reports on recent accidents, mistakes, or problems that have occurred at irradiators, if any;

(D) relevant results of inspections of operator safety performance;

(E) relevant results of the facility's inspection and maintenance checks; and

(F) a drill to practice an emergency or abnormal event procedure.

(5) The licensee must [~~shall~~] evaluate the safety performance of each irradiator operator at least annually ensuring the department's [~~to ensure that agency~~] rules, license conditions, and operating, safety, and emergency procedures are followed. The licensee must [~~shall~~] discuss the results of the evaluation with the operator and must [~~shall~~] instruct the operator [~~on~~] how to correct any mistakes or deficiencies observed.

(6) Individuals [~~who will be~~] permitted unescorted access to the radiation room of the irradiator or the area around the pool of an underwater irradiator, but who have not received the training required for operators and the RSO, must [~~shall~~] be instructed and tested in any precautions they should take to avoid radiation exposure, any procedures or parts of procedures listed in subsection (t) of this section [~~that~~] they are expected to [~~perform or~~] comply with or perform, and their proper response to alarms required in this section. Tests may be oral.

(7) Individuals required [~~who shall be prepared~~] to respond to alarms [~~required~~] by subsections (i)(2) and (9), (k), (l), and (w)(2) of this section must [~~shall~~] be trained and tested on how to respond. Each individual must [~~shall~~] be retested at least once a year. Tests may be oral.

(t) Operating, safety, and emergency procedures.

(1) The licensee must [~~shall~~] have and follow written operating, safety, and emergency procedures for:

(A) operation of the irradiator, including entering and leaving the radiation room;

(B) use of individual monitoring devices;

(C) surveying the shielding of panoramic irradiators;

(D) monitoring pool water for contamination while the water is in the pool and before release of pool water to unrestricted areas;

(E) leak testing of sources;

(F) inspection and maintenance checks required by subsection (x) of this section;

(G) loading, unloading, and repositioning sources, if the operations are [~~will be~~] performed by the licensee; and

(H) inspection of movable shielding required by subsection (i)(8) of this section, if applicable.

(2) The licensee must [~~shall~~] have and follow emergency or abnormal event procedures, appropriate for the irradiator type, for:

(A) sources stuck in the unshielded position;

(B) personnel overexposures;

(C) a radiation alarm from the product exit portal monitor or pool monitor;

(D) detection of leaking source, pool contamination, or alarm caused by contamination of pool water;

(E) a low or high water level indicator, an abnormal water loss, or leakage from the source storage pool;

(F) a prolonged loss of electrical power;

(G) a fire alarm or explosion in the radiation room;

(H) an alarm indicating unauthorized entry into the radiation room, area around pool, or another alarmed area;

(I) natural phenomena, including an earthquake, a tornado, flooding, or other phenomena [~~as~~] appropriate for the geographical location of the facility; and

(J) the jamming of automatic conveyor systems.

(3) The licensee may revise operating, safety, and emergency procedures without [~~agency~~] approval from the department only if all these [~~of the following~~] conditions are met:

(A) the revisions do not reduce the safety of the facility;

(B) the revisions are consistent with the outline or summary of procedures including procedures for changes to operating, safety, and emergency procedures submitted with the license application;

(C) the revisions are [~~have been~~] reviewed and approved by the radiation safety officer (RSO); and

(D) the users or operators are instructed and tested on the revised procedures before they are put into use.

(4) Changes to operating, safety, and emergency procedures must [shall] be submitted to the department [agency] after the provisions of paragraph (3) of this subsection are completed.

(u) Personnel monitoring.

(1) Irradiator operators must [shall] wear an individual monitoring device [that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor] while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The individual monitoring device [personnel dosimeter processor] must be capable of detecting [accredited for] high-energy photons in the normal and accident dose ranges [(see §289.202(p)(3) of this title)]. Each individual monitoring device [personnel dosimeter] must be assigned to and worn by only one individual. Film badges must be replaced [processed] at least monthly, and all other individual monitoring devices requiring replacement [personnel dosimeters] must be replaced [processed] at least quarterly. After replacement, individual monitoring devices requiring processing must [each film badge, a thermoluminescent dosimeter (TLD), or optically stimulated luminescence device (OSL) shall] be returned to the supplier for processing within 14 calendar days of the exchange date specified by the [personnel monitoring] supplier, or as soon as practicable. All individual monitoring devices must be evaluated at least quarterly or promptly after replacement, whichever is more frequent. Circumstances preventing meeting these time limits must be documented, and those records must be available for review by the department. [In circumstances that make it impossible to return each film badge, TLD, or OSL within 14 calendar days, such circumstances shall be documented and available for review by the agency.]

(2) Other individuals entering [who enter] the radiation room of a panoramic irradiator must [shall] wear a dosimeter, which may be a pocket dosimeter. For groups of visitors, only two people entering [who enter] the radiation room are required to wear dosimeters. If pocket dosimeters are used to meet the requirements of this [the] paragraph, a check of their response to radiation must [shall] be done at least annually. Acceptable dosimeters must [shall] read within plus or minus 30 percent [30%] of the true radiation dose.

(v) Radiation surveys.

(1) A radiation survey of the area outside the shielding of the radiation room of a panoramic irradiator must [shall] be conducted with the sources in the exposed position before the facility starts operations [to operate]. A radiation survey of the area above the pool of pool irradiators must [shall] be conducted after the sources are loaded but before the facility starts operations [to operate]. Additional radiation surveys of the shielding must [shall] be performed at intervals not greater than [to exceed] three years and before resuming operations [operation] after addition of new sources or any modification to the radiation room shielding or structure that might increase dose rates.

(2) If the radiation levels specified in subsection (j) of this section are exceeded, the facility must [shall] be modified to comply with the requirements in subsection (j) of this section.

(3) Portable radiation survey meters must [shall] be calibrated at least annually to an accuracy of plus or minus 20 percent [20%] for the gamma energy of the sources in use. The calibration must [shall] be done at two points on each scale or, for digital instruments, at one point per decade over the range [that will be] used. Portable radiation survey meters must [shall] be of a type that does not saturate and read zero at high radiation dose rates.

(4) Water from the irradiator pool, other potentially contaminated liquids, and sediments from pool vacuuming must [shall] be monitored for radioactive contamination before release to unrestricted areas. Radioactive concentrations must [shall] not be greater than [exceed] those specified in Table 2, Column 2, or Table 3 of §289.202(ggg)(2) of this chapter [title].

(5) Before releasing resins for unrestricted use, the resins must [they shall] be monitored in an area with a background level less than 0.05 mrem (0.5 microsieverts (Sv)) [(0.5 Sv)] per hour. The resins may be released only if the survey does not detect radiation levels above background radiation levels. The survey meter used must [shall] be capable of detecting radiation levels of 0.05 mrem (0.5 Sv) per hour.

(w) Detection of leaking sources.

(1) Each dry-source-storage sealed source must [shall] be tested for leakage at intervals not greater than [to exceed] six months using a leak test kit or method approved by the department [agency], the NRC [the commission], or an agreement state[, or a licensing state]. In the absence of a certificate from a transferor that a test was [has been] made within the six months before the transfer, the sealed source must [may] not be used until tested. The test must [shall] be capable of detecting the presence of 0.005 microcurie (200 becquerels) of radioactive material and must [shall] be performed by a person approved by the department [agency], the NRC, or an agreement state[, or a licensing state to perform the test].

(2) For pool irradiators, sources must [may] not be put into the pool unless the licensee tests the sources for leaks or has a certificate from a transferor that a leak test was [has been] done within the six months before the transfer. Water from the pool must [shall] be checked for contamination each day the irradiator operates. The check may be done either by using a radiation monitor on a pool water circulating system or by analysis of a sample of pool water. If a check for contamination is done by analysis of a sample of pool water, the results of the analysis must [shall] be available within 24 hours. If the licensee uses a radiation monitor on a pool water circulating system, the detection of above normal radiation levels must [shall] activate an alarm. The alarm set-point must [shall] be set as low as practical, but high enough to avoid false alarms. The licensee may reset the alarm set-point to a higher level if necessary to operate the pool water purification system to clear up contamination in the pool if specifically provided for in written emergency procedures.

(3) If a leaking source is detected, the licensee must [shall] arrange to remove the leaking source from service and decontaminate, repair, or dispose [have it decontaminated, repaired, or disposed] of it by a department [an agency], NRC, or agreement state[, or licensing state] licensee [who is] authorized to perform these functions. The licensee must [shall] promptly check its personnel, equipment, facilities, and irradiated product for radioactive contamination. No product may be shipped until the product is [has been] checked and found free of contamination. If a product is [has been] shipped and [that] may have been inadvertently contaminated, the licensee must [shall] arrange to locate and survey that product for contamination. If any personnel are found to be contaminated, decontamination must [shall] be performed promptly. If contaminated equipment, facilities, or products are found, the licensee must [shall] arrange to have them decontaminated or disposed of by a department [an agency], NRC, or agreement state[, or licensing state] licensee [who is] authorized to perform these functions. If a pool is contaminated, the licensee must [shall] arrange to clean the pool until the contamination levels are [do] not greater than [exceed] the appropriate concentration in Table 2, Column 2 of §289.202(ggg)(2) of this chapter [title]. (See §289.202(xx) and (yy) of this chapter [title] for reporting requirements.)

(x) Inspection and maintenance.

(1) The licensee must [~~shall~~] perform inspection and maintenance checks, including [~~that include~~], at [~~as~~] a minimum, each of the following, at the frequency specified in the license or license application:

(A) operability of each aspect of the access control system required by subsection (i) of this section;

(B) functionality [~~functioning~~] of the source position indicator required by subsection (m) (2) of this section;

(C) operability of the radiation monitor for radioactive contamination in pool water required by subsection (w)(2) of this section using a radiation check source, if applicable;

(D) operability of the over-pool radiation monitor at underwater irradiators as required by subsection (l)(2) of this section;

(E) operability of the product exit monitor required by subsection (l)(1) of this section;

(F) operability of the emergency source return control required by subsection (m)(3) of this section;

(G) leak-tightness of systems through which pool water circulates (visual inspection);

(H) operability of the heat and smoke detectors and extinguisher system required by subsection (k) of this section (but without turning extinguishers on);

(I) operability of the means of pool water replenishment required by subsection (n)(3) of this section;

(J) operability of the indicators of high and low pool water levels required by subsection (n)(4) of this section;

(K) operability of the intrusion alarm required by subsection (i)(8) of this section, if applicable;

(L) functionality [~~functioning~~] and wear of the system, mechanisms, and cables used to raise and lower sources;

(M) condition of the barrier to prevent products from hitting the sources or source mechanism as required by subsection (o) of this section;

(N) amount of water added to the pool to determine if the pool is leaking;

(O) electrical wiring on required safety systems for radiation damage;

(P) pool water conductivity measurements and analysis as required by subsection (y)(2) of this section; and

(Q) operability of automatic communications systems used to alert individuals to alarms, emergencies, or abnormal event conditions if required by subsection (z)(2)(A) of this section.

(2) Malfunctions and defects found during inspection and maintenance checks must [~~shall~~] be repaired without undue delay. If repairs are required, the irradiator must [~~shall~~] not be operated unless alternative methods are utilized to provide an equivalent level of safety until repairs are completed.

(y) Pool water purity.

(1) Pool water purification system must [~~shall~~] be run sufficiently to maintain the conductivity of the pool water below 20 microsiemens per centimeter under normal circumstances. If pool water conductivity rises above 20 microsiemens per centimeter, the licensee must [~~shall~~] take prompt actions to lower the pool water conductivity and must [~~shall~~] take corrective actions to prevent future recurrences.

(2) The licensee must [~~shall~~] measure the pool water conductivity no less than weekly[~~,~~] to assure [~~that~~] the conductivity remains below 20 microsiemens per centimeter. Conductivity meters must [~~shall~~] be calibrated at least annually.

(z) Attendance during operation.

(1) Both an irradiator operator and at least one other individual, [~~who is~~] trained [~~on how~~] to respond to alarms as specified in [~~accordance with~~] subsection (s)(7) of this section and [~~is~~] prepared to promptly render or summon assistance, must [~~shall~~] be present onsite whenever it is necessary to enter the radiation room.

(2) At least one individual trained [~~who has received the training on how~~] to respond to alarms described in subsection (s)(7) of this section must [~~shall~~] be available and prepared to promptly respond to alarms, emergencies, or abnormal event conditions at any time a panoramic irradiator is operating. If the individual is not onsite, the following requirements must [~~shall~~] be met.

(A) Automatic means of communications must [~~shall~~] be provided from the irradiator control system to alert the individual to alarms, emergencies, or abnormal event conditions. As a minimum, the automatic communication system must [~~shall~~] alert the individual to those emergency or abnormal events listed in subsection (t)(2) of this section.

(B) The irradiator control system must [~~shall~~] be secured from unauthorized access at any time an irradiator operator is not onsite. This security must [~~shall~~] include physically securing the key described in subsection (m)(1) of this section to ensure the key is not removed from the control console.

(3) At an underwater irradiator, an irradiator operator must [~~shall~~] be present at the facility whenever the product is moved into or out of the pool. Individuals who move the product into or out of the pool of an underwater irradiator need not be qualified as irradiator operators; however, they must [~~shall~~] have received the training described in subsection (s)(6) and (7) of this section. Static irradiations may be performed without a person present at the facility.

(aa) Entering and leaving the radiation room.

(1) Upon first entering the radiation room of a panoramic irradiator after an irradiation, the irradiator operator must [~~shall~~] use a survey meter to determine [~~that~~] the source has returned to its fully shielded position. The operator must [~~shall~~] check the functioning of the survey meter with a radiation check source before [~~prior to~~] entry.

(2) Before exiting from and locking the door to the radiation room of a panoramic irradiator before [~~prior to~~] a planned irradiation, the irradiator operator must [~~shall do the following~~]:

(A) visually inspect the entire radiation room to verify [~~that~~] no one else is in it; and

(B) activate a control in the radiation room permitting [~~that permits~~] the sources to be moved from the shielded position only if the door to the radiation room is locked within a preset time after setting the control.

(3) During a power failure, the area around the pool of an underwater irradiator must [~~may~~] not be entered without using an operable and calibrated radiation survey meter unless the over-the-pool monitor required by subsection (l)(2) of this section is operating with backup power.

(bb) Irradiation of explosive or flammable materials.

(1) Irradiation of explosive material is prohibited unless the licensee has received prior written authorization from the department [agency]. Authorization is [will] not [be] granted unless the licensee can demonstrate [that] detonation of the explosive would not rupture the sealed sources, injure personnel, damage safety systems, or cause radiation overexposures of personnel.

(2) Irradiation of more than small quantities of flammable material (flash point below 140 degrees Fahrenheit) is prohibited in panoramic irradiators unless the licensee receives [has received] prior written authorization from the department [agency]. Authorization is [will] not [be] granted unless the licensee can demonstrate [that] a fire in the radiation room could be controlled without damage to sealed sources or safety systems and without radiation overexposures of personnel.

(cc) Records/documents. The licensee must [shall] maintain [the following] records/documents at the irradiator for the time intervals indicated for inspection by the department, including [agency]:

(1) a copy of the license, license conditions, documents incorporated into a license by reference, and amendments to the license until superseded by new documents or until the department [agency] terminates the license;

(2) records of each individual's training, tests, and safety reviews provided meeting [to meet] the requirements of subsection (s)(1) - (4), (6), and (7) of this section until three years after the individual terminates work;

(3) records of the annual evaluations of the safety performance of irradiator operators required by subsection (s)(5) of this section for three years after the evaluation;

(4) a copy of the current operating, safety, and emergency procedures required by subsection (t) of this section until superseded or the department [agency] terminates the license. Records of the RSO review and approval of changes in procedures as required by subsection (t)(3)(C) of this section, retained for three years from the date of the change;

(5) individual monitoring device [film badge, TLD, or OSL] results required by subsection (u) of this section until the department [agency] terminates the license;

(6) records of radiation surveys required by subsection (v) of this section for three years from the date of the survey;

(7) records of radiation survey meter calibrations required by subsection (v) of this section and pool water conductivity meter calibrations required by subsection (y)(2) of this section until three years from the date of calibration;

(8) records of the results of leak tests required by subsection (w)(1) of this section and the results of contamination checks required by subsection (w)(2) of this section for three years from the date of each test;

(9) records of inspection and maintenance checks required by subsection (x) of this section for three years;

(10) records of major malfunctions, significant defects, operating difficulties or irregularities, and major operating problems involving [that involve] required radiation safety equipment for three years after repairs are completed;

(11) records of the receipt, transfer, and disposal[;] of all licensed sealed sources as required by §289.201(d) and §289.252(x) and (cc) of this chapter [title];

(12) records on the design checks required by subsection (q) of this section and the construction control checks [as] required by subsection (r) of this section until the license is terminated. The records must [shall] be signed and dated. The title or qualification of the person signing must [shall] be included; and

(13) records related to decommissioning of the irradiator [as] required by §289.252(gg)(7) of this subchapter [title].

(dd) Reports.

(1) In addition to the reporting requirements in other sections of this chapter [title], the licensee must [shall] report the following events if not reported as specified in [accordance with] other sections of this chapter [title]:

(A) source stuck in an unshielded position;

(B) any fire or explosion in a radiation room;

(C) damage to the source racks;

(D) failure of the cable or drive mechanism used to move the source racks;

(E) inoperability of the access control system;

(F) detection of radiation source by the product exit monitor;

(G) detection of radioactive contamination attributable to licensed radioactive material;

(H) structural damage to the pool liner or walls;

(I) abnormal water loss or leakage from the source storage pool; and

(J) pool water conductivity greater than [exceeding] 100 microsiemens per centimeter during normal operations.

(2) The report must [shall] include a telephone report within 24 hours as described in §289.202(xx)(8)(A) of this chapter [title], and a written report within 30 days as described in §289.202(xx)(8)(B) of this chapter [title].

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on May 29, 2024.

TRD-202402374
Cynthia Hernandez
General Counsel
Department of State Health Services
Earliest possible date of adoption: July 14, 2024
For further information, please call: (512) 834-6655

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SUBCHAPTER E. REGISTRATION REGULATIONS

25 TAC §289.229

The Executive Commissioner of the Texas Health and Human Services Commission (HHSC), on behalf of the Department of State Health Services (DSHS), proposes an amendment to §289.229, concerning Radiation Safety Requirements for Accelerators, Therapeutic Radiation Machines, Simulators, and Electronic Brachytherapy Devices.

BACKGROUND AND PURPOSE

The proposal updates regulations concerning accelerator facilities and operations. These changes address concerns that have developed in the field, requiring a comprehensive update to ensure the safety, quality, and effectiveness of accelerator-based facilities.

Language was added to hold an individual using an accelerator to the requirements in §289.229, even if they are not registered. Veterinary requirements have been removed from this rule and incorporated into §289.233, concerning Radiation Control Regulations for Radiation Machines Used in Veterinary Medicine, which is dedicated to veterinary-specific facilities.

Equipment Performance Evaluation (EPE) requirements have been introduced for Computed Tomography (CT) units used in simulation. This addition enhances safety and promotes the principle of ALARA (as low as reasonably achievable). Since most CT units used for simulation also serve diagnostic imaging purposes, the annual EPE requirement is not considered an excessive regulatory burden.

Safety interlock requirements have been included for add-on equipment. This measure ensures the addition of equipment into accelerator systems, after installation, meets specified safety standards protecting both patients and operators.

The rule has been reorganized with Electronic Brachytherapy (EBT) requirements relocated from the end of the rule to the general requirements section. This reorganization makes the rule more accessible and coherent.

SECTION-BY-SECTION SUMMARY

The proposed amendment revises the title of the rule to "Radiation Safety Requirements for Accelerators, Therapeutic Radiation Machines, Radiation Therapy Simulation Systems, and Electronic Brachytherapy Devices."

Throughout the rule, language has been added to require equipment testing protocols to meet or exceed nationally recognized, published guidelines from a professional body with expertise in the use of therapeutic radiation technologies or manufacturer recommendations.

Edits are made to replace "agency" with "department," "title" with "chapter," and "shall" with "must." Edits are made to improve grammar and clarity, update references, and clarify device names throughout the rule. Formatting edits are made to update numbering.

The proposed amendment to §289.229(a) establishes the purpose for the requirements for the use of accelerators, therapeutic radiation machines, radiation therapy simulation systems, and electronic brachytherapy devices. It includes provisions for registering individuals using radiation machines in healing arts, controls on the receipt and use of radiation machines to ensure radiation dose standards are not exceeded, and specific record keeping obligations.

The proposed amendment to §289.229(b) removes the veterinary accelerator operations from §289.229. New paragraph (4) is added to provide that registrants engaged in veterinary accelerator operations are subject to §289.233, concerning Radiation Control Regulations for Radiation Machines Used in Veterinary Medicine. The requirements were added to §289.233 in April 2021. Edits are also made to improve grammar, update references, clarify device names, and replace "title" with "chapter." Formatting edits are made to update numbering.

The proposed amendment to §289.229(c)(4) prohibits remote operation of any radiation machine.

The proposed amendment to §289.229(d) removes language exempting veterinary accelerator operations from aural communication requirements. The exemption for a sole physician, sole operator, and the only occupationally exposed person was relocated from current subsection (d)(2) and incorporated into subsection (d).

The proposed amendment to §289.229(e) adds definitions for "accelerator beam quality," "conventional radiation therapy simulator," "CT radiation therapy simulator," "image-guided radiation therapy (IGRT)," "intensity-modulated radiation therapy (IMRT)," "irradiation filter," "dynamic or virtual wedge," "multileaf collimator (MLC) wedge filter," "physical wedge filter," "stereotactic radiosurgery (SRS) filter," "quality assurance (QA) check," "radiation machine," "radiation treatment head," "virtual simulation," and "wedge transmission factor." The proposal amends the terms "absorbed dose," "absorbed dose rate," "air kerma," "barrier," "beam-flattening filter," "beam-limiting device," "beam quality," "continuous pressure type switch," "control panel," "CT conditions of operation," "electronic brachytherapy," "electronic brachytherapy device," "field size," "focal spot," "gantry," "gray (Gy)," "half-value layer (HVL)," "healing arts," "image receptor," "Institutional Review Board (IRB)," "kilovolt (kV) (kiloelectron volt (keV))," "kilovolt peak (KVp)," "leakage radiation," "leakage technique factors," "licensed medical physicist," "medical event," "megavolt (MV) (megaelectron volt (MeV))," "mobile electronic brachytherapy device," "moving beam radiation therapy," "nominal treatment distance," "peak tube potential," "physician," "portable shielding," "prescribed dose," "primary dose monitoring system," "protective apron," "protective barrier," "protective glove," "radiation detector," "radiation field," "radiation therapy simulation system simulator," "radiation therapy system," "scan," "scan sequence," "scan time," "scattered radiation," "secondary dose monitoring system," "shutter," "target," "termination of irradiation," "therapeutic radiation machine," "traceable to a national standard," "tube housing assembly," and "useful beam." The proposal deletes the definitions of "beam quality (accelerator)," "beam scattering foil," "detector," "electronic brachytherapy source," "filter," "mA," "primary protective barrier," "radiation head," "radiation oncologist," "secondary protective barrier," "spot check," "veterinarian," and "wedge filter." The proposal deletes and replaces the definition of "dosimetry system" and "supervision." Formatting edits are made to update numbering.

Figure 25 TAC §289.229(e)(14) is amended to update the reference.

The proposed amendment to §289.229(f) updates the lead-in phrase to "Accelerators used for research and development or industrial operations." Paragraph (2)(C)(ii) adds language requiring surveys to be completed upon installation, replacement, or upgrade to a higher energy accelerator. Subsection (f)(3)(A) is amended to add requirements to interlock systems which require inherent, add-on, and aftermarket devices that attach to the accelerator to meet the current interlock requirements for accelerators. Paragraph (3)(B) is amended to add language requiring a registrant to develop, implement, and maintain written operating and safety procedures as specified in subsection (h)(1)(G) of the section. Language regarding operating and safety procedures are removed from paragraph (f)(3)(B) and relocated to subsection (h)(1)(G) to reduce redundancy.

The proposed amendment to §289.229(g) makes edits to improve grammar, updates references, and replaces "chapter" with "title."

The proposed amendment to §289.229(h) revises the lead-in phrase to "Requirements for therapeutic radiation machines, radiation therapy simulation systems used in the healing arts, and EBT devices." Subsection (h)(1)(B) clarifies that any individual possessing a radiation therapy simulation system or a therapeutic radiation machine capable of operating below 1 MeV must apply for a certificate of registration within 30 days after energizing the equipment.

The proposed amendment to §289.229(h)(1)(G)(xiv)-(xvi) adds procedures to the written operating and safety requirements. Procedures include methods utilized for testing interlocks, entrance controls, alarm systems, posting notices to workers, notifications and reports to individuals, and record retention requirements.

Figure: 25 TAC §289.229(h)(2)(A)(i) is amended to meet current standards for leakage technique factors measured at 5 centimeters and 1 meter.

The proposed amendment to §289.229(h)(3)(A)(i) is rewritten and separated into subclauses to help with readability. Clause (ii) is rewritten and adds equipment requirements for dynamic or virtual wedge, MLC, SRS, and physical wedge filters.

New subsection (h)(4) relocates EBT requirements from the end of the rule. This change is needed to improve the flow of the rule.

New subsection (h)(5)(B) adds facility design requirements for radiation therapy simulation systems. The addition of viewing system requirements is needed to ensure the patient is always monitored.

New subsection (h)(5)(C) adds equipment requirements for radiation therapy systems utilizing standard CT systems. These requirements are needed to protect the patient and radiation worker from overexposure.

Figure: 25 TAC §289.229(h)(4)(B)(i) is amended to update a reference and "kVp" is added to the "designed operating range" column.

Figure: 25 TAC §289.229(h)(4)(B)(viii) is amended to update the reference and new language is added to improve clarity.

The proposed amendment to §289.229(i) updates the lead-in phrase to "Medical events" and abbreviates "electronic brachytherapy." The words "shall" and "%" are replaced with "must" and "percent," respectively and the number 3 is spelled out.

The proposed amendment to §289.229(j) updates the lead-in phrase to "Reports of medical events," and replaces "agency" with "department" and "shall" with "must." Other edits are made to improve grammar and correct spelling and punctuation.

Current subsection §289.229(k) is deleted and the contents of the subsection are moved to subsection (h)(4). New subsection (k) is added to describe provisions for emerging and future technologies. These provisions require the registrant to develop, implement, and maintain a dedicated quality management program to control the process of administering therapeutic radiation with newly acquired United States Food and Drug Administration-cleared emerging technologies or previously unused features of a future technology system.

The proposed amendment to §289.229(l) updates the lead-in phrase and replaces "agency" and "shall" with "department" and "must," respectively.

Figure 25 TAC §289.229(l) is updated to reflect formatting changes and updates from reorganization of the rule.

FISCAL NOTE

Christy Havel Burton, DSHS Chief Financial Officer, has determined for each year of the first five years the rule will be in effect, enforcing or administering the rule does not have foreseeable implications relating to costs or revenues of state or local governments.

GOVERNMENT GROWTH IMPACT STATEMENT

DSHS has determined that during the first five years that the rule will be in effect:

(1) the proposed rule will not create or eliminate a government program;

(2) implementation of the proposed rule will not affect the number of DSHS employee positions;

(3) implementation of the proposed rule will result in no assumed change in future legislative appropriations;

(4) the proposed rule will not affect fees paid to DSHS;

(5) the proposed rule will not create a new regulation;

(6) the proposed rule will not expand, limit, or repeal an existing regulation;

(7) the proposed rule will not change the number of individuals subject to the rule; and

(8) the proposed rule will not affect the state's economy.

SMALL BUSINESS, MICRO-BUSINESS, AND RURAL COMMUNITY IMPACT ANALYSIS

Christy Havel Burton, Chief Financial Officer, has also determined that there will be no adverse economic effect on small businesses, micro-businesses, or rural communities.

The rule does not impose any additional costs on small businesses, micro-businesses, or rural communities that are required to comply with the rules.

LOCAL EMPLOYMENT IMPACT

The proposed rule will not affect the local economy.

COSTS TO REGULATED PERSONS

Texas Government Code §2001.0045 does not apply to this rule because the rule is necessary to protect the health, safety, and welfare of the residents of Texas.

PUBLIC BENEFIT AND COSTS

Dr. Timothy Stevenson, Associate Commissioner, Consumer Protection Division, has determined for each year of the first five years the rule is in effect, the public will benefit from the adoption of the rule. The public benefit anticipated as the result of enforcing or administering the rule is to ensure continued enhanced protection of the public, patients, workers, and the environment from unnecessary exposure to radiation.

Christy Havel Burton, Chief Financial Officer, has also determined for the first five years the rule is in effect, there are no anticipated economic costs to persons who are required to comply with the proposed rule because most edits to the rule language

are procedural updates, edits for clarity, and do not impose additional requirements to the registrant.

TAKINGS IMPACT ASSESSMENT

DSHS has determined that the proposal does not restrict or limit an owner's right to their property that would otherwise exist in the absence of government action and, therefore, does not constitute a taking under Texas Government Code §2007.043.

PUBLIC COMMENT

Written comments on the proposal may be submitted to Radiation Section, Consumer Protection Division, DSHS, Mail Code 1987, P.O. Box 149347, Austin, Texas 78714-9347, or street address 1100 West 49th Street, Austin, Texas 78756; fax (512) 206-3793, or by email to CPDRuleComments@dshs.texas.gov.

To be considered, comments must be submitted no later than 31 days after the date of this issue of the *Texas Register.* Comments must be (1) postmarked or shipped before the last day of the comment period, (2) hand-delivered before 5:00 p.m. on the last working day of the comment period; or (3) faxed or emailed before midnight on the last day of the comment period. If the last day to submit comments falls on a holiday, comments must be postmarked, shipped, or emailed before midnight on the following business day to be accepted. When faxing or emailing comments, please indicate "Comments on Proposed Rule 23R013" in the subject line.

STATUTORY AUTHORITY

The amendment is authorized by Texas Health and Safety Code Chapter 401 (the Texas Radiation Control Act), which provides for DSHS radiation control rules and regulatory program to be compatible with federal standards and regulations; §401.051, which provides the required authority to adopt rules and guidelines relating to the control of sources of radiation; §401.064, which provides for the authority to adopt rules related to inspection of x-ray equipment; §401.101, providing for DSHS registration of facilities possessing sources of radiation; Chapter 401, Subchapter J, which authorizes enforcement of the Act; and Texas Government Code §531.0055 and Texas Health and Safety Code §1001.075, which authorize the Executive Commissioner of HHSC to adopt rules and policies for the operation and provision of health and human services by DSHS and the administration of Texas Health and Safety Code Chapter 1001.

The amendment will implement Texas Health and Safety Code Chapters 401 and 1001; and Texas Government Code Chapter 531.

§289.229. Radiation Safety Requirements for Accelerators, Therapeutic Radiation Machines, Radiation Therapy Simulation Systems [~~Simulators~~], and Electronic Brachytherapy Devices.

(a) Purpose. This section establishes the following requirements for using accelerators, therapeutic radiation machines, radiation therapy simulation systems, and electronic brachytherapy (EBT) devices.

(1) Requirements for the registration of a person using radiation machines used in healing arts.

(A) A person must not use radiation machines except as authorized in a certificate of registration issued by the Department of State Health Services (department) as specified in the requirements of this section.

(B) A person who receives, possesses, uses, owns, or acquires radiation machines before receiving a certificate of registration is subject to the requirements of this chapter.

(2) Requirements are intended to control receipt, possession, use, and transfer of radiation machines by any person so the total radiation dose to an individual, excluding background radiation, does not exceed the standards for protection against radiation prescribed in this section. This section does not limit actions necessary to protect public health and safety during an emergency.

(3) Requirements for specific record keeping and general provisions of records and reports.

[~~(a) Purpose. This section establishes radiation safety requirements for the use of accelerators, therapeutic radiation machines, radiation therapy simulation systems (simulators), and electronic brachytherapy devices. No person shall possess, use, transfer, or acquire an accelerator, a therapeutic radiation machine, a radiation therapy simulation system (simulator), or electronic brachytherapy device, except as authorized in a certificate of registration issued in accordance with §289.226 of this title (relating to Registration of Radiation Machine Use and Services) or as otherwise provided for in this chapter.~~]

(b) Scope.

(1) This section applies to a person who receives, possesses, uses, acquires, or transfers an accelerator [~~persons who receive, possess, use or transfer accelerators~~] used in industrial operations and research and development, [~~and~~] therapeutic radiation machines, radiation therapy simulation systems [~~(simulators)~~], and EBT [~~electronic brachytherapy~~] devices used in the healing arts. [~~and veterinary medicine. Use of therapeutic radiation machines in the healing arts or veterinary medicine under this section shall be by or under the supervision of a physician of the healing arts or a veterinarian. Use of electronic brachytherapy devices under this section shall be by or under the supervision of a certified physician.~~] The registrant is [~~shall be~~] responsible for the administrative control and for directing the use of the accelerators, other therapeutic radiation machines, radiation therapy simulation systems, and EBT [~~simulators, or electronic brachytherapy~~] devices.

(2) The requirements of this section are in addition to and not in substitution for other applicable requirements of:

(A) §289.203 of this chapter [~~title~~] (relating to Notices, Instructions, and Reports to Workers; Inspections);[~~,~~]

(B) §289.204 of this chapter [~~title~~] (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services);[~~,~~]

(C) §289.205 of this chapter [~~title~~] (relating to Hearing and Enforcement Procedures);[~~,~~]

(D) §289.226 of this chapter [~~title~~] (relating to Registration of Radiation Machine Use and Services);[~~, and~~]

(E) §289.227 of this chapter (relating to Use of Radiation Machines in the Healing Arts); and

(F) §289.231 of this chapter [~~title~~] (relating to General Provisions and Standards for Protection Against Machine-Produced Radiation).

(3) Registrants engaged in industrial radiographic operations are subject to the requirements of §289.255 of this chapter [~~title~~] (relating to Radiation Safety Requirements and Licensing and Registration Procedures for Industrial Radiography).

(4) Registrants engaged in veterinary accelerator operations are subject to the requirements of §289.233 of this chapter (relating to Radiation Control Regulations for Radiation Machines Used in Veterinary Medicine).

(5) [~~(4)~~] An entity, [~~that is a "covered entity" as that term is~~] defined in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) as a "covered entity" under [~~HIPAA, (the Health Insurance Portability and Accountability Act of 1996,~~] 45 Code of Federal Regulations (CFR)[~~,~~] Parts 160 and 164[~~)~~] may be subject to privacy standards governing how information identifying [~~that identifies~~] a patient can be used and disclosed. Failure to follow HIPAA requirements may result in the department referring [~~making a referral of~~] a potential violation to the United States Department of Health and Human Services.

(c) Prohibitions.

(1) The department prohibits the [~~agency may prohibit~~] use of accelerators, therapeutic radiation machines, radiation therapy simulation systems [~~simulators~~], or EBT [~~electronic brachytherapy~~] devices posing a [~~that pose~~] significant threat or danger to [~~endanger~~] occupational and public health and safety, as specified in [~~accordance with~~] §289.205 [~~of this title~~] and §289.231 of this chapter [~~title~~].

(2) An individual must [~~Individuals shall~~] not be exposed to the useful beam of accelerators, therapeutic radiation machines, radiation therapy simulation systems, or EBT devices except for healing arts purposes and unless a physician of the healing arts has authorized such exposure. [~~such exposure has been authorized by a physician of the healing arts. For electronic brachytherapy devices, individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a certified physician.~~] This provision specifically prohibits the deliberate exposure of an individual for training, demonstration, or other non-healing arts purposes.

(3) Research and development [~~No research and/or development~~] using radiation machines on humans is prohibited [~~shall be conducted~~] unless approved by an Institutional Review Board (IRB) as required by [~~Title~~] 45 [~~45,~~] CFR Part 46 and [~~Title~~] 21 [~~21,~~] CFR Part 56. The IRB must [~~shall~~] include at least one physician of the healing arts to direct any use of radiation as specified in [~~accordance with~~] §289.231(b) of this chapter [~~title~~].

(4) Remote operation of radiation machines is prohibited.

(d) Exemptions. A person who is a sole physician, sole operator, and the only occupationally exposed person is exempt from the following requirements:

(1) §289.203(b) and (c) of this chapter; and

(2) subsection (h)(1)(G) of this section.

[~~(1) Veterinary facilities are exempt from the aural communication requirements for radiation therapy systems and radiation therapy simulators in subsection (h)(2)(B)(i), (h)(3)(B)(v), or (h)(4)(A)(iv) of this section.~~]

[~~(2) Individuals who are sole physicians, sole operators and the only occupationally exposed individual are exempt from the following requirements:~~]

[~~(A) §289.203(b) and (c) of this title; and~~]

[~~(B) subsection (h)(1)(G) of this section.~~]

(e) Definitions. When used in this section, the following words and terms [~~The following words and terms when used in this section shall~~] have the following meaning unless the context [~~clearly~~] indicates otherwise.

(1) Absorbed dose (D)--The mean energy imparted by ionizing radiation to matter. Absorbed dose is determined as the quotient of dE by dM, where dE is the mean energy imparted by ionizing radiation to the [~~matter of~~] mass dM. The System International (SI) [~~SI~~] unit of absorbed dose is joule per kilogram and the special name of the unit of absorbed dose is [~~the~~] gray (Gy). The previously used special unit of absorbed dose (rad) is [~~being~~] replaced by [~~the~~] gray.

(2) Absorbed dose rate--Absorbed dose per unit time[~~,~~] for machines with timers, or dose monitor unit per unit time for linear accelerators.

(3) Accelerator beam quality--The type and penetrating power of the ionizing radiation produced for certain machine settings.

(4) [~~(3)~~] Air kerma--The kinetic energy released in air by ionizing radiation. Kerma is the quotient of dE by dM, where dE is the sum of the initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles in air of mass dM. The SI unit of air kerma is joule per kilogram and the special name for the unit of kerma is Gy [~~the gray (Gy)~~].

(5) [~~(4)~~] Barrier--See [~~(See~~] definition for protective barrier[~~barrier)~~].

(6) [~~(5)~~] Beam axis--The axis of rotation of the beam limiting device.

(7) [~~(6)~~] Beam-flattening filter--See definition for [~~(See~~] field-flattening filter [~~filter)~~].

(8) [~~(7)~~] Beam-limiting device--A field-defining [~~field defining~~] collimator, integral to the therapeutic radiation machine, which provides a means to restrict the dimensions of the useful beam.

(9) [~~(8)~~] Beam monitoring system--A system designed and installed in the radiation head to detect and measure the radiation present in the useful beam.

(10) [~~(9)~~] Beam quality--The [~~A term that describes the~~] penetrating power of the x-ray beam[~~. This is~~] identified numerically by the half-value layer and [~~is~~] influenced by kilovolt peak (kVp) and filtration.

[~~(10) Beam quality (accelerator)--A term that describes the type and penetrating power of the ionizing radiation produced for certain machine settings.~~]

[~~(11) Beam scattering foil--A thin piece of material (usually metallic) placed in the beam to scatter a beam of electrons in order to provide a more uniform electron distribution in the useful beam.~~]

(11) [~~(12)~~] Central axis of the beam--An imaginary line passing through the center of the useful beam and the center of the plane figure formed by the edge of the first beam-limiting device.

(12) [~~13~~] Certified physician--A physician licensed by the Texas Medical Board and certified in radiation oncology or therapeutic radiology.

(13) [~~(14)~~] Coefficient of variation or C--The ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:
Figure: 25 TAC §289.229(e)(13)
[~~Figure: 25 TAC §289.229(e)(14)~~]

(14) [~~(15)~~] Collimator--A device or mechanism by which the x-ray beam is restricted in size.

(15) [~~(16)~~] Computed tomography (CT)--The production of a tomogram by the acquisition and computer processing of x-ray transmission data.

(16) [~~(17)~~] Continuous pressure type switch--A switch that can only power a device when the operator maintains [~~so constructed that a circuit closing contact can be maintained only by~~] continuous pressure on the switch [~~by the operator~~].

(17) [~~(18)~~] Control panel--The part of the radiation machine where the switches, knobs, push buttons, and other hardware necessary for manually setting the technique factors are located. For purposes of this section, console is an equivalent term.

(18) Conventional radiation therapy simulator--A radiation machine with radiographic or fluoroscopic capabilities uniquely designed for the direct purpose of simulating radiation therapy treatment ports.

(19) CT conditions of operation--All selectable parameters governing the operation of a CT x-ray system, including[~~, but not limited to,~~] nominal tomographic section thickness, filtration, and the technique factors as defined in this subsection.

(20) CT radiation therapy simulator--CTs that interface with radiation therapy linear accelerators.

[~~(20) Detector--(See definition for radiation detector).~~]

(21) [~~(21)~~] Diaphragm--A device or mechanism by which the x-ray beam is restricted in size.

(22) Dose monitor unit (DMU)--A unit response from the beam monitoring system from which the absorbed dose can be calculated.

(23) Dosimetry system--An ion chamber used as a dosimeter for measurement of clinical photon and electron beams with calibration coefficients determined either in air or in water and traceable to a national primary standards dosimetry laboratory.

[~~(23) Dosimetry system--A system of devices used for the detection, measurement, and display of qualitative and quantitative radiation exposures.~~]

(24) Electronic brachytherapy--A method of radiation therapy using electrically generated x-rays to deliver a radiation dose at a distance of up to a few centimeters by intracavitary, intraluminal, or interstitial application, or by applications with the source in contact with the body surface or very close to the body surface.

(25) Electronic brachytherapy (EBT) device--The system used to produce and deliver therapeutic radiation, including the x-ray tube, the control mechanism, the cooling system, and the power source.

[~~(26) Electronic brachytherapy source--The x-ray tube component used in an electronic brachytherapy device.~~]

(26) [~~(27)~~] External beam radiation therapy--Therapeutic irradiation in which the source of radiation is at a distance from the body.

(27) [~~(28)~~] Field-flattening filter--A filter used to homogenize the absorbed dose rate over the radiation field.

(28) [~~(29)~~] Field size--The dimensions along the major axes of an area in a plane perpendicular to the central axis of the beam at the nominal [~~normal~~] treatment or examination source-to-image [~~source to image~~] distance and defined by the intersection of the major axes and the 50 percent [~~50%~~] isodose line.

[~~(30) Filter--Material placed in the useful beam to change beam quality in therapeutic radiation machines subject to subsection (h) of this section.~~]

(29) [~~(31)~~] Focal spot--The area projected on the anode of the x-ray tube [~~that is~~] bombarded by the electrons accelerated from the cathode and from which the useful beam originates.

(30) [~~(32)~~] Gantry--The [~~That~~] part of the radiation therapy system that supports and allows [~~supporting and allowing~~] possible movements of the radiation head about the center of rotation.

(31) [~~(33)~~] Gray (Gy)--The [~~For purposes of this section, the~~] SI unit of absorbed dose, kerma, and specific energy imparted equal to 1 joule per kilogram. The [~~For purposes of this section the~~] previous unit of absorbed dose (rad) is [~~being~~] replaced by the gray (1 Gy = 100 rad).

(32) [~~(34)~~] Half-value layer (HVL)--The thickness of a specified material that attenuates [~~which attenuates~~] x-radiation or gamma radiation to the [~~an~~] extent [~~such that~~] the exposure rate (air kerma rate)[~~,~~] or absorbed dose rate is reduced to one-half of the value measured without the material at the same point.

(33) [~~(35)~~] Healing arts--Any treatment, operation, diagnosis, prescription, [~~or practice for the ascertainment,~~] cure, relief, palliation, adjustment, or correction of any human disease, ailment, deformity, injury, or unhealthy or abnormal physical or mental condition.

(34) [~~(36)~~] Image receptor--Any device that transforms[~~, such as a fluorescent screen or radiographic film, that transforms~~] incident x-ray photons either into a visible image or into another form [~~that can be~~] made into a visible image by further transformations.

(35) [~~(37)~~] Institutional Review Board (IRB)--Any board, committee, or other group formally designated by an institution to review, approve the initiation of, and conduct a periodic review of biomedical research involving human subjects.

(36) Image-Guided Radiation Therapy (IGRT)--Radiation therapy employing advanced imaging to maximize accuracy and precision throughout the entire process of treatment delivery with the goal of optimizing the accuracy and reliability of radiation therapy to the target while minimizing dose to normal tissues.

(37) Intensity-Modulated Radiation Therapy (IMRT)--A technology for delivering highly conformal external beam radiation to a well-defined treatment volume with radiation beams whose intensity varies across the beam.

(38) Interlock--A device preventing the start or continued operation of equipment unless certain predetermined conditions prevail.

(39) Interruption of irradiation--The stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

(40) Irradiation--The exposure of a living being or matter to ionizing radiation.

(41) Irradiation filter (filter)--Radiation absorbers or beam-modifying devices placed in the useful high-energy beam to shape the beam and optimize the target volume dose distribution in therapeutic radiation machines subject to subsection (h) of this section. Irradiation filter types are defined as follows.

(A) Dynamic or virtual wedge--A wedge produced by computer-controlled movement of one or more collimator jaws. The wedge generates a spatial dose distribution similar to a physical wedge. The wedge-shaped graduated attenuation across the radiation beam can produce symmetric or asymmetric radiation fields.

(B) Multileaf collimator (MLC) wedge filter--A beam-limiting device made of individual "leaves" of a high atomic numbered

material, usually tungsten, that can move independently in and out of the path of a radiotherapy beam to shape and vary its intensity.

(C) Physical wedge filter--Physical wedges are made of metallic material and are manually placed in the useful radiation beam. The wedges are shaped in such a way as to produce graduated attenuation across the radiation field.

(D) Stereotactic radiosurgery (SRS) filter--A precise form of target localization delivering radiation through narrow circular cones or circular collimator tubes with lenses or computer leaf-driven systems enabling more precise beam filtering or shaping for complex radiation fields.

(42) [~~(41)~~] Isocenter--The center of the sphere through which the useful beam axis passes while the gantry moves through its full range of motions.

(43) [~~(42)~~] Kilovolt (kV) (kilo electron volt (keV))--The energy given to [~~equal to that acquired by~~] a particle with one electron charge when [~~in~~] passing through a potential difference of one thousand volts in a vacuum. (Note: current convention is to use kV for photons and keV for electrons.)

(44) [~~(43)~~] Kilovolt peak (kVp)--See[~~kVp (See~~] definition for peak tube potential[~~potential)~~].

(45) [~~(44)~~] Lead equivalent--The thickness of lead affording the same attenuation, under specified conditions, as the material in question.

(46) [~~(45)~~] Leakage radiation--Radiation emanating from the source [~~source(s)~~] assembly except for the useful beam and radiation produced when the exposure switch or timer is not activated.

(47) [~~(46)~~] Leakage technique factors--The technique factors associated with the source assembly [~~that is~~] used when [~~in~~] measuring leakage radiation.

(48) [~~(47)~~] Licensed medical physicist--A person [~~An individual~~] holding a current Texas license under the Medical Physics Practice Act, Texas Occupations Code Chapter 602[~~, with a specialty in therapeutic radiological physics~~].

(49) [~~(48)~~] Light field--The area illuminated by light, simulating the radiation field.

~~[(49)] mA--Milliampere.]~~

(50) Medical event--An event meeting [~~that meets~~] the criteria specified in subsection (i) of this section.

(51) Megavolt (MV) (megaelectron volt (MeV))--The energy given to [~~equal to that acquired by~~] a particle with one electron charge when [~~in~~] passing through a potential difference of one million volts in a vacuum.

(52) Mobile EBT [~~electronic brachytherapy~~] device--An EBT [~~electronic brachytherapy~~] device [~~that is~~] transported from one address to be used at another address.

(53) Moving beam radiation therapy--Radiation therapy with any planned displacement of radiation field or patient relative to each other, or with any planned change of absorbed dose distribution. It includes arc, skip, conformal, intensity modulation, and rotational therapy.

(54) Nominal treatment distance--The following nominal treatment distances [~~shall~~] apply.

(A) For electron irradiation, the distance from the scattering foil, virtual source, or exit window of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam, as specified by the manufacturer.

(B) For x-ray irradiation, the virtual source or target to isocenter distance along the central axis of the useful beam to the isocenter. For non-isocentric equipment, this distance is [~~shall be that~~] specified by the manufacturer.

(55) Output--The exposure rate (air kerma rate), dose rate, or a quantity related to these rates from a therapeutic radiation machine.

(56) Peak tube potential--The maximum value of the potential difference in kilovolts across the x-ray tube during [~~an~~] exposure.

(57) Phantom--An object behaving in essentially the same manner as tissue, with respect to absorption or scattering of the ionizing radiation in question.

(58) Physician--A person [~~An individual~~] licensed by the Texas Medical Board to practice medicine under Texas Occupations Code Chapter 155.

(59) Port film--An x-ray exposure made with a radiation therapy system to visualize a patient's treatment area using radiographic film.

(60) Portable shielding--Moveable shielding [~~that can be~~] placed in the primary or secondary beam to reduce [~~the~~] radiation exposure to the patient, occupational worker, or a member of the public. The shielding can be easily moved to position using [~~with use of~~] mobility devices or by hand.

(61) Prescribed dose--The total dose and dose per fraction as documented in the written directive. The prescribed dose is an estimation from measured data from a specified therapeutic machine using clinically acceptable and historically consistent assumptions [~~that are clinically acceptable~~] for the treatment technique and calculations [~~and historically consistent with the clinical calculations~~] previously used for patients treated with the same clinical technique.

(62) Primary dose monitoring system--A system monitoring [~~that will monitor~~] the useful beam during irradiation and terminating [~~that will terminate~~] irradiation when a preselected number of [~~dose~~] monitor units are [~~have been~~] delivered.

~~[(63) Primary protective barrier--(See definition for protective barrier).~~

(63) [~~(64)~~] Protective apron--An apron made of radiation-absorbing [~~radiation absorbing~~] materials used to reduce radiation exposure.

(64) [~~(65)~~] Protective barrier--A barrier of radiation-absorbing [~~radiation absorbing~~] materials used to reduce radiation exposure. The types of protective barriers are as follows.[~~:~~]

(A) Primary [~~primary~~] protective barrier.[~~--~~] A barrier sufficient to attenuate the useful beam to the required degree.

(B) Secondary [~~secondary~~] protective barrier.[~~--~~] A barrier sufficient to attenuate the scatter [~~stray~~] radiation to the required degree.

(65) [~~(66)~~]Protective glove--A glove made of radiation-absorbing [~~radiation absorbing~~] materials used to reduce radiation exposure.

(66) Quality assurance (QA) check--A test or analysis performed at a specified interval to verify the consistent output of radiation equipment.

(67) Radiation detector--A device providing, [~~which, in the presence of radiation provides,~~] by either direct or indirect means, a signal or other indication suitable for use in measuring one [~~1~~] or more quantities of incident radiation.

(68) Radiation field--See[~~(See~~] definition for useful beam [~~beam)~~].

[~~(69) Radiation head--The structure from which the useful beam emerges.~~]

(69) Radiation machine--Any device capable of producing ionizing radiation except those devices with radioactive material as the only source of radiation.

[~~(70) Radiation oncologist--A physician with a specialty in radiation therapy].~~

(70) [~~(71)~~] Radiation therapy simulation system [~~(simulator)~~]--An x-ray system intended for localizing and confirming the volume to be irradiated during radiation treatment and confirming the position and size of the therapeutic irradiation field.

(71) [~~(72)~~] Radiation therapy system--A [~~An x-ray~~] system utilizing machine-produced, [~~that utilizes~~] prescribed doses of ionizing radiation for treatment.

(72) Radiation treatment head--The structure from which the useful beam emerges.

(73) Scan--The complete process of collecting x-ray transmission data to produce one or more tomograms. [~~for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.~~]

(74) Scan increment--The amount of relative displacement of the patient with respect to the CT x-ray system between successive scans measured along the direction of such displacement.

(75) Scan sequence--A preselected set of two [~~2~~] or more scans performed consecutively under preselected CT conditions of operation.

(76) Scan time--The period [~~of time~~] between the beginning and end of x-ray transmission data accumulation for a single scan.

(77) Scattered radiation--Secondary radiation occurring when the beam intercepts an object causing the x-rays to be scattered. [~~Radiation that has been deviated in direction during passage through matter.~~]

(78) Secondary dose monitoring system--A system terminating [~~which will terminate~~] irradiation in the event of failure of the primary dose monitoring system.

[~~(79) Secondary protective barrier (See definition for protective barrier)].~~

(79) [~~(80)~~] Shutter--A device attached to the tube housing assembly capable of completely intercepting [~~which can totally intercept~~] the useful beam and with [~~which has~~] a lead equivalency greater than or equal to [~~not less than that of~~] the tube housing assembly.

(80) [~~(81)~~] Source-to-skin distance (SSD)--The distance from the source to the skin of the patient.

[~~(82) Spot check--Those tests and analyses performed at specified intervals for the purpose of verifying the consistent output of radiation equipment.~~]

(81) [~~(83)~~] Stationary beam therapy--Radiation therapy without displacement of one or more mechanical axes relative to the patient during irradiation.

(82) Supervision--Delegating the task of applying radiation to a person by a physician. The physician can only delegate tasks to an individual certified under the Medical Radiologic Technologist Act, Texas Occupations Code Chapter 601. The physician assumes full responsibility for these tasks and ensures the tasks are administered correctly.

[~~(84) Supervision--The delegating of the task of applying radiation in accordance with this section to persons not licensed in the healing arts or veterinary medicine, who provide services under the physician's control. The physician or veterinarian assumes full responsibility for these tasks and shall assure that the tasks will be administered correctly.~~]

(83) [~~(85)~~] Target--The [~~That~~] part of an x-ray tube or accelerator onto which a beam of accelerated particles is directed to produce ionizing radiation [~~or other particles~~].

(84) [~~(86)~~] Termination of irradiation--The stopping of irradiation in a fashion not permitting the continuation [~~which will not permit continuance~~] of irradiation without [~~the~~] resetting [~~of~~] operating conditions at the control panel.

(85) [~~(87)~~] Therapeutic radiation machine--X-ray, particle, or electron-producing [~~X ray or electron producing~~] equipment designed and used for external beam radiation therapy.

(86) [~~(88)~~] Traceable to a national standard--This indicates [~~that~~] a quantity or a measurement has been compared to a national standard, for example[~~,~~] the National Institute of Standards and Technology, directly or indirectly through one or more intermediate steps and that all comparisons have been documented.

(87) [~~(89)~~] Tube housing assembly--The tube housing with tube installed. [~~It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.~~]

(88) [~~(90)~~] Useful beam--Radiation passing [~~that passes~~] through the window, aperture, cone, or other collimating device of the source housing. Also referred to as the primary beam.

[~~(91) Veterinarian--An individual licensed by the Texas Board of Veterinary Medical Examiners.~~]

(89) Virtual simulation--A process using the import, manipulation, display, and storage of electronic patient images to create linear accelerator treatment ports.

(90) [~~(92)~~] Virtual source--A point from which radiation appears to originate.

[~~(93) Wedge filter--An added filter effecting continuous progressive attenuation on all or part of the useful beam.~~]

(91) Wedge transmission factor--The ratio of doses, with and without the wedge, at a point along the central axis of the useful beam that compensates for the decrease in dose produced by the filter.

(92) [~~(94)~~] Written directive--An order in writing for the administration of radiation to a specific patient as specified in subsection (h)(1)(F)(ii) of this section.

(f) Accelerators used for research and development or [~~and~~] industrial operations.

(1) Registration. Each person possessing an accelerator for non-human use[~~,~~] must [~~shall~~] apply for and receive a certificate of registration from the department [~~agency~~] before beginning use of the accelerator. A person may energize the accelerator for purposes of installation and acceptance testing before receiving a certificate of registra-

tion from the department as specified in [~~agency in accordance with~~] §289.226(i)(1) of this chapter [~~title~~].

(2) Facility requirements.

(A) Each accelerator facility must [~~shall~~] be provided with primary and [~~and/or~~] secondary barriers [~~as are~~] necessary to assure compliance with §289.231(m) and (o) of this chapter [~~title~~].

(B) A radiation survey must [~~shall~~] be conducted when the accelerator is registered and [~~is~~] capable of producing radiation to determine compliance with §289.231(m) and (o) of this chapter [~~title~~].

(C) The registrant must maintain a copy of the initial and all subsequent vault survey reports for inspection by the department as specified in subsection (l) of this section. Vault surveys must be performed: [~~Initial surveys shall be performed as follows.~~]

(i) on all [~~All~~] new and existing facilities not previously surveyed [~~shall have a survey made~~] by, or under the direction of, the registrant; and[~~.~~]

(ii) upon installation, replacement, or upgrade to a higher energy accelerator.

(D) The registrant must maintain a copy of the initial survey report for inspection by the agency in accordance with subsection (l) of this section. A completed survey report must include:

~~*(ii)* A survey report shall be made and shall include, but not be limited to, the following:~~

(i) [~~(I)~~] a diagram of the facility detailing [~~that details~~] building structures and the position of the accelerator, control panel, and associated equipment;

(ii) [~~(II)~~] a description of the accelerator, including the manufacturer, model and serial number, beam type, and beam energy;

(iii) [~~(III)~~] a description of the instrumentation used to determine radiation measurements, including the date and source of the most recent calibration for each instrument used;

(iv) [~~(IV)~~] conditions under which radiation measurements were taken; [~~and~~]

(v) [~~(V)~~] survey data including:

(I) [~~(-a-)~~] projected annual total effective dose equivalent (TEDE) in areas adjacent to the accelerator; and

(II) [~~(-b-)~~] a description of workload, use, and occupancy factors employed in determining the projected annual TEDE; and[~~.~~]

~~*(iii)* The registrant shall maintain a copy of the initial survey report for inspection by the agency in accordance with subsection (l) of this section.~~]

(vi) [~~(iv) The survey report shall include~~] documentation of all instances where the facility violates this chapter's applicable requirements [~~is in violation of applicable requirements of this chapter~~]. Any deficiencies detected during the survey must [~~shall~~] be corrected before [~~prior to~~] using the accelerator.

(3) Safety requirements.

(A) Interlock systems, including inherent, add-on, and aftermarket devices attaching to the accelerator, must [~~shall~~] comply with the following requirements.

(i) Instrumentation, readouts, and controls in the accelerator console are [~~shall be~~] clearly identified.

(ii) Each entrance into a target room or other high radiation area is [~~shall be~~] provided with a safety interlock terminating the useful beam [~~that shuts down the machine~~] under conditions of barrier penetration.

(iii) When the production of radiation has been interrupted, it is [~~shall~~] only [~~be~~] possible to resume operation of the accelerator by manually resetting the interlock at the console.

(iv) Each safety interlock is [~~shall be~~] on an electrical circuit allowing [~~that allows~~] the interlock to operate independently of all other safety interlocks.

(v) All safety interlocks are [~~shall be~~] designed so [~~that~~] any defect or component failure in the interlock system prevents operating [~~operation of~~] the accelerator.

(vi) A scram button or other emergency power cut-off switch is [~~switches shall be~~] labeled. The scram button or cut-off switch includes [~~switches shall include~~] a manual reset so [~~that~~] the accelerator cannot be restarted from the accelerator console without resetting the cut-off switch.

(vii) The safety interlock system includes [~~shall have~~] a visible or audible alarm indicating [~~that will indicate~~] when any interlock has been activated.

(viii) All interlocks and visible or audible alarms are [~~shall be~~] tested for proper operation at intervals meeting or exceeding nationally recognized, published guidelines from a professional body with expertise in accelerator radiation technologies, or manufacturer recommendations [~~not to exceed three months~~].

(ix) If an interlock or alarm is operating improperly, it is [~~shall be~~] immediately labeled as defective and repaired within seven [~~7~~] calendar days.

(x) Records of tests and repairs required by this paragraph are [~~shall be~~] made and maintained as specified in [~~accordance with~~] subsection (l) of this section for inspection by the department [~~agency~~].

(B) Each registrant must develop, implement, and maintain [~~shall develop and implement~~] written operating and safety procedures (OSP) as specified in subsection (h)(1)(G) of this section. [~~The procedures may be documented in an electronic reporting system and shall include, but not be limited to, the following:~~]

~~*(i)* methods used to secure the accelerator from unauthorized use;~~]

~~*(ii)* methods of testing and training operators in accordance with paragraph (4) of this subsection;~~]

~~*(iii)* procedures for notifying the proper personnel in the event of an accident;~~]

~~*(iv)* posting requirements;~~]

~~*(v)* procedures for testing interlocks, entrance controls, and alarm systems;~~]

~~*(vi)* personnel monitoring;~~]

~~*(vii)* maintenance of records; and~~]

~~*(viii)* procedures for necessary area surveys and time intervals.~~]

(C) The registrant must ensure [~~shall ensure that~~] radiation measurements are performed with a calibrated dosimetry system. The dosimetry system calibration must [~~shall~~] be traceable to a national standard. Instruments and equipment must be calibrated at an inter-

val not to exceed 24 months. Each accelerator facility must have appropriate portable monitoring equipment available that is operable and calibrated for the radiation produced at the facility. [~~The calibration interval shall not exceed 24 months. There shall be available at each accelerator facility, appropriate portable monitoring equipment that is operable and has been calibrated for the appropriate radiations being produced at the facility.~~]

(D) A radiation protection survey must [~~shall~~] be performed and the results recorded when changes have been made in shielding, operation, equipment, or occupancy of adjacent areas.

(E) For portable or mobile accelerators, such as neutron generators [~~that are~~] used at temporary job sites where permanent shielding is not available, radiation protection must [~~shall~~] be provided by temporary shielding or by providing an adequate exclusion area around the accelerator while it is in use.

(F) Records of calibration and survey results made as specified in [~~in accordance with~~] subparagraphs (C) and (D) of this paragraph must [~~shall~~] be maintained according to [~~in accordance with~~] subsection (l) of this section.

(G) The registrant must [~~shall~~] perform radiation surveys and contamination smears before [~~prior to~~] the transfer or disposal of an accelerator operating at or above 10 MeV. The survey must [~~Such survey(s) shall~~] be documented and maintained by the registrant for inspection by the department as specified in [~~agency in accordance with~~] subsection (l) of this section.

(H) The registrant must [~~shall~~] retain records of receipt, transfer, and disposal of all radiation machines specific to each authorized use location. The records must be maintained by the registrant for inspection by the department as specified in subsection (l) of this section. The records must [~~shall~~] include the:

(i) date;[~~,~~]

(ii) manufacturer name;[~~,~~]

(iii) model;[~~and~~]

(iv) serial number from the control panel or console of the radiation machine; and

(v) name [~~identification~~] of the person making the record.

(4) Training requirements for operators.

(A) A person must not [~~No person shall be permitted to~~] operate an accelerator unless the [~~such~~] person has received instruction in and demonstrated competence with the following:

(i) OSP [~~operating and safety procedures~~] as specified in [~~accordance with~~] paragraph (3)(B) of this subsection;

(ii) radiation warning and safety devices incorporated into the equipment and in the room;

(iii) identification of radiation hazards associated with the use of the equipment; and

(iv) procedures for reporting a medical event or an actual or suspected exposure to the operator.

(B) Records of the training specified in subparagraph (A) of this paragraph must [~~shall~~] be made and maintained for department [~~agency~~] inspection as specified in [~~accordance with~~] subsection (l) of this section.

(g) Requirements for an accelerator [~~accelerator(s)~~] used in industrial radiography. In addition to the requirements in subsections (f)(1), (f)(2)[~~(2)~~], and (f)(3)(C) - (H) [~~(3)(C) - (H)~~] of this section, accelerators used for industrial radiography must [~~shall~~] meet the applicable requirements of §289.255 of this chapter [~~title~~].

(h) Requirements for therapeutic [~~Therapeutic~~] radiation machines, radiation therapy simulation systems [~~simulators~~] used in the healing arts, [~~veterinary medicine,~~] and EBT [~~electronic brachytherapy~~] devices.

(1) General requirements.

(A) Each person possessing a therapeutic radiation machine capable of operating at or above 1 MeV or an EBT device must [~~million electron volts (MeV) shall~~] apply for and receive a certificate of registration from the department [~~agency~~] before using the accelerator for human use. A person may energize the accelerator for purposes of installation and acceptance testing before receiving a certificate of registration from the department [~~agency~~].

(B) A person possessing a radiation therapy simulation system or a therapeutic radiation machine capable of operating below 1 MeV must apply for a certificate of registration within 30 days after energizing the equipment.

[~~(B) Each person possessing a simulator, a therapeutic radiation machine capable of operating below 1 MeV, and/or an electronic brachytherapy device, shall apply for a certificate of registration within 30 days after energizing the equipment.~~]

(C) A person who operates a radiation machine for human use must [~~Individuals who operate radiation machines for human use shall~~] meet the appropriate credentialing requirements [~~issued~~] as specified in [~~accordance with~~] the Medical Radiologic Technologist Certification Act, Texas Occupations Code[~~,~~] Chapter 601. Copies of the credentialing document must [~~shall~~] be maintained at the location [~~locations(s)~~] where the person [~~individual~~] is working. A copy of the credentialing document must be maintained by the registrant for inspection by the department as specified in subsection (l) of this section.

(D) The EBT registration requires [~~electronic brachytherapy registrant shall require~~] the physician to be:

(i) licensed by the Texas Medical Board; and

(ii) certified in:

(I) radiation oncology or therapeutic radiology by the American Board of Radiology; or

(II) radiation oncology by the American Osteopathic Board of Radiology.[~~;~~]

(E) The registrant must ensure an operator of an EBT device completes device-specific training and maintains a record of each person's training as specified in subsection (l) of this section. [~~Operators of the electronic brachytherapy~~] The [~~device shall complete~~] device-specific training must include [~~as follows~~]:

(i) completing [~~completion of~~] a training program provided by the manufacturer; or

(ii) training [~~received that is~~] substantially equivalent to the manufacturer's training program from a certified physician or a licensed medical physicist [~~who is~~] trained to use the device.

[~~*(iii)* The registrant shall retain a record of each individual's device-specific training in accordance with subsection (l) of this section for inspection by the agency.~~]

(F) Each facility must[~~, including facilities using electronic brachytherapy devices, shall~~] develop a written QA [~~quality assurance~~] program [~~in writing~~] or [~~in~~] an electronic reporting system.

The QA [~~quality assurance~~] program must [~~shall~~] be implemented to minimize [~~as a method of minimizing~~] deviations from facility procedures and to document preventative measures taken before [~~prior to~~] serious patient injury or therapeutic misadministration.

(i) The QA [~~quality assurance~~] program must include [~~shall include but not be limited to~~] the following topics:

(I) treatment planning and patient simulation;

(II) charting and documenting treatment field parameters;

(III) dose calculation and review procedures;

(IV) review of daily treatment records; and

(V) for EBT devices [~~electronic brachytherapy~~], verification of catheter placement and device exchange procedures. [~~;~~]

(ii) A written directive must [~~shall~~] be prepared before [~~prior to~~] administration of a therapeutic radiation dose except where a delay in providing [~~to provide~~] a written directive would jeopardize the patient's health. If an oral directive must be made, the [~~The~~] information contained in the oral directive must [~~shall~~] be documented immediately in the patient's record. A[~~and a~~] written directive must be prepared within 24 hours of the oral directive.

(iii) A written directive changing [~~that changes~~] an existing written directive for any therapeutic radiation procedure is only acceptable if the revision is dated and signed by a certified physician before [~~prior to~~] the administration of the therapeutic dose, or the next fractional dose.

(iv) Deviations from the prescribed treatment, from the facility's QA [~~facilities quality assurance~~] program, or [~~and~~] from the OSP must [~~operating and safety procedures shall~~] be investigated and brought to the attention of the certified physician or licensed medical physicist, and the radiation safety officer (RSO).

(v) The patient's identity must [~~shall~~] be verified by more than one method as the individual named in the written directive before [~~prior to~~] administration.

(vi) The discovery of each medical event must [~~or misadministration shall~~] be reported as specified in subsections [~~in accordance with subsection~~] (i) and [~~or~~] (j) of this section.

(vii) The review of the QA [~~quality assurance~~] program must [~~shall~~] include all the deviations from the prescribed treatment and must [~~shall~~] be conducted at intervals not to exceed 14 months. A signed record of each dated review must [~~shall~~] be maintained for inspection by the department as specified in [~~agency in accordance with~~] subsection (l) of this section and must [~~shall~~] include evaluations and findings of the review.

(G) Written OSP must [~~operating and safety procedures shall~~] be developed by a licensed medical physicist with a specialty in therapeutic radiological physics and must [~~shall~~] include any restrictions required for the safe operation of each [~~the particular~~] therapeutic radiation machine. These procedures must [~~shall~~] be available in the control area of the therapeutic radiation machine, radiation therapy simulation system, or EBT [~~and an electronic brachytherapy~~] device. The registrant must maintain records of OSP as specified in subsection (l) of this section for inspection by the department. The operator must [~~operator(s) shall~~] be able to demonstrate familiarity with these procedures. The OSP must address the following requirements [~~These procedures shall include, but are not limited to the following~~]:

(i) therapeutic radiation machines must [~~shall~~] not be used for irradiation of a patient [~~patients~~] unless full calibration measurements and QA [~~quality assurance~~] checks have been completed;

(ii) therapeutic radiation machines must [~~shall~~] not be used in the administration of radiation therapy if a QA [~~spot~~] check indicates a significant change in the operating characteristics of a system as specified in the written procedures;

(iii) therapeutic radiation machines must [~~shall~~] not be left unattended unless secured by a locking device, or computerized password system, preventing [~~which will prevent~~] unauthorized use [~~(A computerized pass-word system would also constitute a locking device)~~];

(iv) mechanical supporting or restraining devices must be used when there is a need to immobilize a patient or port film for radiation therapy[~~, mechanical supporting or restraining devices shall be used~~];

(v) no individual, other than the patient, is allowed [~~shall be~~] in the treatment room during exposures from therapeutic radiation machines operating above 150 kV;

(vi) at energies less than or equal to 150 kV, any individual in the treatment room, other than the patient, must [~~in the treatment room shall~~] be protected by a barrier sufficient to meet the requirements of §289.231(m) and (o) of this chapter [~~title~~];

(vii) [~~use of~~] a technique chart for radiation therapy simulation systems must be used as specified in [~~simulators in accordance with~~] paragraph (5)(A)(i) [~~(4)(A)(i)~~] of this subsection;

(viii) occupational and public radiation dose [~~requirements~~] must be controlled as specified in [~~accordance with~~] §289.231(m) and (o) of this chapter [~~title~~];

(ix) occupational dose must be monitored as specified in [~~personnel monitoring requirements in accordance with~~] §289.231(n) of this chapter [~~title~~];

(x) [~~use of~~] protective devices must be used for radiation therapy simulation systems as specified in [~~simulators in accordance with~~] paragraph (5)(A)(iii) [~~(4)(A)(iii)~~] of this subsection;

(xi) operators of radiation machines must be credentialled as specified in [~~credentialing requirements for individuals operating radiation machines in accordance with~~] subparagraph (C) of this paragraph;

(xii) film processing program for conventional radiation therapy simulation systems must be performed as specified in [~~simulators in accordance with~~] paragraph (5)(E)(i) [~~(4)(A)(viii)~~] of this subsection; [~~and~~]

(xiii) procedures for restriction and alignment of the beam for conventional radiation therapy simulation systems as specified in [~~simulators in accordance with~~] paragraph (5)(F)(iii) [~~(4)(B)(iii)~~] of this subsection;[~~.~~]

(xiv) methods utilized for testing interlocks, entrance controls, and alarm systems;

(xv) notifications and reports must be provided to individuals as specified in §289.203(d) of this chapter; and

(xvi) notices to workers must be posted as specified in §289.203(b) of this chapter.

(H) A registrant [~~Registrants~~] with equipment granted [~~that has been issued~~] variances by the United States Food and Drug Administration (FDA) to [~~Title~~] 21 [~~21,~~] CFR Part 1020 must [~~shall~~]

maintain copies of those variances at authorized use locations as specified in [accordance with] subsection (l) of this section.

(I) The registrant must [shall] perform radiation surveys and contamination smears before [prior to] the transfer or disposal of an accelerator operating at or above 10 MeV. Surveys must [Such survey(s) shall] be documented and maintained by the registrant for inspection by the department as specified in [agency in accordance with] subsection (l) of this section.

(J) Where applicable, the licensed medical physicist must [shall] perform acceptance testing on the treatment planning system of therapy-related computer systems as specified in [accordance with published] protocols accepted by nationally recognized, published guidelines, from a professional body with expertise in the use of therapeutic radiation technologies [bodies]. In the absence of such a published protocol, the manufacturer's current protocol must [shall] be followed.

(2) Therapeutic radiation machines capable of operating at energies below 1 MeV.

(A) Equipment requirements.

(i) When the tube is operated at its leakage technique factors, the leakage radiation must [shall] not exceed the values specified at the distance stated for the classification of the [that] radiation machine system shown in the following Table I. The leakage technique factors are the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.
Figure: 25 TAC §289.229(h)(2)(A)(i)
[Figure: 25 TAC §289.229(h)(2)(A)(i)]

(ii) Permanent fixed diaphragms or cones used for limiting the useful beam must [shall] provide the same or a higher degree of protection as required for the tube housing assembly.

(iii) Removable and adjustable beam-limiting devices must [shall] meet the following requirements.

(I) Removable beam-limiting devices must [shall], for the portion of the useful beam to be blocked by these devices, transmit not more than 1 percent [1.0%] of the useful beam at the maximum kVp and maximum treatment filter. This requirement does not apply to auxiliary blocks or materials placed in the x-ray field to shape the useful beam to the individual patient.

(II) Adjustable beam-limiting devices must [installed before March 1, 1989, shall], for the portion of the x-ray beam to be blocked by these devices, transmit not more than 5 percent [5.0%] of the useful beam at the maximum kVp and maximum treatment filter.

(III) Adjustable beam-limiting devices must [installed after March 1, 1989, shall] meet the requirements of subclause (I) of this clause.

(iv) The filter system must [shall] be [so] designed so [that]:

(I) the filters cannot be accidentally displaced at any possible tube orientation;

(II) [for equipment installed after March 1, 1989,] an interlock system prevents irradiation if the proper filter is not in place;

(III) the air kerma rate escaping from the filter slot must not exceed 1 centigray/hour (cGy/hr) at 1 meter (m) under any operating conditions [the radiation at 5 centimeters (cm) from the filter insertion slot opening does not exceed 30 roentgens per hour (R/hr) (300 mGy/hr) under any operating conditions]; and

(IV) each filter is marked as to its material of construction and its thickness. For wedge filters, the wedge angle must [shall] appear on the wedge or wedge tray.

(v) The tube housing assembly must [shall] be capable of being immobilized for stationary treatments.

(vi) The tube housing assembly must be marked so [shall be so marked] [that] it is possible to determine the location of the focal spot to within 5 millimeters (mm), and such marking must [shall] be readily accessible for use during calibration procedures.

(vii) The contact [Contact] therapy tube housing assembly must [assemblies shall] have a removable shield of at least 0.5 mm lead equivalency at 100 kVp capable of being [that can be] positioned over the entire useful beam exit port during periods when the beam is not in use.

(viii) The timer must [shall]:

(I) have a display provided at the treatment control panel and a pre-set time selector;

(II) activate with the production of radiation and retain its reading after irradiation is interrupted;[. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to zero;]

(III) be reset to zero after irradiation is terminated and before irradiation can be re-initiated;

(IV) [(III)] terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system present has not previously terminated irradiation;

(V) [(IV)] permit selection of exposure times as short as 1 [one] second;

(VI) [(V)] not permit [an] exposure if set at zero;

(VII) [(VI)] not activate until the shutter is opened when irradiation is controlled by a shutter mechanism unless calibration includes a timer factor to compensate for mechanical lag; and

(VIII) [(VII)] be accurate to within 1 percent [1.0%] of the selected value or 1 second, whichever is greater.

(ix) The control panel, in addition to the displays required in clause (viii)(I) of this subparagraph, must [shall] have the following:

(I) an indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible;

(II) an indication of whether x-rays [x rays] are being produced;

(III) means for indicating x-ray tube potential and current;

(IV) means for terminating an exposure at any time;

(V) a locking device preventing [that will prevent] unauthorized use of the therapeutic radiation system (a computerized password system also constitutes [pass-word system would also constitute] a locking device);

(VI) [~~for therapeutic radiation systems manufactured after March 1, 1989,~~] a positive display of specific filters in the beam; and

(VII) emergency buttons or switches [~~buttons/switches that shall be~~] clearly labeled as to their functions.

(x) There must [~~shall~~] be a means of initially determining [~~initially~~] the SSD to within 1 centimeter (cm) [~~cm~~] and of reproducing this measurement to within 2 mm [~~thereafter~~].

(xi) Unless it is possible to bring the radiation output to the prescribed exposure parameters within 5 seconds, the beam must [~~shall~~] be attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly. After the unit is at operating parameters, the shutter must [~~shall~~] be controlled electrically by the operator from the control panel. An indication of shutter position must [~~shall~~] appear at the control panel.

(xii) Each therapeutic radiation system equipped with a beryllium or other low-filtration window must [~~shall~~] be clearly labeled on [~~as such upon~~] the tube housing assembly and at the control panel.

(B) Facility requirements for therapeutic radiation systems capable of operating above 50 kVp.

(i) Provision must [~~shall~~] be made for continuous two-way aural communication between the patient and the operator at the control panel.

(ii) Windows, mirrors, closed-circuit television, or an equivalent system must [~~shall~~] be provided to permit continuous observation of the patient during irradiation and be [~~shall be so~~] located so [~~that~~] the operator can observe the patient from the control panel.

(I) If [~~Should~~] the viewing system described in clause (ii) of this subparagraph fails or is [~~fail or be~~] inoperative, treatment must [~~shall~~] not be performed with the unit until the system is restored.

(II) If [~~In~~] a facility [~~that~~] has a primary viewing system by electronic means and an alternate viewing system, and [~~should~~] both viewing systems described in clause (ii) of this subparagraph fail or are [~~be~~] inoperative, treatment must [~~shall~~] not be performed with the unit until one of the systems is restored.

(C) Additional facility requirements for therapeutic radiation systems capable of operation above 150 kVp.

(i) Each installation must [~~shall~~] be provided with primary and [~~and/or~~] secondary barriers as [~~are~~] necessary to assure compliance with §289.231(m) and (o) of this chapter [~~title~~]. All protective barriers must [~~shall~~] be fixed except for entrance doors or beam interceptors.

(ii) The control panel must [~~shall~~] be located outside the treatment room or in an enclosed booth inside the room.

(iii) Interlocks must [~~shall~~] be provided to ensure [~~such that~~] all entrance doors are [~~shall be~~] closed, including doors to any interior booths, before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it must [~~shall~~] not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel. When any door is opened while the x-ray tube is activated, the exposure at a distance of 1 m from the source must [~~shall~~] be reduced to less than 1 milligray per hour (mGy/hr) (100 millirad per hour (mrad/hr)) [~~100 mR/hr (1 mGy/hr)~~].

(D) Surveys, calibrations, and QA [~~spot~~] checks.

(i) Surveys must [~~shall~~] be performed as follows.

(I) All new and existing facilities not previously surveyed must [~~shall~~] have an initial shielding survey made by a licensed medical physicist, as authorized by 22 Texas Administrative Code (TAC) §160.17 (relating to Medical Physicist Scope of Practice), who must [~~with a specialty in therapeutic radiological physics, who shall~~] provide a written report of the survey to the registrant. Additional surveys must [~~shall~~] be done after any change in the facility, facility design, or equipment that might cause a significant increase in radiation hazard.

(II) The registrant must [~~shall~~] maintain a copy of the initial survey report and all subsequent survey reports required by subclause (I) of this clause as specified in [~~accordance with~~] subsection (l) of this section for inspection by the department [~~agency~~].

(III) The survey report must [~~shall~~] indicate all instances where the installation violates this chapter's applicable requirements [~~is in violation of applicable requirements of this chapter~~].

(ii) Full calibrations must [~~Calibrations shall~~] be performed as follows.

(I) The calibration of a therapeutic radiation system must [~~shall~~] be performed at intervals not to exceed 12 months [~~1 year~~] and after any change or replacement of components that could cause a change in the radiation output. The calibrations must ensure [~~shall be such that~~] the dose at a reference point in a water or plastic phantom can be calculated to within an uncertainty of 5 percent [~~5.0%~~].

(II) The calibration of the radiation output of the therapeutic radiation system is [~~shall be~~] performed by a licensed medical physicist with a specialty in therapeutic radiological physics, [~~who is~~] physically present at the facility during such calibration.

(III) The calibration of the therapeutic radiation system includes[~~shall include, but not be limited to, the following determinations~~]:

(-a-) verification [~~that~~] the radiation therapy system is operating in compliance with the design specifications;

(-b-) HVL for each kV setting and filter combination used;

(-c-) the exposure rates (air kerma rates) as a function of field size, technique factors, filter, and treatment distance used; and

(-d-) the degree of congruence between the radiation field and the field indicated by the localizing device, if such device is present, which must [~~shall~~] be within 5 mm for any field edge.

(IV) Calibration measurements of the radiation output of a therapeutic radiation system must [~~shall~~] be performed with a calibrated dosimetry system. Calibration of the dosimetry system must be performed and completed at intervals not to exceed 24 months and traceable to a national standard. [~~The dosimetry system calibration shall be traceable to a national standard. The calibration interval shall not exceed 24 months.~~]

(V) Records of calibration measurements specified in this clause [~~(ii) of this subparagraph~~] must [~~shall~~] be maintained by the registrant as specified in [~~accordance with~~] subsection (l) of this section for inspection by the department [~~agency~~].

(VI) A copy of the latest calibrated absorbed dose rate measured on a particular therapeutic radiation system must [~~shall~~] be available at a designated area within the therapy facility housing the [~~that~~] therapeutic radiation system.

(iii) QA [~~Spot~~] checks must [~~shall~~] be performed on therapeutic radiation systems capable of operation at greater than 150

kVp. Such measurements must [~~shall~~] meet the following requirements.

(I) The QA [~~spot~~] check procedures must [~~shall~~] be in writing[~~,~~] or documented in an electronic reporting system, and must [~~shall~~] have been developed by a licensed medical physicist with a specialty in therapeutic radiological physics.

(II) If a licensed medical physicist does not perform the QA [~~spot~~] check measurements, the results of the QA [~~spot~~] check measurements must [~~shall~~] be reviewed by a licensed medical physicist with a specialty in therapeutic radiological physics within five [~~5~~] treatment days and a record made of the review. If the output varies by more than 5 percent [~~5.0%~~] from the expected value, a licensed medical physicist with a specialty in therapeutic radiological physics must [~~shall~~] be notified immediately.

(III) The written QA [~~spot~~] check procedures must [~~shall~~] specify the testing or measurement frequency [~~that tests or measurements are to be performed~~] and state that the QA [~~spot~~] check must [~~shall~~] be performed during the calibration specified in clause (ii) of this subparagraph. The acceptable tolerance for each parameter measured when compared to the value for that parameter determined in the calibration specified in clause (ii) of this subparagraph must [~~shall~~] be stated.

(IV) The written QA [~~spot~~] check procedures must [~~shall~~] include special operating instructions required to [~~that shall~~] be carried out whenever a parameter in subclause (III) of this clause exceeds an acceptable tolerance.

(V) Whenever a QA [~~spot~~] check indicates a significant change in the operating characteristics of a system, as specified in the procedures, the system must [~~shall~~] be recalibrated, as required in clause (ii) of this subparagraph.

(VI) Records of written QA [~~spot~~] checks and any necessary corrective actions must [~~shall~~] be maintained by the registrant as specified in [~~accordance with~~] subsection (l) of this section for inspection by the department [~~agency~~]. A copy of the most recent QA [~~spot~~] check must [~~shall~~] be available at a designated area within the therapy facility housing the [~~that~~] therapeutic radiation system.

(VII) QA [~~Spot~~] checks must [~~shall~~] be obtained using a system satisfying the requirements of clause (ii)(IV) of this subparagraph.

(iv) All testing reports must meet or exceed nationally recognized, published guidelines from a professional body with expertise in the use of therapeutic radiation technologies or manufacturer recommendations.

(3) Therapeutic radiation machines capable of operating at energies of 1 MeV and above.

(A) Equipment requirements.

(i) For operating conditions producing maximum leakage radiation, the absorbed dose in rads (mGy) due to leakage radiation (including x-rays, electrons, and neutrons) must not exceed 0.1 percent of the maximum absorbed dose in rads (mGy) of the unattenuated useful beam. The absorbed dose for this leakage radiation requirement must be measured at any point in a circular plane of 2 m radius centered on and perpendicular to the central axis of the beam at the isocenter or nominal treatment distance and outside the maximum useful beam size. The unattenuated useful beam must be measured at the point of intersection of the central axis of the beam and the plane surface.

(I) Measurements excluding those for neutrons must be averaged over an area up to, but not exceeding, 100 square centimeters (cm^2) at the positions specified.

(II) Measurements of the portion of the leakage radiation dose contributed by neutrons must be averaged over an area up to, but not exceeding, 200 cm^2.

(III) For each system, the registrant must determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified for the specified operating conditions.

(IV) Records on leakage radiation measurements must be maintained as specified in subsection (l) of this section for inspection by the department.

(ii) Irradiation filters.

(I) Dynamic or virtual wedge filter.

(-a-) An interlock system must be provided to prevent irradiation if any virtual or dynamic wedge selected in the treatment room does not agree with the virtual or dynamic wedge selection and operation carried out at the treatment console.

(-b-) The dose distribution selected must include:

(-1-) beam energy;

(-2-) field size; and

(-3-) wedge angle.

(-c-) A virtual wedge transmission factor must be established and utilized.

(II) Multileaf collimator (MLC) filter.

(-a-) An interlock system must be provided to prevent irradiation if the spatial dose distribution selected in the treatment room does not agree with the filter selection and operation carried out at the treatment console.

(-b-) The distribution selected must include:

(-1-) beam energy; and

(-2-) MLC selection.

(III) Stereotactic radiosurgery (SRS) filter.

(-a-) An interlock system must be provided to prevent irradiation if the spatial dose distribution selected in the treatment room does not agree with the filter selection and operation carried out at the treatment console.

(-b-) The distribution selected must include:

(-1-) beam energy;

(-2-) SRS cone; or

(-3-) MLC selection.

(-c-) A virtual wedge transmission factor must be established and utilized.

(IV) Physical wedge filter.

(-a-) Each wedge filter removable from the system must be marked with an identification number.

(-b-) Documentation must be available at the console containing a description of the filter.

(-c-) The wedge angle must appear on the wedge or wedge tray (if permanently mounted to the tray).

(-d-) If the wedge or wedge tray is damaged, the wedge must be removed from clinical service.

(-e-) Irradiation must not be possible until a selection of a filter or a positive selection to use "no filter" has been made at the treatment console, either manually or automatically.

(-f-) A display must be provided at the treatment console showing the accelerator beam quality in use.

(-g-) An interlock system must be provided to prevent irradiation if any filter selection operation carried out in the treatment room does not agree with the filter selection and operation carried out at the treatment console.

~~*(ii)* For operating conditions producing maximum leakage radiation, the absorbed dose in rads (mGy) due to leakage radiation, including x rays, electrons, and neutrons, at any point in a circular plane of 2 m radius centered on and perpendicular to the central axis of the beam at the isocenter or normal treatment distance and outside the maximum useful beam size shall not exceed 0.1% of the maximum absorbed dose in rads (mGy) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the plane surface. Measurements excluding those for neutrons shall be averaged over an area up to, but not exceeding, 100 square centimeters (cm^2) at the positions specified. Measurements of the portion of the leakage radiation dose contributed by neutrons shall be averaged over an area up to, but not exceeding, 200 cm^2. For each system, the registrant shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified for the specified operating conditions. Records on leakage radiation measurements shall be maintained in accordance with subsection (l) of this section for inspection by the agency.~~

~~*(ii)* Each wedge filter that is removable from the system shall be clearly marked with an identification number. Documentation available at the control panel shall contain a description of the filter. The wedge angle shall appear on the wedge or wedge tray (if permanently mounted to the tray). If the wedge tray is damaged, the wedge transmission factor shall be redetermined. Equipment manufactured after March 1, 1989, shall meet the following requirements.~~

~~*(I)* Irradiation shall not be possible until a selection of a filter or a positive selection to use "no filter" has been made at the treatment console, either manually or automatically.~~

~~*(II)* An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position.~~

~~*(III)* A display shall be provided at the treatment console showing the beam quality in use.~~

~~*(IV)* An interlock shall be provided to prevent irradiation if any filter selection operation carried out in the treatment room does not agree with the filter selection operation carried out at the treatment console.~~

(iii) Beam Quality. The registrant must [~~shall~~] determine data sufficient to assure [~~that~~] the following beam quality requirements in tissue equivalent material are met.

(I) The absorbed dose resulting from x-rays [~~x rays~~] in a useful electron beam at a point on the central axis of the beam 10 cm greater than the practical range of the electrons must [~~shall~~] not exceed the values stated in [~~the following~~] Table II. Linear interpolation must [~~shall~~] be used for values not stated.
Figure: 25 TAC §289.229(h)(3)(A)(iii)(I) (No change.)

(II) Compliance with subclause (I) of this clause must [~~shall~~] be determined using:

(-a-) a measurement within a tissue equivalent phantom with the incident surface of the phantom at the nominal [~~normal~~] treatment distance and normal to the central axis of the beam;

(-b-) a field size of 10 cm by 10 cm; and

(-c-) a phantom whose cross-sectional dimensions exceed the measurement radiation field by at least 5 cm and whose depth is sufficient to perform the required measurement.

(III) The absorbed dose at a surface located at the nominal [~~normal~~] treatment distance, at the point of intersection of that surface with the central axis of the useful beam during x-ray irradiation, must [~~shall~~] not exceed the limits stated in the following Table III. Linear interpolation must [~~shall~~] be used for values not stated.
Figure: 25 TAC §289.229(h)(3)(A)(iii)(III) (No change.)

(IV) Compliance with subclause (III) of this clause must [~~shall~~] be determined by measurements [~~made as follows~~]:

(-a-) within a tissue equivalent phantom using an instrument allowing [~~that will allow~~] extrapolation to the surface absorbed dose;

(-b-) using a phantom whose size and placement meet the requirements of subclause (II) of this clause;

(-c-) after removal of all beam-modifying [~~beam modifying~~] devices capable of being [~~that can be~~] removed without the use of tools, except for beam-scattering [~~beam scattering~~] or beam-flattening filters; and

(-d-) using the largest field size available not exceeding [~~that does not exceed~~] 15 cm by 15 cm.

(iv) All therapeutic radiation systems must [~~shall~~] be provided with radiation detectors in the gantry [~~radiation~~] head. These must [~~shall~~] include the following, as appropriate.

(I) At [~~Equipment manufactured after March 1, 1989, shall be provided with at~~] least two [~~2~~] independent radiation detectors must be used. The detectors must [~~shall~~] be incorporated into two [~~2~~] independent dose monitoring systems.

~~*(II)* Equipment manufactured on or before March 1, 1989, shall be provided with at least 1 radiation detector. This detector shall be incorporated into a primary dose monitoring system.~~

(II) [~~(III)~~] The incorporated detector and monitoring system must [~~the system into which that detector is incorporated shall~~] meet the following requirements.

(-a-) Each detector must [~~shall~~] be removable only with tools and must [~~shall~~] be interlocked to prevent incorrect positioning.

(-b-) Each detector must [~~shall~~] form part of a dose monitoring system from whose readings in dose monitor units the absorbed dose at a reference point in the treatment volume can be calculated.

(-c-) Each dose monitoring system must [~~shall~~] be capable of independently monitoring, interrupting, and terminating irradiation.

(-d-) The [~~For equipment manufactured after March 1, 1989, the~~] design of the dose monitoring systems must [~~shall~~] assure [~~that~~] the malfunctioning of one [~~1~~] system does [~~shall~~] not affect the correct functioning of the secondary system; and failure of any element common to both systems affecting [~~that could affect~~] the correct function of both systems must [~~shall~~] terminate irradiation.

(-e-) Each dose monitoring system must [~~shall~~] have a legible display at the treatment console. Each display must [~~For equipment manufactured after March 1, 1989, each display shall~~]:

(-1-) maintain a reading until intentionally reset to zero;

(-2-) have only one scale and no scale multiplying factors;

(-3-) utilize a design so [~~such that~~] increasing dose is displayed by increasing numbers and if there is [~~shall~~

be so designed that, in the event of] an overdosage of radiation, the absorbed dose may be accurately determined; and

(-4-) retain the dose monitoring information in at least one system for 15 minutes [a 15-minute period of time] in the event of a power failure.

(v) For equipment [In equipment manufactured after March 1, 1989,] inherently capable of producing useful beams with unintentional asymmetry exceeding 5 percent [5.0%], the asymmetry of the radiation beam in two orthogonal directions must [shall] be monitored before the beam passes through the beam-limiting device. If the difference in dose rate between one region and another region symmetrically displaced from the central axis of the beam exceeds 5 percent [5.0%] of the central axis dose rate, an indication of this condition must [shall] be displayed at the console; and if this difference exceeds 10 percent [10%] of the central axis dose rate, the irradiation must [shall] be terminated.

(vi) Selection and display of dose monitor units must [shall] meet the following requirements.

(I) Irradiation must [shall] not be possible until a selection of [a number of] dose monitor units has been made at the treatment console.

(II) The preselected number of dose monitor units must [shall] be displayed at the treatment console until reset manually for the next irradiation.

(III) After termination of irradiation, it must [shall] be necessary to reset the dosimeter display to zero before subsequent treatment can be initiated.

(IV) After [For equipment manufactured after March 1, 1989, after] termination of irradiation, [it shall be necessary to manually reset] the preselected dose monitor units must be reset manually before irradiation can be initiated.

(vii) Termination of irradiation by the dose monitoring system or systems during stationary beam therapy must [shall] meet the following requirements.

(I) Each primary system must [shall] terminate irradiation when the preselected number of dose monitor units has been detected by the system.

[(II) If original design of the equipment includes a secondary dose monitoring system, that system shall be capable of terminating irradiation when not more than 15% or 40 dose monitor units, whichever is smaller, above the preselected number of dose monitor units set at the console has been detected by the secondary dose monitoring system.]

(II) [(III)] A [For equipment manufactured after March 1, 1989, a] secondary dose monitoring system must [shall] be present. The [That] system must [shall] be capable of terminating irradiation when not more than 10 percent [10%] or 25 dose monitoring units, whichever is smaller, above the preselected number of dose monitor units set at the console has been detected by the secondary dose monitoring system.

(III) [(IV)] An [For equipment manufactured after March 1, 1989, an] indicator on the console must show [shall show] which dose monitoring system has terminated irradiation.

(viii) A locking device must [shall] be provided in the system to prevent unauthorized use of the x-ray system. A computerized password system would also constitute a locking device.

(ix) It must [shall] be possible to interrupt irradiation and equipment movements at any time from the operator's position at the treatment console. Following an interruption, it must [shall] be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a preselected value during an interruption, irradiation and equipment movements must [shall] be automatically terminated.

(x) It must [shall] be possible to terminate irradiation and equipment movements or go from an interruption condition to termination conditions at any time from the operator's position at the treatment console.

(xi) Timers must [shall] meet the following requirements.

(I) A timer with [that has] a display is [shall be] provided at the treatment console. The timer has [shall have] a preset time selector and an elapsed time indicator.

(II) The timer is [shall be] a cumulative timer activating [that activates] with the production of radiation and retaining [retains] its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it is [shall be] necessary to reset the elapsed time indicator to zero.

(III) After [For equipment manufactured after March 1, 1989, after] termination of irradiation and before irradiation can be reinitiated, [it shall be necessary to manually reset] the preset time selector is reset manually.

(IV) The timer terminates [shall terminate] irradiation when a preselected time has elapsed if the dose monitoring systems have not previously terminated irradiation.

(xii) Equipment capable of producing more than one [1] radiation type must [shall] meet the following additional requirements.

(I) Irradiation is not [shall not be] possible until a selection of radiation type has been made at the treatment console.

(II) An interlock system is [shall be] provided to:

(-a-) ensure [that] the equipment can emit only the radiation type [that has been] selected;

(-b-) prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment console;

(-c-) prevent irradiation with x-rays except to obtain a port film when electron applicators are fitted; and

(-d-) prevent irradiation with electrons when accessories specific for x-ray therapy are fitted.

(III) The radiation type selected is [shall be] displayed at the treatment console before and during irradiation.

(xiii) Equipment capable of generating radiation beams of different energies must [shall] meet the following requirements.

(I) Irradiation is not [shall not be] possible until a selection of energy has been made at the treatment console.

(II) An interlock system is [shall be] provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment console.

(III) The nominal energy value selected is [shall be] displayed at the treatment console before and during irradiation.

(xiv) Equipment capable of both stationary beam therapy and moving beam therapy must [~~shall~~] meet the following requirements.

(I) Irradiation is not [~~shall not be~~] possible until a selection of stationary beam therapy or moving beam therapy has been made at the treatment console.

(II) An interlock system is [~~shall be~~] provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment console.

(III) The selection of stationary or moving beam is [~~shall be~~] displayed at the treatment console. An interlock system must [~~shall~~] be provided to ensure [~~that~~] the equipment can only operate in the selected mode [~~that has been selected~~].

(IV) An [~~For equipment manufactured after March 1, 1989, an~~] interlock system is [~~shall be~~] provided to terminate irradiation if movement of the gantry occurs during stationary beam therapy or stops during moving beam therapy unless such stoppage is a preplanned function.

(V) Moving beam therapy is [~~shall be~~] controlled to obtain the selected relationships between incremental dose monitor units and incremental angle of movement.

(-a-) An [~~For equipment manufactured after March 1, 1989, an~~] interlock system must [~~shall~~] be provided to terminate irradiation if the number of dose monitor units delivered in any 10 degrees of arc differs by more than 20 percent [~~20%~~] from the selected value.

(-b-) Where [~~For equipment manufactured after March 1, 1989, where~~] gantry angle terminates the irradiation in arc therapy, the dose monitor units must be within 5 percent [~~shall differ by less than 5.0%~~] from the value calculated from the absorbed dose per unit angle relationship.

(VI) Where the dose monitor system terminates the irradiation in moving beam therapy, the termination of irradiation must meet the requirements of [~~shall be as required by~~] clause (vii) of this subparagraph.

(xv) A [~~For equipment manufactured after March 1, 1989, a~~] system must [~~shall~~] be provided from whose readings the absorbed dose rate at a reference point in the treatment volume can be calculated. The radiation detectors specified in clause (iv) of this subparagraph [~~subparagraph (iv) of this paragraph~~] may form part of this system. In addition, the dose monitor unit rate must [~~shall~~] be displayed at the treatment console. If the equipment can deliver, under any conditions, an absorbed dose rate at the nominal [~~normal~~] treatment distance more than twice the maximum value specified by the manufacturer for any machine parameters utilized, a device must [~~shall~~] be provided to terminate [~~that terminates~~] irradiation when the absorbed dose rate exceeds a value twice the specified maximum. The dose rate at which the irradiation will be terminated must [~~shall~~] be in a record maintained by the registrant as specified in [~~accordance with~~] subsection (l) of this section for department [~~agency~~] inspection.

(xvi) The registrant must [~~shall~~] determine, or obtain from the manufacturer, the location with reference to an accessible point on the gantry, [~~radiation head~~] of the x-ray target, or the virtual source of x-rays and the electron window, or the virtual source of electrons if the system has electron beam capabilities.

(xvii) Capabilities must [~~shall~~] be provided so [~~that~~] all radiation safety interlocks can be checked for correct operation.

(B) Facility and shielding requirements.

(i) Each installation must [~~shall~~] be provided with primary and [~~and/or~~] secondary barriers as are necessary to assure compliance with §289.231(m) and (o) of this chapter [~~title~~].

(ii) All protective barriers must [~~shall~~] be fixed except for entrance doors or beam interceptors.

(iii) The console must [~~shall~~] be located outside the treatment room and all emergency buttons or switches must [~~buttons/switches shall~~] be clearly labeled as to their functions.

(iv) Windows, mirrors, closed-circuit television, or an equivalent system must [~~shall~~] be provided to permit continuous observation of the patient following positioning and during irradiation and must be [~~shall be so~~] located so [~~that~~] the operator can see [~~may observe~~] the patient from the console.

(I) If [~~Should~~] the viewing system described in clause (iv) of this subparagraph fails or is inoperable [~~fail or be inoperative~~], treatment must [~~shall~~] not be performed with the unit until the system is restored.

(II) In a facility with [~~that has~~] a primary viewing system by electronic means and an alternate viewing system, if [~~should~~] both viewing systems described in clause (iv) of this subparagraph fail or are [~~be~~] inoperative, treatment must [~~shall~~] not be performed with the unit until one of the systems is restored.

(v) Provision must [~~shall~~] be made for continuous two-way aural communication between the patient and the operator at the console independent of the accelerator. However, where excessive noise levels or treatment requirements make aural communication impractical, other methods of communication must [~~shall~~] be used. When this is the case, a description of the alternate method must [~~shall~~] be submitted to and approved by the department [~~agency~~].

(vi) Treatment room entrances must [~~shall~~] be provided with a warning light in a readily observable position near the outside of all access doors to indicate when the useful beam is "on."

(vii) Interlocks must [~~shall~~] be provided to ensure [~~such that~~] all entrance doors are [~~shall be~~] closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it must [~~shall~~] not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the console.

(C) Surveys, dose calibrations, QA [~~spot~~] checks, and operational requirements.

(i) Surveys must [~~shall~~] be performed as follows.

(I) All new and existing facilities not previously surveyed must [~~shall~~] have an initial shielding survey made by a licensed medical physicist as authorized by 22 TAC §160.17 who must [~~with a specialty in therapeutic radiological physics, who shall~~] provide a written report of the survey to the registrant. The physicist who performs the survey must [~~shall~~] be a person who:

(-a-) did not consult in the design of the therapeutic radiation machine installation and;

(-b-) is not employed by or within any corporation or partnership with the person who consulted in the design of the installation. [~~In addition, such surveys shall be done after any change in the facility or equipment that might cause a significant increase in radiation hazard.~~]

(II) The survey report must [~~shall~~] include[~~, but not be limited to the following~~]:

(-a-) a diagram of the facility detailing [~~that details~~] building structures and the position of the console, therapeutic radiation machine, and associated equipment;

(-b-) a description of the therapeutic radiation system, including the manufacturer, model and serial number, beam type, and beam energy;

(-c-) a description of the instrumentation used to determine radiation measurements, including the date and source of the most recent calibration for each instrument used;

(-d-) conditions under which radiation measurements were taken; and

(-e-) survey data including:

(-1-) projected annual TEDE in areas adjacent to the therapy room; and

(-2-) a description of workload, use, and occupancy factors employed in determining the projected annual TEDE.

(III) The registrant must [~~shall~~] maintain a copy of the survey report, and a copy of the survey report must [~~shall~~] be provided to the department [~~agency~~] within 30 days of completion of the survey. Records of the survey report must [~~shall~~] be maintained as specified in [~~accordance with~~] subsection (l) of this section for inspection by the department [~~agency~~].

(IV) The survey report must [~~shall~~] include documentation of all instances where the installation is in violation of applicable regulations. Any deficiencies detected during the survey must [~~shall~~] be corrected before [~~prior to~~] using the machine.

(V) In addition, such surveys must be done after any change in the facility or equipment that might cause a significant increase in radiation hazard.

(ii) Dose calibrations. Records of calibration measurements specified in subclause (I) of this clause and dosimetry system calibrations specified in subclause (III) of this clause must be maintained by the registrant as specified in subsection (l) of this section for inspection by the department. A copy of the latest calibrated absorbed dose rate measured as specified in subclause (I) of this clause must be available at a designated area within the facility housing the radiation therapy system. Calibrations of therapeutic systems must [~~shall~~] be performed as follows.

(I) The calibration of systems subject to this subsection are [~~shall be~~] performed as specified in [~~accordance with~~] an established calibration protocol before the system is first used for irradiation of a patient and then at intervals not exceeding [~~thereafter at time intervals that do not exceed~~] 12 months and after any change [~~that might~~] significantly altering [~~alter~~] the calibration, spatial distribution, or other characteristics of the therapy beam.

(-a-) The calibration procedures must [~~shall~~] be in writing, or documented in an electronic reporting system, and must [~~shall~~] have been developed by a licensed medical physicist with a specialty in therapeutic radiological physics.

(-b-) Acceptance testing, commissioning, and dose calibration must be performed as specified in current published recommendations from a nationally recognized professional association with expertise in the use of therapeutic radiation technologies. In the absence of a protocol published by a national professional association, the manufacturer's protocol, or equivalent quality, safety, and security protocols, must be followed. [~~The calibration protocol entitled, "Protocol for Clinical Reference Dosimetry of High-Energy Photon and Electron Beams," Task Group 51, Radiation Therapy Committee, American Association of Physicists in Medicine, Medical Physics 26(9): 1847 - 1870, September 1999, would be accepted as an established protocol.~~]

(-c-) At a minimum, the calibration protocol must [~~shall~~] include all items in subclauses (III) - (V) of this clause [~~below~~].

(II) The calibration is [~~shall be~~] performed by a licensed medical physicist with a specialty in therapeutic radiological physics who is physically present at the facility during the calibration.

(III) Calibration radiation measurements required by subclause (I) of this clause are [~~shall be~~] performed using a dosimetry system:

(-a-) having a calibration factor for cobalt-60 gamma rays traceable to a national standard;

(-b-) [~~that is~~] traceable to a national standard and at an interval not to exceed 24 months;

(-c-) [~~that has been~~] calibrated to the extent [~~in such a fashion that~~] an uncertainty can be stated for the radiation quantities monitored by the system; and

(-d-) having [~~that has had~~] constancy checks performed [~~on the system~~] as specified by the licensed medical physicist with a specialty in therapeutic radiological physics.

(IV) Calibrations must [~~shall~~] be in sufficient detail to ensure [~~that~~] the dose at a reference point in a tissue equivalent phantom can be calculated to within an uncertainty of 5 percent [~~5.0%~~].

(V) The calibration of the therapy unit must include [~~shall include, but not be limited to,~~] the following determinations.

(-a-) Verification that the equipment is operating in compliance with the design specifications concerning the light field, patient positioning lasers, and back-pointer lights with the isocenter when applicable;[~~,~~] variation in the axis of rotation for the table, gantry, and collimator system;[~~,~~] and beam flatness and symmetry at the specified depth.

(-b-) Verification of the [~~The~~] accuracy of the absorbed dose rate at various depths in a tissue equivalent phantom for the range of field sizes and effective energies used in all therapy procedures[~~, for each effective energy, that will verify the accuracy of the dosimetry of all therapy procedures utilized with that therapy beam~~].

(-c-) Uniformity [~~The uniformity~~] of the radiation field to include symmetry, flatness, and dependence on the gantry angle.

(-d-) Verification that existing isodose charts applicable to the specific machine continue to be valid or are updated to existing machine conditions.

(-e-) Verification of transmission factors for all accessories such as wedges, block trays, and [~~and/or~~] universal and custom-made [~~custom made~~] beam modifying devices.

(VI) Calibration of therapeutic systems containing asymmetric jaws, multileaf collimation, or dynamic or virtual wedges must [~~dynamic/virtual wedges shall~~] be performed with an established protocol. The procedures must [~~shall~~] be developed by a licensed medical physicist with a specialty in therapeutic radiological physics and must [~~shall~~] be in writing or documented in an electronic reporting system. [~~Current recommendations by a national professional association as the American Association of Physicists in Medicine, Task Group 142 report: "Quality Assurance of Medical Accelerators" published August 17, 2009, would be considered an established protocol.~~]

~~(VII)~~ ~~Records of calibration measurements specified in subclause (I) of this clause and dosimetry system cali-~~

brations specified in subclause (III) of this clause shall be maintained by the registrant in accordance with subsection (l) of this section for inspection by the agency.]

[(VIII) A copy of the latest calibrated absorbed dose rate measured in accordance with subclause (I) of this clause shall be available at a designated area within the facility housing that radiation therapy system.]

(iii) QA [Spot] checks must [shall] be performed on systems subject to this paragraph during calibrations and then[thereafter] at weekly intervals with the period between QA [spot] checks not to exceed five [5] treatment days. Such radiation output measurements must [shall] meet the following requirements.

(I) The QA [spot] check procedures must [shall] be performed as specified in [accordance with] established protocol, [shall be] be in writing[,] or documented in an electronic reporting system, and be [shall have been] developed by a licensed medical physicist with a specialty in therapeutic radiological physics. The protocol must meet or exceed nationally recognized, published guidelines from a professional body with expertise in the use of therapeutic radiation technologies or manufacturer recommendations. [Either the spot check protocol entitled, "Comprehensive QA for Radiation Oncology," Task Group 40, Radiation Therapy Committee, American Association of Physicists in Medicine, Medical Physics 21(4): 581-618, April, 1994, or Task Group 142 report: Quality Assurance of Medical Accelerators, published by American Association of Physicists in Medicine on August 17, 2009, are accepted as an established protocol.] At a minimum, the QA [spot] check protocol must [shall] include all items in subclauses (III) - (VI) of this clause.

(II) If a licensed medical physicist does not perform the QA [spot] check measurements, the results of the QA [spot] check measurements must [shall] be reviewed by a licensed medical physicist at a frequency not to exceed five [5] treatment days and a record kept of the review. If the output varies by more than 3 percent [3.0%] from the expected value, a licensed medical physicist must [shall] be notified immediately.

(III) The written QA [spot] check procedures must [shall] specify the frequency at which tests or measurements are [to be] performed and the acceptable tolerance for each parameter measured in the QA [spot] check when compared to the value for that parameter determined in the calibration.

(IV) Where a system has built-in devices providing [that provide] a measurement of any parameter during irradiation, such measurement must [shall] not be utilized as a QA [spot] check measurement.

(V) A parameter exceeding a tolerance set by a licensed medical physicist must [shall] be corrected before the system is used for patient irradiation.

(VI) Whenever a QA [spot] check indicates a significant change in the operating characteristics of a system, as specified in a licensed medical physicist's written procedures, the system must [shall] be recalibrated[, as required in this clause of this subparagraph].

(VII) Records of QA [spot] check measurements and any necessary corrective actions must [shall] be maintained by the registrant as specified in [accordance with] subsection (l) of this section for inspection by the department [agency].

(VIII) QA checks must [Spot checks shall] be completed [obtained] using a system satisfying the requirements of clause (ii)(III) of this subparagraph.

(iv) Facilities with therapeutic radiation machines with energies of 1 MeV and above must [shall] procure the services of a licensed medical physicist with a specialty in therapeutic radiological physics.

(I) The physicist must [shall] be responsible for:

(-a-) dose calibration of radiation machines;

(-b-) supervision and review of beam and clinical dosimetry;

(-c-) measurement, analysis, and tabulation of beam data;

(-d-) establishment of QA [quality assurance] procedures and performance of QA [spot] check review; and

(-e-) review of absorbed doses delivered to patients.

(II) The licensed medical physicist described in subclause (I) of this clause must [shall] also be available and responsive to immediate problems or emergencies.

(4) Requirements for EBT devices. In addition to the requirements in paragraph (1) of this subsection, EBT devices must meet the requirements in this paragraph.

(A) Technical requirements for EBT devices.

(i) The timer must:

(I) have a display provided at the treatment control panel and a pre-set time selector;

(II) activate with the production of radiation and retain its reading after irradiation is interrupted;

(III) be reset to zero after irradiation is terminated and before irradiation can be re-initiated;

(IV) terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system present has not previously terminated irradiation;

(V) permit selection of exposure times as short as 1 second;

(VI) not permit an exposure if set at zero; and

(VII) be accurate to within 1 percent of the selected value or 1 second, whichever is greater.

(ii) The control panel, in addition to the displays required in subparagraph (A)(i) of this paragraph, must have:

(I) an indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible;

(II) means for indicating x-rays are being produced;

(III) means for indicating x-ray tube potential and current; and

(IV) means for terminating an exposure at any time.

(iii) All emergency buttons or switches must be clearly labeled as to their functions.

(B) Surveys, calibrations, and QA checks.

(i) Survey procedures.

(I) All new and existing facilities with an EBT device must have an initial shielding survey made by a licensed medical physicist, as authorized by 22 TAC §160.17, who must provide a

written survey report to the registrant. Additional surveys must be done when:

(-a-) making any change in the portable shielding; and

(-b-) relocating the electronic therapy device.

(II) The registrant must maintain a copy of the initial survey report and all subsequent survey reports as specified in subsection (l) of this section for inspection by the department.

(III) The survey report must indicate all instances where the installation is in violation of the applicable requirements of this chapter.

(ii) Calibrations procedures. Records of calibration measurements must be maintained by the registrant as specified in subsection (l) of this section for inspection by the department. A copy of the latest calibrated absorbed dose rate measured on the EBT device must be available at a designated area within the therapy facility housing the EBT device.

(I) Calibration procedures must be in writing, or documented in an electronic reporting system, and must have been developed by a licensed medical physicist with a specialty in therapeutic radiological physics.

(II) The registrant must make calibration measurements required by this section as specified in any current recommendations from a recognized national professional association (such as the American Association of Physicists in Medicine Report Number 152) for an EBT device, when available. Equivalent alternative methods are acceptable. In the absence of a protocol by a national professional association, a published protocol included in the device manufacturer operator's manual must be followed.

(III) The calibration of the EBT device must be performed after changing the x-ray tube or replacing components that could cause a change in the radiation output. The calibration must ensure the dose at a reference point in a water or plastic phantom can be calculated to within an uncertainty of 5 percent.

(IV) The calibration of the radiation output of the EBT device must be performed by a licensed medical physicist with a specialty in therapeutic radiological physics who is physically present at the facility during such calibration.

(V) The calibration of the therapeutic EBT device must include verification that the EBT device is operating in compliance with the design specifications.

(VI) Calibration of the radiation output of the EBT device must be performed with a calibrated dosimetry system. The dosimetry calibration must be traceable to a national standard. The calibration interval must not exceed 24 months.

(iii) QA check. Records of the written QA checks and any necessary corrective actions must be maintained by the registrant as specified in subsection (l) of this section for inspection by the department. A copy of the most recent QA check must be available at a designated area within the therapy facility housing the therapeutic radiation system.

(I) QA check procedures must be in writing, or documented in an electronic reporting system, and must have been developed by a licensed medical physicist with a specialty in therapeutic radiological physics.

(II) If a licensed medical physicist does not perform the QA check measurements, the results of the QA check measurements must be reviewed by a licensed medical physicist with a specialty in therapeutic radiological physics within two treatment days, and a record made of the review.

(III) The written QA check procedures must specify the operating instructions required to be carried out whenever a parameter exceeds an acceptable tolerance as established by the licensed medical physicist.

(IV) The certified physician or licensed medical physicist must prevent the clinical use of a malfunctioning device until the malfunction identified in the QA check has been evaluated and corrected or, if necessary, the equipment repaired.

(V) QA checks must be completed using a dosimetry system satisfying the requirements of clause (ii)(VI) of this subparagraph.

(5) Radiation therapy simulation systems.

[~~(4)~~] [~~Radiation therapy simulators.~~]

(A) General requirements. In addition to the [~~general~~] requirements in paragraph (1)(B), (C), (F), and (H) of this subsection, radiation therapy simulation systems must [~~simulators shall~~] comply with the following:

(i) Technique chart. A technique chart relevant to the [~~particular~~] radiation machine is [~~shall be~~] provided or electronically displayed in the vicinity of the console and used by all operators.

(ii) Operating and safety procedures. Each registrant develops, implements, and maintains [~~shall have and implement~~] written OSP as specified in [~~operating and safety procedures in accordance with~~] paragraph (1)(G) of this subsection and §289.227(i)(2)(A) of this chapter.

(iii) Protective devices. When utilized, protective devices [~~shall~~] meet the following requirements.

(I) Protective devices must [~~shall~~] be made of no less than 0.25 mm lead equivalent material.

(II) Protective devices, including aprons, gloves, and shields, are [~~shall be~~] checked annually for defects, such as holes, cracks, and tears. The registrant must perform these checks [~~These checks may be performed by the registrant~~] by visual, tactile, or x-ray imaging. If a defect is found, equipment must [~~shall~~] be replaced or removed from service until repaired. A record of this test is [~~shall be~~] made and maintained by the registrant as specified in [~~accordance with~~] subsection (l) of this section for inspection by the department [~~agency~~].

(iv) Viewing system. Windows, mirrors, closed circuit television, or an equivalent system is [~~shall be~~] provided to permit the operator to continuously observe the patient during irradiation. The operator is [~~shall be~~] able to maintain continuous verbal, visual, and aural contact with the patient.

(v) Operator position. The operator's position during the exposure ensures [~~shall be such that~~] the operator's exposure is as low as reasonably achievable (ALARA). The [~~and the~~] operator is a minimum of 6 feet from the source of radiation or protected by an apron, gloves, or other shielding having a minimum of 0.25 mm lead equivalent material.

(vi) Holding of the tube. An [~~In no case shall an~~] individual does not hold the tube or tube housing assembly supports during any radiographic exposure.

(vii) No individuals other than the patient and the operator are allowed [~~operator(s) shall be~~] in the treatment room during the operation of the simulator.

(B) Facility design requirements.

(i) Provision must be made for two-way aural communication between the patient and the operator at the control panel.

(ii) Windows, mirrors, closed-circuit television, or an equivalent must be provided to permit continuous patient observation during irradiation and be located so the operator can see the patient from the console. If the viewing system described in this clause fails or is inoperable, the unit must not be used until the system is restored.

(iii) In a facility with a primary viewing system by electronic means and an alternate viewing system, and both viewing systems described in this clause fail or are inoperative, the unit must not be used until one of the systems is restored.

(C) Requirements for radiation therapy simulation systems utilizing standard CT systems.

(i) Equipment requirements.

(I) Tomographic systems must meet the following requirements.

(-a-) For any single tomogram system, means must be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

(-b-) For any multiple tomogram system, means must be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

(-c-) If a device using a light source is used to satisfy the requirements of item (-a-) or (-b-) of this subclause, the light source must provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.

(II) The CT system must be designed so the CT conditions of operation to be used during a scan or a scan sequence are indicated before the initiation of a scan or a scan sequence. For equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions must be visible from any position from which scan initiation is possible.

(III) The CT control and gantry must provide visual indication whenever x-rays are produced and, if applicable, whether the shutter is open or closed.

(IV) Means must be provided to require operator initiation of each individual scan or series of scans.

(V) All emergency buttons or switches must be clearly labeled as to their functions.

(VI) Termination of exposure must meet the following requirements.

(-a-) Means must be provided to terminate the x-ray exposure automatically by either de-energizing the x-ray source or shuttering the x-ray beam in the event of equipment failure affecting data collection. Such termination must occur within an interval limiting the total scan time to no more than 110 percent of its preset value using either a backup timer or a device that monitors equipment function.

(-b-) A signal visible to the operator must indicate when the x-ray exposure has been terminated through the means required by item (-a-) of this subclause.

(-c-) The operator must be able to terminate the x-ray exposure at any time during a scan or series of scans under CT system control of greater than 0.5 second duration. Termination of the x-ray exposure must necessitate resetting the CT conditions of operation before initiation of another scan.

(VII) CT systems containing a gantry must meet the following requirements.

(-a-) The total error in the indicated location of the tomographic plane or reference plane must not exceed 5 mm.

(-b-) If the x-ray production period is less than 0.5 seconds, the indication of x-ray production must be actuated for at least 0.5 seconds. Indicators at or near the gantry must be discernible from any point external to the patient opening, where insertion of any part of the human body into the primary beam is possible.

(-c-) The deviation of indicated scan increment versus actual increment must not exceed plus or minus 1 mm with any mass from 0 to 100 kilograms (kg) resting on the support device. The patient support device must be incremented from a typical starting position to the maximum incremented distance or 30 cm, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment can be taken anywhere along this travel.

(ii) Additional requirements for CT systems integrated with virtual simulation features and linear accelerator capabilities (e.g., 3-D cone beam or modulation).

(I) QA procedures for the CT simulation system must be performed with an established protocol meeting or exceeding nationally recognized, published guidelines from a professional body with expertise in the use of therapeutic radiation technologies or manufacturer recommendations.

(II) QA procedures for the CT simulation system must be in writing, or documented in an electronic reporting system, by a licensed medical physicist with a specialty in therapeutic radiological physics.

(III) The electronic transfer of the treatment delivery parameters to the delivery system must be verified at the treatment location. The CT simulation treatment planning and the linear accelerator must interface accurately.

(iii) QA for CT simulation software.

(I) QA procedures for CT simulation software systems must be in writing, or documented in an electronic reporting system, by a licensed medical physicist with a specialty in therapeutic radiological physics.

(II) The protocol established must meet or exceed nationally recognized, published guidelines from a professional body with expertise in the use of therapeutic radiation technologies or manufacturer recommendations.

(III) The CT QA procedures must include:

(-a-) spatial/geometry accuracy tests;

(-b-) evaluation of digitally reconstructed radiographs; and

(-c-) periodic QA testing.

(IV) The electronic transfer of the treatment delivery parameters to the delivery system must be verified at the treatment location. The software for the CT simulation treatment planning computer and the linear accelerator must interface accurately.

(iv) Dose measurements of the radiation output of the CT system.

(I) Dose measurements must be completed as specified in §289.227(n)(3) of this chapter.

(II) Equipment performance evaluations (EPEs) must be completed as specified in §289.227(o) of this chapter.

(III) Records of dose measurements and EPEs specified in subclause (I) and (II) of this clause must be maintained by the registrant as specified in subsection (l) of this section for inspection by the department.

(D) A maintenance schedule must be developed as specified by the manufacturer. The schedule must include:

(i) dose measurements required by subparagraph (C)(iv) of this paragraph; and

(ii) acquisition of images obtained with phantoms using the same processing mode and CT conditions of operation as are used to perform dose measurements required by subparagraph (F) of this paragraph. The registrant must maintain either of the following as specified in subsection (l) of this section for inspection by the department:

(I) copies of the images obtained from the image display device; or

(II) images stored in digital form.

(E) Conventional radiation therapy simulation systems designed with x-ray or fluoroscopic capabilities.

(i) [~~(viii)~~] Film processing.

(I) Films must [~~shall~~] be developed according to [~~in accordance with~~] the time-temperature relationships recommended by the film manufacturer. The specified developer temperature for automatic processing and the time-temperature chart for manual processing must [~~shall~~] be posted in the darkroom. If the registrant determines an alternate time-temperature relationship is more appropriate for a specific facility, the [~~that~~] time-temperature relationship must [~~shall~~] be documented and posted.

(II) Chemicals must [~~shall~~] be replaced according to the chemical manufacturer's or supplier's recommendations or at an interval not to exceed three [~~3~~] months.

(III) Darkroom light leak tests must [~~shall~~] be performed and any light leaks corrected at intervals not to exceed six [~~6~~] months.

(IV) Lighting in the film processing and loading [~~processing/loading~~] area must [~~shall~~] be maintained with the filter, bulb wattage, and distances recommended by the film manufacturer for that film emulsion or with products providing [~~that provide~~] an equivalent level of protection against fogging.

(V) Corrections or repairs of the light leaks or other deficiencies in subclauses (II), (III), and (IV) of this clause must [~~shall~~] be initiated within 72 hours of discovery and completed no longer than 15 days from detection of the deficiency unless a longer time is authorized by the department [~~agency~~]. Records of the correction or repairs must [~~shall~~] include the date and initials of the person [~~individual~~] performing these functions and must [~~shall~~] be maintained as specified in [~~accordance with~~] subsection (l) of this section for inspection by the department [~~agency~~].

(VI) Documentation of the items in subclauses (II), (III), and (V) of this clause must [~~shall~~] be maintained at the site where performed and must [~~shall~~] include the date and initials of the person [~~individual~~] completing these items. These records must [~~shall~~] be kept as specified in [~~accordance with~~] subsection (l) of this section for inspection by the department [~~agency~~].

(ii) [~~(ix)~~] Alternative processing systems. Users of daylight processing systems, laser processors, self-processing film units, or other alternative processing systems must [~~shall~~] follow the manufacturer's recommendations for image processing. Documentation that the registrant is following the manufacturer's recommendations must [~~shall~~] include the date and initials of the person [~~individual~~] completing the document and must [~~shall~~] be maintained at the site where performed as specified in [~~accordance with~~] subsection (l) of this section for inspection by the department [~~agency~~].

(iii) [~~(x)~~] Digital imaging acquisition systems. Users of digital imaging acquisition systems must follow the QA [~~shall follow quality assurance/quality control~~] protocol for image processing established by the manufacturer or, if no manufacturer's protocol is available, by the registrant. The registrant must [~~shall~~] include the protocol, whether established by the registrant or the manufacturer, in its OSP [~~operating and safety procedures~~]. The registrant must [~~shall~~] document the frequency at which the QA [~~quality assurance/quality control~~] protocol is performed. Documentation must [~~shall~~] include the date and initials of the person [~~individual~~] completing the document and must [~~shall~~] be maintained at the site where performed as specified in [~~accordance with~~] subsection (l) of this section for inspection by the department [~~agency~~].

(F) [~~(B)~~] Additional requirements for conventional radiation therapy simulation systems [~~simulators~~] used in the general radiographic mode of operation for radiation therapy port documentation.

(i) Beam quality [~~(HVL)~~]. The half-value layer of the useful beam for a given x-ray tube potential must [~~shall~~] not be less than the values shown in [~~the following~~] Table IV. If it is necessary to determine such half-value layer at an x-ray tube potential [~~that is~~] not listed in Table IV, linear interpolation may be made.
Figure: 25 TAC §289.229(h)(5)(F)(i)
[~~Figure: 25 TAC §289.229(h)(4)(B)(i)~~]

(ii) Technique and exposure indicators.

(I) The technique factors to be used during an exposure must [~~shall~~] be indicated before the exposure begins except when automatic exposure controls are used, in which case the technique factors [~~that are~~] set before [~~prior to~~] the exposure must [~~shall~~] be indicated.

(II) The indicated technique factors must meet [~~shall be accurate to within~~] the manufacturer's specifications. If these specifications are not available from the manufacturer, the factors must [~~shall~~] be accurate to within plus or minus 10 percent [~~±10%~~] of the indicated setting.

(iii) Beam limitation.

(I) The beam limiting device (collimator) must [~~shall~~] restrict the useful beam to the area of clinical interest.

(II) A method must [~~shall~~] be provided to visually define the center (cross-hair centering) of the x-ray field to within a 2 mm diameter.

(III) A method must [~~shall~~] be provided to accurately indicate the distance to within 2 mm.

(IV) The delineator wires must [~~shall~~] be accurate with the indicated setting within 2 mm.

(V) The x-ray field must [~~shall~~] be congruent with the light field within 2 mm.

(iv) Timers. Means must [~~shall~~] be provided to terminate the exposure at a preset time interval, a preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it must [~~shall~~] not be possible to make an exposure when the timer is set to a "zero" or "off" position [~~if ei-~~

ther position is provided] and a visual and [and/or] audible signal must [shall] indicate when an exposure has been terminated.

(v) Automatic exposure control (AEC) [AEC]. When an AEC is provided, an indication must [shall] be made on the control panel when this mode of operation is selected.

(vi) Timer reproducibility. When all technique factors are held constant, including control panel selections associated with AEC systems, the coefficient of variation of exposure interval for both manual and AEC systems must [shall] not exceed 0.05. This requirement applies to clinically used techniques.

(vii) Exposure reproducibility. When all technique factors are held constant, including control panel selections associated with AEC systems, the coefficient of variation of exposure for both manual and AEC systems must [shall] not exceed 0.05. This requirement applies to clinically used techniques.

(viii) Linearity.

Figure: 25 TAC §289.229(h)(5)(F)(viii)

[Figure: 25 TAC §289.229(h)(4)(B)(viii)]

(G) [(C)] Additional requirements for radiation therapy simulation systems [simulators] utilizing fluoroscopic capabilities.

(i) X-ray production in the fluoroscopic mode must [shall] be controlled by a device requiring [that requires] continuous pressure by the fluoroscopist for the entire time of the exposure (continuous pressure type switch).

(ii) During fluoroscopy and cinefluorography, the kV and the Milliampere (mA) must [mA shall] be continuously indicated at the control panel and [and/or] the fluoroscopist's position.

(iii) The SSD must [shall] not be less than [the] 20 cm for image-intensified fluoroscopes used for examinations as specified in the registrant's OSP [operating and safety procedures]. The written OSP [operating and safety procedures] must [shall] provide precautionary measures to be adhered to during the use of this device. The procedures must [shall] provide information on the means to restore the unit to a 30 cm SSD when the unit is returned to general service.

(iv) Fluoroscopic timers must [shall] meet the following requirements.

(I) Means must [shall] be provided to preset the cumulative on-time of the fluoroscopic x-ray tube. The maximum cumulative time of the timing device must [shall] not exceed five [5] minutes without resetting.

(II) A signal audible to the fluoroscopist must [shall] indicate the completion of any preset cumulative on-time. The signal must [Such signal shall] continue to sound while x-rays are produced until the timing device is reset. In lieu of such a signal, the timer must [shall] terminate the beam after the preset cumulative on-time is completed.

(v) The exposure foot switch must [shall] be permanently mounted in the control booth to ensure [that] the operator cannot enter the simulator room while the fluoroscope is activated.

(vi) Radiation therapy simulation systems must [Simulators shall] duplicate the geometric conditions of the radiation therapy equipment plan, and therefore measurements regarding geometric conditions must [shall] be performed as specified in [accordance with] subsection (h)(3)(C)(iii)(I) of this section.

(vii) If the treatment-planning system is different from the treatment-delivery system, the accuracy of electronic transfer of the treatment-delivery parameters to the treatment-delivery unit must [shall] be verified at the treatment location.

[(D) Additional requirements for radiation therapy simulators utilizing CT capabilities. CT simulators producing digital images only are exempt from the requirements of this subparagraph and paragraph (h)(4)(A)(i), (viii), and (ix) of this subsection.]

[(i) Equipment requirements.]

[(I) Tomographic systems shall meet the following requirements.]

[(-a-) For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.]

[(-b-) For any multiple tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.]

[(-c-) If a device using a light source is used to satisfy the requirements of item (-a-) or (-b-) of this subclause, the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.]

[(II) The CT x-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence are indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions shall be visible from any position from which scan initiation is possible.]

[(III) The x-ray control and gantry shall provide visual indication whenever x rays are produced and, if applicable, whether the shutter is open or closed.]

[(IV) Means shall be provided to require operator initiation of each individual scan or series of scans.]

[(V) All emergency buttons/switches shall be clearly labeled as to their functions.]

[(VI) Termination of exposure shall be as follows.]

[(-a-) Means shall be provided to terminate the x-ray exposure automatically by either de-energizing the x-ray source or shuttering the x-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110% of its preset value through the use of either a backup timer or devices that monitor equipment function.]

[(-b-) A signal visible to the operator shall indicate when the x-ray exposure has been terminated through the means required by item (-a-) of this subclause.]

[(-c-) The operator shall be able to terminate the x-ray exposure at any time during a scan or series of scans under CT x-ray system control, of greater than 0.5 second duration. Termination of the x-ray exposure shall necessitate resetting of the CT conditions of operation prior to initiation of another scan.]

[(VII) CT x-ray systems containing a gantry manufactured after September 3, 1985, shall meet the following requirements.]

[(-a-) The total error in the indicated location of the tomographic plane or reference plane shall not exceed 5 mm.]

[(-b-) If the x-ray production period is less than 0.5 second, the indication of x-ray production shall be actuated for at least 0.5 second. Indicators at or near the gantry shall be dis-

cernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.]

[(-c-) The deviation of indicated scan increment versus actual increment shall not exceed ±1 mm with any mass from 0 to 100 kilograms (kg) resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 cm, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment can be taken anywhere along this travel.]

[(ii) Facility design requirements.]

[(I) Provision shall be made for two-way aural communication between the patient and the operator at the control panel.]

[(II) Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the console.]

[(-a-) Should the viewing system described in subclause (II) of this clause fail or be inoperative, treatment shall not be performed with the unit until the system is restored.]

[(-b-) In a facility that has a primary viewing system by electronic means and an alternate viewing system, should both viewing systems described in subclause (II) of this clause fail or be inoperative, treatment shall not be performed with the unit until 1 of the systems is restored.]

[(iii) Dose measurements of the radiation output of the CT x-ray system.]

[(I) Dose measurements of the radiation output of the CT x-ray system shall be performed by a licensed medical physicist with a specialty in diagnostic radiological physics. If the CT system is used for simulation purposes only, the following requirements do not apply. If the unit is also used for diagnostic procedures, the measurements shall be performed as follows:]

[(-a-) within 30 days after installation and thereafter, at intervals not to exceed 14 months;]

[(-b-) when major maintenance that could affect radiation output is performed; or]

[(-c-) when a major change in equipment operation (e.g. introduction of a new software package) is accomplished.]

[(II) Measurements of the radiation output of a CT x-ray system shall be performed with a calibrated dosimetry system. The dosimetry system calibration shall be traceable to a national standard. The calibration interval shall not exceed 24 months.]

[(III) Records of dose measurements specified in clause (iii) of this subparagraph shall be maintained by the registrant in accordance with subsection (l) of this section for inspection by the agency.]

[(iv) A maintenance schedule shall be developed in accordance with the manufacturer's United States Department of Health and Human Services maintenance schedule. The schedule shall include, but need not be limited to the following:]

[(I) dose measurements required by clause (iii)(I) of this subparagraph; and]

[(II) acquisition of images obtained with phantoms using the same processing mode and CT conditions of operation as are used to perform dose measurements required by clause (iii)(I) of this subparagraph. The registrant shall retain either of the following in accordance with subsection (l) of this section for inspection by the agency:]

[(-a-) photographic copies of the images obtained from the image display device; or]

[(-b-) images stored in digital form.]

(i) Medical events [(misadministrations)].

(1) Medical events involving equipment operating at energies below 1 MeV and EBT [electronic brachytherapy] devices[,] must [shall] be reported when:

(A) the event involves the wrong individual, or the wrong treatment site;

(B) the treatment consists of three [3] or fewer fractions, and the calculated total administered dose differs from the total prescribed dose by more than 10 percent [10% of the total prescribed dose]; or

(C) the calculated total administered dose differs from the total prescribed dose by more than 20 percent [20% of the total prescribed dose].

(2) Medical events involving equipment operating with energies of 1 MeV and above must [shall] be reported when:

(A) the event involves the wrong individual, wrong type of radiation, wrong energy, or wrong treatment site;

(B) the treatment consists of three [3] or fewer fractions, and the calculated total administered dose differs from the total prescribed dose by more than 10 percent [10% of the total prescribed dose];

(C) the calculated total administered dose differs from the total prescribed dose by more than 20 percent [20% of the total prescribed dose]; or

(D) the combination of external beam radiation therapy and radioactive material therapy causes over-radiation of a patient resulting in physical injury or death.

(j) Reports of medical events [(misadministrations)].

(1) For a medical event, a registrant must [shall] do the following:

(A) notify the department [agency] by telephone no later than 24 hours after the discovery of the event;

(B) notify the referring physician and [also notify] the patient of the event no later than 24 hours after its discovery, unless the referring physician personally informs the registrant that either the referring physician [that he or she] will inform the patient or that [,] based on medical judgment [judgement], telling the patient would be harmful. The registrant is not required to notify the patient without first consulting the referring physician. If the referring physician or patient cannot be reached within 24 hours, the registrant must [shall] notify the patient as soon as possible [thereafter]. The registrant may not delay any appropriate medical care for the patient, including any necessary remedial care as a result of the event, because of any delay in notification;

(C) submit a written report to the department [agency] within 15 days after the discovery of the event. The report must [shall] not include the patient's name or other information that could lead to the identification of the patient. The written report must [shall] include the following:

(i) registrant's name and certificate of registration number;

(ii) prescribing physician's name;

(iii) a brief description of the event;

(iv) why the event occurred;

(v) the effect on the patient;

(vi) what improvements are needed to prevent recurrence;

(vii) actions taken to prevent recurrence;

(viii) whether the registrant notified the patient, or the patient's responsible relative or guardian (this person will be subsequently referred to as "the patient"); and if not, why not; and

(ix) if the patient was notified, what information was provided to the patient; and

(D) furnish the following to the patient within 15 days after discovery of the event if the patient was notified:

(i) a copy of the report that was submitted to the department [~~agency~~]; or

(ii) a brief description of both the event and the consequences, as they may affect the patient, provided a statement is included that the report submitted to the department [~~agency~~] can be obtained from the registrant.

(2) Each registrant must [~~shall~~] retain a record of each event as specified in [~~accordance with~~] subsection (l) of this section for inspection by the department [~~agency~~]. The record must [~~shall~~] contain the following:

(A) the names of all [~~individuals~~] involved (including the prescribing physician, allied health personnel, the patient, and the patient's referring physician);

(B) the patient's identification number;

(C) a brief description of the event;

(D) why it occurred;

(E) the effect on the patient;

(F) what improvements are needed to prevent recurrence; and

(G) the actions taken to prevent a recurrence.

(3) Aside from the notification requirement, nothing in subsection (i) of this section and paragraphs (1) and (2) of this subsection affects [~~shall affect~~] any rights or duties of registrants, and physicians in relation to each other, patients, or the patient's responsible relatives or guardians.

(k) Emerging and future technologies.

(1) Each registrant must develop, implement, and maintain a dedicated quality management program to control the process of administering therapeutic radiation with newly acquired FDA-cleared emerging technologies or previously unused features of a future technology system.

(2) Implementation and ongoing clinical use of the technology dated before the technology arrives at the facility or the new features are used must include:

(A) an explicit strategy to ensure the quality of processes and patient safety; and

(B) an approval from facility management and the radiation oncology safety team before the technology arrives or new features are used.

(3) The radiation oncology safety team must develop the quality management program.

(4) The quality management program must address, at a minimum:

(A) education and training about the new technology and features;

(B) a system and timeline for ongoing competency assessment;

(C) a system for real-time recording of ongoing issues related to the technology and clinical use of the new technology or features;

(D) a strategy for timely investigation and adjudication of accidents and process deviations that may be captured in the system developed in paragraph (2) of this subsection;

(E) a strategy for routine review at intervals not to exceed 12 months of the clinical use of the new technology and features, which includes an assessment of the current use compared to paragraph (2) of this subsection and plan to either update the clinical use plan or steps to bring the clinical use back into alignment with paragraph (2) of this subsection;

(F) a strategy to ensure the quality of equipment functions; and

(G) an explicit strategy for ensuring quality after hardware and software updates and after equipment repair.

(5) The quality management program must follow current published recommendations from a recognized national professional association with expertise in therapeutic radiation technologies. In the absence of a protocol published by a national professional association, the manufacturer's protocol or equivalent quality, safety, and security protocol must be followed.

(6) New technology issues must be reported to the manufacturer and the department, and be reviewed and addressed via the registrant's reporting system.

[~~(k) Additional requirements for electronic brachytherapy devices.~~]

[~~(1) Technical requirements for electronic brachytherapy devices.~~]

[~~(A) The timer shall:~~]

[~~(i)~~ ~~have a display provided at the treatment control panel and a pre-set time selector;~~]

[~~(ii)~~ ~~activate with the production of radiation and retain its reading after irradiation is interrupted. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to zero;~~]

[~~(iii)~~ ~~terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system present has not previously terminated irradiation;~~]

[~~(iv)~~ ~~permit selection of exposure times as short as 1 second;~~]

[~~(v)~~ ~~not permit an exposure if set at zero; and~~]

[~~(vi)~~ ~~be accurate to within 1.0% of the selected value or 1 second, whichever is greater.~~]

[~~(B) The control panel, in addition to the displays required in subparagraph (A) of this paragraph, shall have the following:~~]

[(i) an indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible;]

[(ii) means for indicating x-rays are being produced;]

[(iii) means for indicating x-ray tube potential and current; and]

[(iv) means for terminating an exposure at any time.]

[(C) All emergency buttons/switches shall be clearly labeled as to their functions.]

[(2) Surveys, calibrations, and spot checks.]

[(A) Surveys shall be performed as follows.]

[(i) All facilities having electronic brachytherapy device(s) shall have an initial survey made by a licensed medical physicist, with a specialty in therapeutic radiological physics, who shall provide a written report of the survey to the registrant. Additional surveys shall be done as follows:]

[(I) when making any change in the portable shielding;]

[(II) when making any change in the location where the electronic brachytherapy device is used within the treatment room; and]

[(III) when relocating the electronic therapy device.]

[(ii) The registrant shall maintain a copy of the initial survey report and all subsequent survey reports in accordance with subsection (l) of this section for inspection by the agency.]

[(iii) The survey report shall indicate all instances where the installation is in violation of applicable requirements of this chapter.]

[(B) Calibrations shall be performed as follows.]

[(i) Calibration procedures shall be in writing, or documented in an electronic reporting system, and shall have been developed by a licensed medical physicist with a specialty in therapeutic radiological physics.]

[(ii) The registrant shall make calibration measurements required by this section in accordance with any current recommendations from a recognized, national professional association (such as the American Association of Physicists in Medicine Report Number 152) for electronic brachytherapy, when available. Equivalent alternative methods are acceptable. In the absence of a protocol by a national professional association, published protocol included in the device manufacturer operator's manual should be followed.]

[(iii) The calibration of the electronic brachytherapy device shall be performed after change of the x-ray tube or replacement of components that could cause a change in the radiation output. The calibrations shall be such that the dose at a reference point in water or plastic phantom can be calculated to within an uncertainty of 5.0%.]

[(iv) The calibration of the radiation output of the electronic brachytherapy device shall be performed by a licensed medical physicist with a specialty in therapeutic radiological physics who is physically present at the facility during such calibration.]

[(v) The calibration of the therapeutic electronic brachytherapy device shall include verification that the electronic brachytherapy device is operating in compliance with the design specifications.]

[(vi) Calibration of the radiation output of the electronic brachytherapy device shall be performed with a calibrated dosimetry system. The dosimetry calibration shall be traceable to a national standard. The calibration interval shall not exceed 24 months.]

[(vii) Records of calibration measurements shall be maintained by the registrant in accordance with subsection (l) of this section for inspection by the agency.]

[(viii) A copy of the latest calibrated absorbed dose rate measured on the electronic brachytherapy device shall be available at a designated area within the therapy facility housing the electronic brachytherapy device.]

[(C) Spot check procedures.]

[(i) Spot check procedures shall be in writing, or documented in an electronic reporting system, and shall have been developed by a licensed medical physicist with a specialty in therapeutic radiological physics.]

[(ii) If a licensed medical physicist does not perform the spot check measurements, the results of the spot check measurements shall be reviewed by a licensed medical physicist with a specialty in therapeutic radiological physics within 2 treatment days and a record made of the review.]

[(iii) The written spot check procedures shall specify the operating instructions that shall be carried out whenever a parameter exceeds an acceptable tolerance as established by the licensed medical physicist.]

[(iv) The certified physician or licensed medical physicist shall prevent the clinical use of a malfunctioning device until the malfunction identified in the spot check has been evaluated and corrected or, if necessary, the equipment repaired.]

[(v) Records of the written spot checks and any necessary corrective actions shall be maintained by the registrant in accordance with subsection (l) of this section for inspection by the agency. A copy of the most recent spot check shall be available at a designated area within the therapy facility housing that therapeutic radiation system.]

[(vi) Spot checks shall be obtained using a dosimetry system satisfying the requirements of subparagraph (B)(vi) of this paragraph.]

(l) Records for department [agency] inspection. The registrant must [shall] maintain the following records at the time intervals specified, for inspection by the department [agency]. The records may be maintained in electronic format.

Figure: 25 TAC §289.229(l)

[Figure: 25 TAC §289.229(l)]

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on May 29, 2024.

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Cynthia Hernandez
General Counsel
Department of State Health Services
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For further information, please call: (512) 834-6655

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TITLE 26. HEALTH AND HUMAN SERVICES

PART 1. HEALTH AND HUMAN SERVICES COMMISSION

CHAPTER 506. SPECIAL CARE FACILITIES
SUBCHAPTER C. OPERATIONAL REQUIREMENTS

26 TAC §506.40

The Executive Commissioner of the Texas Health and Human Services Commission (HHSC) proposes new §506.40, concerning Advance Directives Reporting Requirements.

BACKGROUND AND PURPOSE

The purpose of the proposal is to implement House Bill (H.B.) 3162, 88th Legislature, Regular Session, 2023. H.B. 3162 amended Texas Health and Safety Code (HSC) Chapter 166 Subchapters B and E and HSC Chapter 313.

HSC §166.046, as amended by H.B. 3162, in part requires a facility's ethics or medical committee to review a physician's refusal to honor an advance directive or health care or treatment decision made by or on behalf of a patient determined to be incompetent or otherwise mentally or physically incapable of communication. Amended HSC §166.046 also requires the facility to provide a written notice to the person responsible for the patient's health care decisions that the facility's ethics or medical committee will meet at least seven days later to review the physician's refusal to honor the patient's advanced directive or health care treatment decision.

HSC §166.054, as added by H.B. 3162, requires health care facilities to report certain information to HHSC within 180 days after the health care facility provides the written notice required under HSC §166.046. New HSC §166.054 also requires HHSC to adopt rules for reporting, protecting, and aggregating this information.

SECTION-BY-SECTION SUMMARY

Proposed new §506.40(a) ensures consistency with amended HSC §166.054 by requiring a facility to complete and submit the Ethics or Medical Committee Reporting Form to HHSC after the facility provides the written notice required under HSC §166.046(b)(1) and describes the information collected in the form.

New subsection (b) describes the process of publishing the aggregate report.

New subsection (c) provides how the information in the forms may not be used.

FISCAL NOTE

Trey Wood, HHSC Chief Financial Officer, has determined that for each year of the first five years that the rule will be in effect, enforcing or administering the rule does not have foreseeable implications relating to costs or revenues of state or local governments.

GOVERNMENT GROWTH IMPACT STATEMENT

HHSC has determined that during the first five years that the rule will be in effect:

(1) the proposed rule will not create or eliminate a government program;

(2) implementation of the proposed rule will not affect the number of HHSC employee positions;

(3) implementation of the proposed rule will result in no assumed change in future legislative appropriations;

(4) the proposed rule will not affect fees paid to HHSC;

(5) the proposed rule will create a new regulation;

(6) the proposed rule will not expand existing regulations;

(7) the proposed rule will not change the number of individuals subject to the rule; and

(8) the proposed rule will not affect the state's economy.

SMALL BUSINESS, MICRO-BUSINESS, AND RURAL COMMUNITY IMPACT ANALYSIS

Trey Wood has also determined that there will be no adverse economic effect on small businesses, micro-businesses, or rural communities because the proposed rule does not impose a cost or require small businesses, micro-businesses, or rural communities to alter their current business practices.

LOCAL EMPLOYMENT IMPACT

The proposed rule will not affect a local economy.

COSTS TO REGULATED PERSONS

Texas Government Code §2001.0045 does not apply to this rule because the rule does not impose a cost on regulated persons and is necessary to implement legislation that does not specifically state that §2001.0045 applies to the rule.

PUBLIC BENEFIT AND COSTS

Stephen Pahl, Deputy Executive Commissioner for Regulatory Services, has determined that for each year of the first five years the rule is in effect, the public will benefit from increased consistency between the special care facility rules and new statutory requirements for advanced directives.

Trey Wood has also determined that for the first five years the rule is in effect, there are no anticipated economic costs to persons who are required to comply with the proposed rule because the rule does not require persons subject to the rules to alter their current business practices; these entities are required to comply with the law as added by H.B. 3162 and the proposed new section only ensures consistency with current statutory requirements and codifies the name of the reporting form in rule.

TAKINGS IMPACT ASSESSMENT

HHSC has determined that the proposal does not restrict or limit an owner's right to the owner's property that would otherwise exist in the absence of government action and, therefore, does not constitute a taking under Texas Government Code §2007.043.

PUBLIC COMMENT

Written comments on the proposal may be submitted to Rules Coordination Office, P.O. Box 13247, Mail Code 4102, Austin,

Texas 78711-3247, or street address 701 W. 51st Street, Austin, Texas 78751; or emailed to HCR_PRU@hhs.texas.gov.

To be considered, comments must be submitted no later than 31 days after the date of this issue of the *Texas Register.* Comments must be (1) postmarked or shipped before the last day of the comment period; (2) hand-delivered before 5:00 p.m. on the last working day of the comment period; or (3) emailed before midnight on the last day of the comment period. If the last day to submit comments falls on a holiday, comments must be postmarked, shipped, or emailed before midnight on the following business day to be accepted. When emailing comments, please indicate "Comments on Proposed Rule 24R003" in the subject line.

STATUTORY AUTHORITY

The new section is authorized by Texas Government Code §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of services by the health and human services agencies; HSC §248.006, which requires HHSC to adopt rules establishing minimum standards for special care facilities; and HSC §166.054, which requires HHSC to adopt rules to establish a standard form for the requirements for reporting meetings of an ethics or medical committee meeting to review a physician's refusal to honor an advance directive of or health care or treatment decision made by or on behalf of a patient who is determined to be incompetent or is otherwise mentally or physically incapable of communication and to protect and aggregate any information HHSC receives under this section.

The new section implements Texas Government Code §531.0055 and HSC §166.046, §166.0465, §166.052, and §166.054.

§506.40. Advance Directives Reporting Requirements.

(a) Pursuant to Texas Health and Safety Code (HSC) §166.054, a facility shall complete and submit to the Texas Health and Human Services Commission (HHSC) the Ethics or Medical Committee Reporting Form, which is located on the Texas HHSC website, no later than the 180th day after the facility delivers the written notice required under HSC §166.046(b)(1). The Ethics or Medical Committee Reporting Form collects the following information:

(1) the number of days that elapsed from the patient's admission to the facility to the date notice was provided under HSC §166.046(b)(1);

(2) whether the ethics or medical committee met to review the case under HSC §166.046 and, if the committee did meet, the number of days that elapsed from the date notice was provided under HSC §166.046(b)(1) to the date the meeting was held;

(3) whether the patient was:

(A) transferred to a physician within the same facility who was willing to comply with the patient's advance directive or a health care or treatment decision made by or on behalf of the patient;

(B) transferred to a different health care facility; or

(C) discharged from the facility to a private residence or other setting that is not a health care facility;

(4) whether the patient died while receiving life-sustaining treatment at the facility;

(5) whether life-sustaining treatment was withheld or withdrawn from the patient at the facility after expiration of the time period described by HSC §166.046(e) and, if so, the disposition of the patient after the withholding or withdrawal of life-sustaining treatment at the facility, as selected from the following categories:

(A) the patient died at the facility;

(B) the patient is currently a patient at the facility;

(C) the patient was transferred to a different health care facility; or

(D) the patient was discharged from the facility to a private residence or other setting that is not a health care facility;

(6) the age group of the patient selected from the following categories:

(A) 17 years of age or younger;

(B) 18 years of age or older and younger than 66 years of age; or

(C) 66 years of age or older;

(7) the health insurance coverage status of the patient selected from the following categories:

(A) private health insurance coverage;

(B) public health plan coverage; or

(C) uninsured;

(8) the patient's sex;

(9) the patient's race;

(10) whether the facility was notified of and able to reasonably verify any public disclosure of the contact information for the facility's personnel, physicians or health care professionals who provide care at the facility, or members of the ethics or medical committee in connection with the patient's stay at the facility; and

(11) whether the facility was notified of and able to reasonably verify any public disclosure by facility personnel of the contact information for the patient's immediate family members or the person responsible for the patient's health care decisions in connection with the patient's stay at the facility.

(b) In accordance with HSC §166.054(c)-(e), HHSC publishes on its website an aggregate report of information submitted under subsection (a) of this section in the preceding year by April 1 of each year.

(c) Pursuant to HSC §166.054(g), information collected or submitted under subsection (a) of this section:

(1) is not admissible in a civil or criminal proceeding in which a physician, health care professional acting under the direction of a physician, or health care facility is a defendant;

(2) may not be used in relation to any disciplinary action by a licensing or regulatory agency with oversight over a physician, health care professional acting under the direction of a physician, or health care facility; and

(3) is not public information or subject to disclosure under Texas Government Code Chapter 552, except as permitted by Texas Government Code §552.008.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on May 29, 2024.

TRD-202402385

Karen Ray
Chief Counsel
Health and Human Services Commission
Earliest possible date of adoption: July 14, 2024
For further information, please call: (512) 834-4591

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CHAPTER 550. LICENSING STANDARDS FOR PRESCRIBED PEDIATRIC EXTENDED CARE CENTERS

The Executive Commissioner of the Texas Health and Human Services Commission (HHSC) proposes amendments to §§550.1, 550.5, 550.101 - 550.106, 550.108 - 550.115, 550.118 - 550.123, 550.202, 550.203, 550.205 - 550.207, 550.210, 550.211, 550.301, 550.303 - 550.306, 550.308 - 550.311, 550.402 - 550.406, 550.409 - 550.411, 550.413, 550.415, 550.417, 550.418, 550.504, 550.506 - 550.508, 550.510, 550.511, 550.601 - 550.608, 550.701, 550.703, 550.705, 550.707, 550.802, 550.803, 550.901 - 550.906, 550.1001 - 550.1003, 550.1101, 550.1102, 550.1202 - 550.1204, 550.1206, 550.1207, 550.1211, 550.1215, 550.1217 - 550.1220, 550.1222, 550.1224, 550.1301 - 550.1305, and 550.1401 - 550.1408.

BACKGROUND AND PURPOSE

The purpose of this proposal is to implement provisions of House Bill (H.B.) 1009 and H.B. 3550 from the 88th Legislature, Regular Session, 2023, that apply to Prescribed Pediatric Extended Care Centers (PPECC). H.B. 1009 requires a facility to suspend an employee who has been found by HHSC to have engaged in reportable conduct for purposes of inclusion on the Employee Misconduct Registry during any appeals. H.B. 3550 establishes minimum standards for transportation services whereby a center coordinates the schedule of transportation services with a minor's parent, guardian, or other legally authorized representative; determines what type of provider needs to be present during transportation; and permits a minor's parent, guardian, or other legally authorized representative to decline a center's transportation services entirely or only on a specific date. The proposed rules also set forth that a center may not require a plan of care or physician's order to document a minor's need for transportation services to access PPECC services or consider transportation services as nursing services in a minor's plan of care. In addition, the proposed rules update terminology and references and reflect current processes.

SECTION-BY-SECTION SUMMARY

Proposed amendments throughout the chapter update citations and references and restructure sentences to use active voice. Proposed amendments throughout the chapter replace "facility" with "center" for consistency.

The proposed amendment to §550.1, Purpose, replaces references to DADS and updates wording for better understanding.

The proposed amendment to §550.5, Definitions, corrects capitalization errors, deletes definitions made obsolete by organizational changes, corrects numbering changed by the deletion of obsolete definitions, updates the definition for "center," and adds a definition for "online portal." It also defines "immediate threat to the health or safety of a minor."

The proposed amendment to §550.101, Criteria and Eligibility for a License, updates outdated agency references.

The proposed amendment to §550.102, General Application Requirements, updates outdated references to DADS and Texas Administrative Code (TAC), Title 40 §15, and updates processes.

The proposed amendment to §550.103, Building Approval, updates outdated references to DADS and updates processes.

The proposed amendment to §550.104, Applicant Disclosure Requirements, updates outdated references to DADS and updates processes.

The proposed amendment to §550.105, Initial License Application Procedures and Issuance, updates outdated references to 40 TAC §15, updates processes, and deletes obsolete portions of the processes.

The proposed amendment to §550.106, Renewal License Application Procedures and Issuance, updates outdated references to 40 TAC §15, updates processes, and deletes obsolete portions of the processes.

The proposed amendment to §550.108, Change of Ownership License Application Procedures and Issuance and Notice of Changes, adds language to clarify processes.

The proposed amendment to §550.109, Increase in Capacity, updates outdated references to DADS and 40 TAC §15 and updates processes.

The proposed amendment to §550.110, Decrease in Capacity, updates processes.

The proposed amendment to §550.111, Relocation, updates outdated references to DADS and 40 TAC §15, updates processes, and deletes obsolete portions of the processes.

The proposed amendment to §550.112, Licensing Fees, updates outdated references to 40 TAC §15.

The proposed amendment to §550.113, Plan Review Fees, updates outdated references to DADS.

The proposed amendment to §550.114, Time Periods for Processing All Types of License Applications, updates outdated references to DADS and 40 TAC §15, updates processes, and deletes obsolete portions of the processes.

The proposed amendment to §550.115, Criteria for Denial of a License, updates outdated references to DADS and 40 TAC §15, updates processes, and deletes obsolete portions of the processes.

The proposed amendment to §550.118, Reporting Changes in Application Information, updates outdated references to DADS and 40 TAC §15 and updates processes.

The proposed amendment to §550.119, Notification Procedures for a Change in Administration and Management, updates outdated references to DADS and updates processes.

The proposed amendment to §550.120, Notification Procedures for a Change of Contact Information, updates processes.

The proposed amendment to §550.121, Notification Procedures for a Change in Operating Hours, updates outdated references to DADS and updates processes.

The proposed amendment to §550.122, Notification Procedures for a Name Change, updates outdated references to DADS and 40 TAC §15 and updates processes.

The proposed amendment to §550.123, Request and Issuance of Temporary License, updates outdated references to DADS and 40 TAC §15 and updates processes.

The proposed amendment to §550.202, Suspension of Operations, updates outdated references to DADS and 40 TAC §15 and updates processes.

The proposed amendment to §550.203, Financial Solvency and Business Records, updates outdated references to DADS.

The proposed amendment to §550.205, Safety Provisions, makes clarifying edits and updates outdated references to DADS.

The proposed amendment to §550.206, Person-Centered Direction and Guidance, updates an outdated reference to DADS.

The proposed amendment to §550.207, Protective Devices and Restraints, makes clarifying edits and updates outdated references to 40 TAC §15.

The proposed amendment to §550.210, Sanitation, Housekeeping, and Linens, makes clarifying edits.

The proposed amendment to §550.211, Infection Prevention and Control Program and Vaccinations Requirements, clarifies references.

The proposed amendment to §550.301, License Holder's Responsibilities, updates outdated references to DADS and 40 TAC §15 and §99 and clarifies processes.

The proposed amendment to §550.303, Administrator and Alternate Administrator Qualifications and Conditions, updates outdated references to 40 TAC §15 and §99 and clarifies wording.

The proposed amendment to §550.304, Administrator Responsibilities, updates outdated references to 40 TAC §15 and updates processes.

The proposed amendment to §550.305, Initial Training in Administration, updates outdated references to DADS and 40 TAC §15 and makes minor edits to improve readability.

The proposed amendment to §550.306, Continuing Training in Administration, updates outdated references to DADS and 40 TAC §15.

The proposed amendment to §550.308, Medical Director Responsibilities, updates an outdated reference to 40 TAC §15.

The proposed amendment to §550.309, Nursing Director and Alternate Nursing Director Qualifications and Conditions, makes edits for clarity and consistency.

The proposed amendment to §550.310, Nursing Director Responsibilities and Supervision Responsibilities, updates outdated references to 40 TAC §15.

The proposed amendment to §550.311, Prohibition of Solicitation, updates an outdated reference to DADS.

The proposed amendment to §550.402, Registered Nurse Qualifications, corrects a medical term and updates outdated references to 40 TAC §15.

The proposed amendment to §550.403, Registered Nurse Responsibilities, updates wording for active voice and renumbers accordingly.

The proposed amendment to §550.404, Licensed Vocational Nurse Qualifications, updates outdated references to 40 TAC §15 and corrects a spelling mistake.

The proposed amendment to §550.405, Licensed Vocational Nurse Responsibilities, updates wording for active voice and renumbers accordingly.

The proposed amendment to §550.406, Student Nurses, updates outdated references to 40 TAC §15.

The proposed amendment to §550.409, Direct Care Staff Qualifications, updates outdated references to 40 TAC §15 and corrects a medical term.

The proposed amendment to §550.410, Nursing Services Staffing Ratio, updates outdated references to 40 TAC §15, renames the figure, and deletes an inaccurate sentence.

The proposed amendment to §550.411, Rehabilitative and Ancillary Professional Staff and Qualifications, updates wording for active voice.

The proposed amendment to §550.413, Contractors, updates outdated references to 40 TAC §15 and DADS.

The proposed amendment to §550.415, Staffing Policies for Staff Orientation, Development, and Training, updates outdated references to 40 TAC §15 and corrects grammatical errors.

The proposed amendment to §550.417, Personnel Records, updates outdated references to 40 TAC §15.

The proposed amendment to §550.418, Criminal History Checks, Nurse Aide Registry (NAR), and Employee Misconduct Registry (EMR) Requirements, updates the section title and outdated references to DADS, replaces acronyms with proper names, updates a process, and implements H.B. 1009 by requiring a facility to suspend an employee HHSC has found to have engaged in reportable conduct and placed on the EMR and to maintain that suspension during any appeals process.

The proposed amendment to §550.504, Psychosocial Treatment and Services, updates outdated references to 40 TAC §15.

The proposed amendment to §550.506, Rehabilitative Services, updates an outdated reference to 40 TAC §15.

The proposed amendment to §550.507, Functional Developmental Services, corrects a reference.

The proposed amendment to §550.508, Educational Developmental Services, moves an acronym definition and updates an outdated United States Code reference.

The proposed amendment to §550.510, Nutritional Counseling, updates an outdated reference to 40 TAC §15.

The proposed amendment to §550.511, Dietary Services, updates outdated references to 40 TAC §15 and updates the agency name.

The proposed amendment to §550.601, Admission Criteria, adds detail to who can consent admission to a center and updates an outdated reference to 40 TAC §15.

The proposed amendment to §550.602, Pre-admission Conference, updates an outdated reference to 40 TAC §15 and clarifies wording.

The proposed amendment to §550.603, Agreement and Disclosure, updates outdated references to 40 TAC §15, corrects grammatical errors, updates the agency name, and adds wording for clarity.

The proposed amendment to §550.604, Admission Procedures, updates an outdated reference to 40 TAC §15.

The proposed amendment to §550.605, Initial and Updated Comprehensive Assessment, adds language for clarity and corrects grammatical errors.

The proposed amendment to §550.606, Interdisciplinary Team, updates an outdated reference to 40 TAC §15.

The proposed amendment to §550.607, Initial and Updated Plan of Care, corrects grammatical errors.

The proposed amendment to §550.608, Discharge or Transfer Notification, updates an outdated reference to 40 TAC §15 and replaces a word for clarity.

The proposed amendment to §550.701, Physician Orders, corrects a grammatical error.

The proposed amendment to §550.703, Pharmacist Services, updates outdated references to 40 TAC §15.

The proposed amendment to §550.705, Administration of Medication, adds a word for clarity.

The proposed amendment to §550.707, Disposal of Special or Medical Waste, updates the agency name and a reference.

The proposed amendment to §550.802, Coordination of Services, updates wording for active voice.

The proposed amendment to §550.803, Census, updates outdated references to DADS.

The proposed amendment to §550.901, Rights and Responsibilities, updates outdated references to 40 TAC §15 and DADS, updates processes, and corrects a grammatical error.

The proposed amendment to §550.902, Advance Directives, updates an outdated reference to DADS and replaces a word for clarity.

The proposed amendment to §550.903, Abuse, Neglect, or Exploitation Reportable to DADS, updates the section title and outdated references to DADS, corrects a grammatical error, and updates processes.

The proposed amendment to §550.904, Investigations of a Complaint and Grievance, updates an outdated reference to DADS.

The proposed amendment to §550.905, Reporting of a Minor's Death, updates outdated references to DADS.

The proposed amendment to §550.906, Examination of Inspection Results, updates an outdated reference to DADS.

The proposed amendment to §550.1001, Medical Records, updates outdated references to 40 TAC §15, corrects grammatical errors, and rewords language for clarity.

The proposed amendment to §550.1002, Quality Assessment and Performance Improvement, updates an outdated reference to DADS and replaces an acronym with a proper name.

The proposed amendment to §550.1003, Dissolution, updates an outdated reference to 40 TAC §15.

The proposed amendment to §550.1101, Transportation Services, implements H.B. 3550 by clarifying which staff accompany minors during transportation and how that is determined.

The proposed amendment to §550.1102, Transportation Safety Provisions, implements H.B. 3550 by clarifying which staff accompany minors during transportation and how that is determined and replaces a proper name with an acronym.

The proposed amendment to §550.1202, Plan Reviews, updates outdated references to DADS and 40 TAC §15, rewords language for clarity, and corrects a grammatical error.

The proposed amendment to §550.1203, Design Criteria, updates outdated references to DADS.

The proposed amendment to §550.1204, Fire Safety, updates outdated references to DADS and replaces an acronym with a proper name.

The proposed amendment to §550.1206, Exterior Spaces, updates an outdated reference to DADS.

The proposed amendment to §550.1207, Interior Spaces, updates an outdated reference to 40 TAC §15.

The proposed amendment to §550.1211, Linen Storage, updates outdated references to 40 TAC §15.

The proposed amendment to §550.1215, Garbage, updates an outdated reference to 40 TAC §15.

The proposed amendment to §550.1217, Laundry, updates an outdated reference to 40 TAC §15.

The proposed amendment to §550.1218, Housekeeping, updates outdated references to 40 TAC §15 and corrects a typo.

The proposed amendment to §550.1219, Maintenance, updates an outdated reference to 40 TAC §15.

The proposed amendment to §550.1220, Heating, Ventilation, Air Conditioning (HVAC), updates the section title, replaces an acronym with a proper name, and adds a word for clarity.

The proposed amendment to §550.1222, Sewage, updates an outdated reference to 40 TAC §15.

The proposed amendment to §550.1224, Waivers, updates outdated references to DADS.

The proposed amendment to §550.1301, Inspections and Visits, updates outdated references to DADS.

The proposed amendment to §550.1302, Investigation of Complaints and Self-Reported Incidents, updates outdated references to DADS.

The proposed amendment to §550.1303, Cooperation with an Inspection and Visit, updates outdated references to DADS and adds subsections to clarify requirements and limitations for a center recording HHSC staff.

The proposed amendment to §550.1304, Staff Requirements for an Inspection, updates outdated references to DADS and to 40 TAC §15.

The proposed amendment to §550.1305, General Provisions, updates outdated references to DADS, adds an acronym, corrects a grammatical error, and adds wording for clarity.

The proposed amendment to §550.1401, Denial of License Application, updates outdated references to DADS and 40 TAC §15.

The proposed amendment to §550.1402, License Suspension, updates outdated references to DADS, 40 TAC §15, and 26 TAC §99.

The proposed amendment to §550.1403, Emergency License Suspension, updates outdated references to DADS and corrects grammatical errors.

The proposed amendment to §550.1404, License Revocation, updates outdated references to DADS, 40 TAC §15, and 26 TAC §99, and replaces a proper name with an acronym.

The proposed amendment to §550.1405, Probation, updates outdated references to DADS.

The proposed amendment to §550.1406, Injunctive Relief or Civil Penalties, updates outdated references to DADS.

The proposed amendment to §550.1407, Opportunity to Show Compliance, updates outdated references to DADS and corrects a grammar error.

The proposed amendment to §550.1408, Administrative Penalties, corrects the figure name to Figure 26 TAC §550.1408(m) to show that it has moved from 40 TAC §15.

FISCAL NOTE

Trey Wood, Chief Financial Officer, has determined that for each year of the first five years that the rules will be in effect, enforcing or administering the rules does not have foreseeable implications relating to costs or revenues of state or local government.

GOVERNMENT GROWTH IMPACT STATEMENT

HHSC has determined that during the first five years that the rules will be in effect:

(1) the proposed rules will not create or eliminate a government program;

(2) implementation of the proposed rules will not affect the number of HHSC employee positions;

(3) implementation of the proposed rules will result in no assumed change in future legislative appropriations;

(4) the proposed rules will not affect fees paid to HHSC;

(5) the proposed rules will create new regulations;

(6) the proposed rules will expand existing regulations;

(7) the proposed rules will not change the number of individuals subject to the rules; and

(8) the proposed rules will not affect the state's economy.

SMALL BUSINESS, MICRO-BUSINESS, AND RURAL COMMUNITY IMPACT ANALYSIS

Trey Wood has also determined that there will be an adverse economic effect on small businesses or micro-businesses, or rural communities.

A PPECC may incur a cost due to the implementation of H.B. 1009 if an agency staff person is suspended while he or she goes through due process or appeals process for being added to the EMR. This might not impact all PPECCs but could affect those that may need to hire additional staff on a temporary basis while the staff person is on suspension.

HHSC lacks sufficient information to determine the number of small businesses, micro-businesses, or rural communities subject to the rule.

HHSC determined that alternative methods to achieve the purpose of the proposed rule for small businesses, micro-businesses, or rural communities would not be consistent with ensuring the health and safety of PPECC clients.

LOCAL EMPLOYMENT IMPACT

The proposed rules will not affect a local economy.

COSTS TO REGULATED PERSONS

Texas Government Code §2001.0045 does not apply to these rules because the rules are necessary to protect the health, safety, and welfare of the residents of Texas, including clients of PPECCs, and to implement legislation that does not specifically state that §2001.0045 applies to the rule.

PUBLIC BENEFIT AND COSTS

Stephen Pahl, Deputy Executive Commissioner for Regulatory Services, has determined that for each year of the first five years the rules are in effect, the public will benefit from increased clarity in the rules and guidance in the requirements for PPECCs.

Trey Wood has also determined that there could be a cost for providers required to comply with this proposed rule.

A PPECC may incur a cost due to the implementation of H.B. 1009 if an agency staff person is suspended while he or she goes through due process or appeals process for being added to the EMR. This might not impact all PPECCs but could affect those that may need to hire additional staff on a temporary basis while the staff person is on suspension.

HHSC lacks sufficient information to determine the number of small businesses, micro-businesses, or rural communities subject to the rule.

TAKINGS IMPACT ASSESSMENT

HHSC has determined that the proposal does not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, does not constitute a taking under Texas Government Code §2007.043.

PUBLIC COMMENT

Questions about the content of this proposal may be directed to Cecilia Cavuto in HHSC Long-term Care Regulation at HHSCLTCRRules@hhs.texas.gov.

Written comments on the proposal may be submitted to Cecilia Cavuto, Program Specialist, Texas Health and Human Services Commission, Mail Code E-370, 701 W. 51st Street, Austin, Texas 78751, or by email to HHSCLTCRRules@hhs.texas.gov.

To be considered, comments must be submitted no later than 31 days after the date of this issue of the *Texas Register.* Comments must be (1) postmarked or shipped before the last day of the comment period; (2) hand-delivered before 5:00 p.m. on the last working day of the comment period; or (3) emailed before midnight on the last day of the comment period. If the last day to submit comments falls on a holiday, comments must be postmarked, shipped, or emailed before midnight on the following business day to be accepted. When emailing comments, please indicate "Comments on Proposed Rule 23R061" in the subject line.

SUBCHAPTER A. PURPOSE, SCOPE, LIMITATIONS, COMPLIANCE, AND DEFINITIONS

26 TAC §550.1, §550.5

STATUTORY AUTHORITY

The amendments are authorized by Texas Government Code §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of services by the health and human services agencies, and Texas

Human Resources Code §103.004 and §103.005, which respectively provide that the Executive Commissioner of HHSC shall adopt rules for implementing Chapter 103 and adopt rules for licensing and setting standards for facilities licensed under Chapter 103.

The amendments implement Texas Government Code §531.0055 and Texas Human Resources Code, Chapter 103.

§550.1. Purpose.

(a) The purpose of this chapter is to implement THSC Chapter 248A, which directs the executive commissioner [~~of the Texas Health and Human Services Commission~~] to adopt minimum standards that a person must meet to be licensed as a center.

(b) Except as provided by THSC §248A.002, a person may not own or operate a center unless the person holds a license issued by HHSC [~~DADS~~] under THSC Chapter 248A and this chapter.

(c) An applicant may not provide services under a license for which an application has been submitted [~~filed~~] until HHSC [~~DADS~~] issues the license.

§550.5. Definitions.

The following words and terms, when used in this chapter, have the following meanings unless the context clearly indicates otherwise.

(1) Active Play--Any physical activity from which a minor derives amusement, entertainment, enjoyment, or satisfaction by taking a participatory rather than a passive role. Active play includes various forms of activities, from the exploration of objects and toys to the structured play of formal games, sports, and hobbies.

(2) Actual census--The number of minors at a center at any given time.

(3) Administration of medication--The direct application of a medication to the body of a minor by any route. This includes removing an individual or unit dose from a previously dispensed, correctly labeled container, verifying it with the medication order, giving the correct medication and the correct dose to the correct minor at the correct time by the correct route, and accurately recording the time and dose given.

(4) Administrator--The person who is responsible for implementing and supervising the administrative polices and operations of a center and for administratively supervising the provision of services to minors and their parents on a day-to-day basis.

(5) Adult minor--A minor who is 18 years of age or older or is emancipated[~~,~~] and has not been adjudged incompetent.

(6) Affiliate--With respect to an applicant or license holder that is:

(A) a corporation--means an officer, director, or stockholder with direct ownership or disclosable interest of at least five percent, a subsidiary, or a parent company;

(B) a limited liability company--means an officer, member, or parent company;

(C) an individual--means:

(i) the individual's spouse;

(ii) each partnership and each partner thereof of which an individual or any affiliate of an individual is a partner; and

(iii) each corporation in which an individual is an officer, director, or stockholder with a direct ownership of at least five percent;

(D) a partnership--means a partner or a parent company of the partnership; and

(E) a group of co-owners under any other business arrangement means an officer, director, or the equivalent under the specific business arrangement or a parent company.

(7) Applicant--A person who applies for a license to operate a center under THSC Chapter 248A and this chapter. The applicant is the person in whose name HHSC issues the license.

(8) Audiologist--A person who has a valid license under Texas Occupations Code, Chapter 401, as an audiologist.

(9) Basic services--Include:

(A) the development, implementation, and monitoring of a comprehensive protocol of care that:

(i) is provided to a medically dependent or technologically dependent minor;

(ii) is developed in conjunction with the minor's parent; and

(iii) specifies the medical, nursing, psychosocial, therapeutic, and developmental services required by the minor; and

(B) the caregiver training needs of a medically dependent or technologically dependent minor's parent.

(10) Behavioral emergency--A situation that occurs after which preventative or de-escalating techniques are attempted and determined to be ineffective and it is immediately necessary to restrain a minor to prevent immediate probable death or substantial bodily harm to the minor or to others because the minor is attempting serious bodily harm or immediate physical harm to the minor or to others.

(11) Business day--Any day except a national or state holiday listed in Texas Government Code §662.003(a) or (b). The term includes Saturday or Sunday if the center is open on that day.

(12) Center--A Prescribed Pediatric Extended Care Center [~~prescribed pediatric extended care center~~]. A facility operated for profit or on a nonprofit basis that provides nonresidential basic services to four or more medically dependent or technologically dependent minors who require the services of the center [~~facility~~] and who are not related by blood, marriage, or adoption to the owner or operator of the center [~~facility~~].

(13) Change of ownership--An event that results in a change to the federal taxpayer identification number of the license holder of a facility. The substitution of a personal representative for a deceased license holder is not a change of ownership.

(14) Chemical restraint--The use of any chemical, including pharmaceuticals, through topical application, oral administration, injection, or other means, to restrict the free movement of all or a portion of a minor's body for the purpose of modifying or controlling the minor's behavior and which is not a standard treatment for a minor's medical or psychosocial condition.

(15) Chief financial officer--An individual who is responsible for supervising and managing all financial activities for a center.

(16) Clinical note--A notation of a contact with a minor or a minor's family member that is written and dated by any staff providing services on behalf of a center and that describes signs and symptoms of the minor, and treatments and medications administered to the minor, including the minor's reaction or response, and any changes in physical, emotional, psychosocial, or spiritual condition of the minor during a given period of time.

[(17) Commission--The Texas Health and Human Services Commission.]

[(18) Commissioner--The term referred to the commissioner of DADS; it now refers to the executive commissioner of HHSC.]

(17) [(19)] Community disaster resources--A local, statewide, or nationwide emergency system that provides information and resources during a disaster, including weather information, transportation, evacuation and shelter information, disaster assistance and recovery efforts, evacuee and disaster victim resources, and resources for locating evacuated friends and relatives.

(18) [(20)] Complaint--An allegation against a center or involving services provided at a center that involves a violation of this chapter or THSC Chapter 248A.

(19) [(21)] Continuous face-to-face observation--Maintaining an in-person line of sight of a minor that is uninterrupted and free from distraction.

(20) [(22)] Contractor--An individual providing services ordered by a prescribing physician on behalf of a center that the center would otherwise provide by its employees.

(21) [(23)] Controlling person--A person who has the ability, acting alone or in concert with others, to directly or indirectly influence, direct, or cause the direction of the management of, expenditure of money for or policies of a center or other person.

(A) A controlling person includes:

(i) a management company, landlord, or other business entity that operates or contracts with another person for the operation of a center;

(ii) any person who is a controlling person of a management company or other business entity that operates a center or that contracts with another person for the operation of a center; and

(iii) any other person who, because of a personal, familial, or other relationship with the owner, manager, landlord, tenant, or provider of a center, is in a position of actual control of or authority with respect to the center, regardless of whether the person is formally named as an owner, manager, director, officer, provider, consultant, contractor, or employee of the center.

(B) Notwithstanding any other provision of this paragraph, a controlling person of a center or of a management company or other business entity described by subparagraph (A)(i) of this paragraph that is a publicly traded corporation or is controlled by a publicly traded corporation means an officer or director of the corporation. The term does not include a shareholder or lender of the publicly traded corporation.

(C) A controlling person described by subparagraph (A)(iii) of this paragraph does not include a person, including an employee, lender, secured creditor, or landlord, who does not exercise any formal or actual influence or control over the operation of the center.

(22) [(24)] Conviction--An adjudication of guilt based on a finding of guilt, a plea of guilty, or a plea of nolo contendere.

[(25) DADS--The term referred to the Department of Aging and Disability Services; it now refers to HHSC.]

(23) [(26)] Daily census--The number of minors served at a center during a center's hours of operation for a 24-hour period, starting at midnight.

(24) [(27)] Day--A calendar day, unless otherwise specified in the text. A calendar day includes Saturday, Sunday, and a holiday.

(25) [(28)] Dietitian--A person who has a valid license under the Licensed Dietitian Act, Texas Occupations Code, Chapter 701, as a licensed dietitian or provisional licensed dietitian, or who is registered as a dietitian by the Commission on Dietetic Registration of the American Dietetic Association.

(26) [(29)] Direct ownership interest--Ownership of equity in the capital, stock, or profits of, or a membership interest in, an applicant or license holder.

(27) [(30)] Disclosable interest--Five percent or more direct or indirect ownership interest in an applicant or license holder.

(28) [(31)] Emergency situation--An impending or actual situation that:

(A) interferes with normal activities of a center or minors at a center;

(B) may:

(i) cause injury or death to a minor or individual at the center; or

(ii) cause damage to the center's property;

(C) requires the center to respond immediately to mitigate or avoid injury, death, damage, or interference; and

(D) does not include a situation that arises from the medical condition of a minor such as cardiac arrest, obstructed airway, or cerebrovascular accident.

(29) [(32)] Executive commissioner--The executive commissioner of the Texas Health and Human Services Commission.

(30) [(33)] Functional assessment--An evaluation of a minor's abilities, wants, interests, and needs related to self-care, communication skills, social skills, motor skills, play with toys or objects, growth, and development appropriate for age.

(31) [(34)] Health care provider--An individual or facility licensed, certified, or otherwise authorized to administer health care in the ordinary course of business or professional practice.

(32) [(35)] Health care setting--A location at which licensed, certified, or otherwise regulated health care is administered.

(33) [(36)] HHSC--The Texas Health and Human Services Commission.

(34) [(37)] IDT--Interdisciplinary team. Individuals who work together to meet the medical, nursing, psychosocial, and developmental needs of a minor and a minor's parent's training needs.

(35) Immediate threat to the health or safety of a minor--A situation that causes, or is likely to cause, serious injury, harm, or impairment to, or the death of a minor.

(36) [(38)] Inactive medical record--A record for a minor who was admitted by a center to receive services and was subsequently discharged by the center.

(37) [(39)] Indirect ownership interest--Any ownership or membership interest in a person that has a direct ownership interest in an applicant or license holder.

(38) [(40)] Inspection--An on-site examination or audit of a center by HHSC to determine compliance with THSC Chapter 248A and this chapter.

(39) [~~(41)~~] Isolation--The involuntary confinement of a minor in a room of a center for the purposes of infection control, assessment, and observation away from other minors in a room at the center. When in isolation, a minor is physically prevented from contact with other minors.

(40) [~~(42)~~] Joint training--Training provided by HHSC to service providers and HHSC inspectors on subjects that address the 10 most commonly cited violations of state law governing centers, as published in HHSC annual reports. HHSC determines the frequency of joint training.

(41) [~~(43)~~] License--A license to operate a center issued by HHSC under THSC, Chapter 248A, and this chapter. The term includes initial, renewal, and temporary licenses unless specifically stated otherwise.

(42) [~~(44)~~] Licensed assistant in speech-language pathology--A person who has a valid license under Texas Occupations Code, Chapter 401, as a licensed assistant in speech-language pathology and who provides speech language support services under the supervision of a licensed speech-language pathologist.

(43) [~~(45)~~] License holder--A person that holds a license to operate a center under THSC Chapter 248A and this chapter.

(44) [~~(46)~~] Life Safety Code--A publication of the National Fire Protection Association (NFPA), also known as NFPA 101, 2000 edition.

(45) [~~(47)~~] Local emergency management agencies--The local emergency management coordinator, fire, police, and emergency medical services.

(46) [~~(48)~~] Local emergency management coordinator--The person identified as the emergency management coordinator by the mayor or county judge for the geographical area in which a center is located.

(47) [~~(49)~~] LVN--Licensed vocational nurse. A person who has a valid license under Texas Occupations Code, Chapter 301, as a licensed vocational nurse.

(48) [~~(50)~~] Mechanical restraint--The use of any mechanical device, material, or equipment to restrict the free movement of all or a portion of a minor's body for the purpose of modifying or controlling the minor's behavior.

(49) [~~(51)~~] Medical director--A physician who has the qualifications described in §550.307 of this chapter (relating to Medical Director Qualifications and Conditions) and has the responsibilities described in §550.308 of this chapter (relating to Medical Director Responsibilities).

(50) [~~(52)~~] Medical record--A record composed first-hand for a minor who has or is receiving services at a center.

(51) [~~(53)~~] Medically dependent or technologically dependent--The condition of an individual who, because of an acute, chronic, or intermittent medically complex or fragile condition or disability, requires ongoing, technology-based skilled nursing care prescribed by a physician to avert death or further disability, or the routine use of a medical device to compensate for a deficit in a life-sustaining body function. The term does not include a controlled or occasional medical condition that does not require continuous nursing care, including asthma or diabetes, or a condition that requires an epinephrine injection.

(52) [~~(54)~~] Medication administration record--A record used to document the administration of a minor's medications and pharmaceuticals.

(53) [~~(55)~~] Medication list--A list that includes all prescriptions, over-the-counter pharmaceuticals, and supplements that a minor is prescribed or taking, including the dosage, preparation, frequency, and the method of administration.

(54) [~~(56)~~] Minor--An individual younger than 21 years of age who is medically dependent or technologically dependent.

(55) [~~(57)~~] Mitigation--An action taken to eliminate or reduce the probability of an emergency or public health emergency or reduce an emergency's severity or consequences.

(56) [~~(58)~~] Nursing director--The individual responsible for supervising skilled services provided at a center and who has the qualifications described in §550.309 of this chapter (relating to Nursing Director and Alternate Nursing Director Qualifications and Conditions).

(57) [~~(59)~~] Nutritional counseling--Advising and assisting an adult minor or a minor's parent or family on appropriate nutritional intake by integrating information from a nutrition assessment with information on food and other sources of nutrients and meal preparation consistent with cultural background and socioeconomic status, with the goal being health promotion, disease prevention, and nutrition education. The term includes:

(A) dialogue with an adult minor or a minor's parent to discuss current eating habits, exercise habits, food budget, and problems with food preparation;

(B) discussion of dietary needs to help an adult minor or the minor's parent understand why certain foods should be included or excluded from the minor's diet and to help with adjustment to the new or revised or existing diet plan;

(C) a personalized written diet plan as ordered by the minor's prescribing physician, to include instructions for implementation;

(D) providing the adult minor or the minor's parent with motivation to help them understand and appreciate the importance of the diet plan in getting and staying healthy; or

(E) working with the adult minor or the minor's parent by recommending ideas for meal planning, food budget planning, and appropriate food gifts.

(58) [~~(60)~~] Occupational therapist--A person who has a valid license under Texas Occupations Code, Chapter 454, as an occupational therapist.

(59) [~~(61)~~] Occupational therapy assistant--A person who has a valid license under Texas Occupations Code, Chapter 454, as an occupational therapy assistant who assists in the practice of occupational therapy under the general supervision of an occupational therapist.

(60) Online portal--A secure portal provided on the HHSC website for licensure activities, including for an applicant to submit licensure applications and information.

(61) [~~(62)~~] Operating hours--The days of the week and the hours of day a center is open for services to a minor as identified in a center's written policy as required by §550.201 of this chapter (relating to Operating Hours).

(62) [~~(63)~~] Overnight--The hours between 9:00 p.m. and 5:00 a.m. during the days of the week a center operates.

(63) [~~(64)~~] Over-the-counter pharmaceuticals--A drug or formulary for which a physician's prescription is not needed for purchase or administration.

(64) [~~(65)~~] Parent--A person authorized by law to act on behalf of a minor with regard to a matter described in this chapter. The term includes:

(A) a biological, adoptive, or foster parent;

(B) a guardian;

(C) a managing conservator; and

(D) a non-parent decision-maker as authorized by Texas Family Code §32.001.

(65) [~~(66)~~] Parent company--A person, other than an individual, who has a direct 100 percent ownership interest in the owner of a center.

(66) [~~(67)~~] Person--An individual, firm, partnership, corporation, association, or joint stock association, and the legal successor thereof.

(67) [~~(68)~~] Personal care services--Services required by a minor, including:

(A) bathing;

(B) maintaining personal hygiene;

(C) routine hair and skin care;

(D) grooming;

(E) dressing;

(F) feeding;

(G) eating;

(H) toileting;

(I) maintaining continence;

(J) positioning;

(K) mobility and bed mobility;

(L) transfer and ambulation;

(M) range of motion;

(N) exercise; and

(O) use of durable medical equipment.

(68) [~~(69)~~] Pharmaceuticals--Of or pertaining to drugs, including over-the-counter drugs and those requiring a physician's prescription for purchase or administration.

(69) [~~(70)~~] Pharmacist--A person who is licensed to practice pharmacy under Texas Occupations Code, Chapter 558.

(70) [~~(71)~~] Pharmacy--A facility at which a prescription drug or medication order is received, processed, or dispensed as defined in Texas Occupations Code §551.003.

(71) [~~(72)~~] Physical restraint--The use of physical force, except for physical guidance or prompting of brief duration, that restricts the free movement of all or a portion of a minor's body for the purpose of modifying or controlling the minor's behavior.

(72) [~~(73)~~] Physical therapist--A person who has a valid license under Texas Occupations Code, Chapter 453, as a physical therapist.

(73) [~~(74)~~] Physical therapist assistant--A person who has a valid license under Texas Occupations Code, Chapter 453, as a physical therapist assistant and:

(A) who assists and is supervised by a physical therapist in the practice of physical therapy; and

(B) whose activities require an understanding of physical therapy.

(74) [~~(75)~~] Physician--A person who:

(A) has a valid license in Texas to practice medicine or osteopathy in accordance with Texas Occupations Code, Chapter 155;

(B) has a valid license in Arkansas, Louisiana, New Mexico, or Oklahoma to practice medicine, who is the treating physician of a minor, and orders services for the minor, in accordance with Texas Occupations Code, Chapter 151; or

(C) is a commissioned or contract physician or surgeon who serves in the United States uniformed services or Public Health Service if the person is not engaged in private practice, in accordance with Texas Occupations Code, Chapter 151.

(75) [~~(76)~~] Place of business--An office of a center where medical records are maintained and from which services are directed.

(76) [~~(77)~~] Plan of care--A protocol of care.

(77) [~~(78)~~] Positive intervention--An intervention that is based on or uses a minor's preferences as positive reinforcement, and focuses on positive outcomes and wellness for the minor.

(78) [~~(79)~~] Pre-licensing program training--Computer-based training, available on the HHSC website, designed to acquaint center staff with licensure standards.

(79) [~~(80)~~] Premises--The term includes the center, any lots on which the center is located, any outside ground areas, any outside play areas, and the parking lot.

(80) [~~(81)~~] Preparedness--Actions taken in anticipation of a disaster including a public health disaster.

(81) [~~(82)~~] Prescribing physician--A physician who is authorized to write and issue orders for services at a center.

(82) [~~(83)~~] Progress note--A dated and signed written notation summarizing facts about services provided to a minor and the minor's response during a given period of time.

(83) [~~(84)~~] Protective device--A mechanism or treatment, including sedation, that is:

(A) used:

(i) for body positioning;

(ii) to immobilize a minor during a medical, dental, diagnostic, or nursing procedure;

(iii) to permit wounds to heal; or

(iv) for a medical condition diagnosed by a physician; and

(B) not used as a restraint to modify or control behavior.

(84) [~~(85)~~] Protocol of care--A comprehensive, interdisciplinary plan of care that includes the medical physician's plan of care, nursing care plan and protocols, psychosocial needs, and therapeutic and developmental service needs required by a minor and family served.

(85) [~~(86)~~] Psychologist--A person who has a valid license under Texas Occupations Code, Chapter 501, as a psychologist.

(86) [~~(87)~~] Psychosocial treatment--The provision of skilled services to a minor under the direction of a physician that includes one or more of the following:

(A) assessment of alterations in mental status or evidence of suicide ideation or tendencies;

(B) teaching coping mechanisms or skills;

(C) counseling activities; or

(D) evaluation of a plan of care.

(87) [~~(88)~~] Quiet time--A behavior management technique used to provide a minor with an opportunity to regain self-control, where the minor enters and remains for a limited period of time in a designated area from which egress is not prevented.

(88) [~~(89)~~] Recovery--Activities implemented during and after a disaster response, including a public health disaster response, designed to return a center to its normal operations as quickly as possible.

(89) [~~(90)~~] Relocation--The closing of a center and the movement of its business operations to another location.

(90) [~~(91)~~] Respiratory therapist--A person who has a valid license under Texas Occupations Code, Chapter 604, as a respiratory care practitioner.

(91) [~~(92)~~] Response--Actions taken immediately before an impending disaster or during and after a disaster, including a public health disaster, to address the immediate and short-term effects of the disaster.

(92) [~~(93)~~] Restraint--Physical restraint, chemical restraint, or mechanical restraint.

(93) [~~(94)~~] RN--Registered nurse. A person who has a valid license under Texas Occupations Code, Chapter 301, to practice professional nursing.

(94) [~~(95)~~] RN delegation--Delegation of tasks by an RN in accordance with 22 Texas Administrative Code Chapter 224 (relating to Delegation of Nursing Tasks by Registered Professional Nurses to Unlicensed Personnel for Clients with Acute Conditions or in Acute Care Environments).

(95) [~~(96)~~] Sedation--The act of allaying nervous excitement by administering medication that commonly induces the nervous system to calm. Sedation is a protective device.

(96) [~~(97)~~] Social worker--A person who has a valid license under Texas Occupations Code, Chapter 505, as a social worker.

(97) [~~(98)~~] Speech-language pathologist--A person who has a valid license under Texas Occupations Code, Chapter 401, as a speech-language pathologist.

(98) [~~(99)~~] Substantial compliance--A finding in which a center receives no recommendation for enforcement action after an inspection.

(99) [~~(100)~~] Supervision--Authoritative procedural guidance by a qualified person that instructs another person and assists in accomplishing a function or activity. Supervision includes initial direction and periodic inspection of the actual act of accomplishing the function or activity.

(100) [~~(101)~~] Support services--Social, spiritual, and emotional care provided to a minor and a minor's parent by a center.

(101) [~~(102)~~] THSC--Texas Health and Safety Code.

(102) [~~(103)~~] Total census--The total number of minors with active plans of care at a center.

(103) [~~(104)~~] Transition support--Planning, coordination, and assistance to move the location of services provided to a minor from a center to the least restrictive setting appropriate.

(104) [~~(105)~~] Violation--A finding of noncompliance with this chapter or THSC Chapter 248A resulting from an inspection.

(105) [~~(106)~~] Volunteer--An individual who provides assistance to a center without compensation other than reimbursement for actual expenses.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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SUBCHAPTER B. LICENSING APPLICATION, MAINTENANCE, AND FEES

26 TAC §§550.101 - 550.106, 550.108 - 550.115, 550.118 - 550.123

STATUTORY AUTHORITY

The amendments are authorized by Texas Government Code §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of services by the health and human services agencies, and Texas Human Resources Code §103.004 and §103.005, which respectively provide that the Executive Commissioner of HHSC shall adopt rules for implementing Chapter 103 and adopt rules for licensing and setting standards for facilities licensed under Chapter 103.

The amendments implement Texas Government Code §531.0055 and Texas Human Resources Code, Chapter 103.

§550.101. Criteria and Eligibility for a License.

(a) To obtain a license, a person must meet the application requirements in this subchapter and meet the criteria for a license.

(b) A center must be located in Texas. The center must have a Texas mailing address.

(c) A person may not operate a center on the same premises as:

(1) a child-care center licensed in accordance with Texas Human Resource Code, Chapter 42; or

(2) any other facility licensed by HHSC [~~DADS~~] or the Texas Department of State Health Services.

(d) A separate license is required for each center located on separate premises, regardless of whether the centers are owned or operated by the same person.

(e) The actual census for a center must not exceed the capacity authorized by HHSC [~~DADS~~], as indicated on the license.

(f) Before issuing a license, HHSC [~~DADS~~] considers the background and qualifications of:

(1) the applicant;

(2) a controlling person of the applicant;

(3) a person with a disclosable interest;

(4) an affiliate of the applicant;

(5) the administrator; and

(6) the chief financial officer, if the center has a chief financial officer.

(g) An applicant must affirmatively show that the center:

(1) obtained approval of building plans through plan review by the HHSC [~~DADS~~] Architectural Unit as required by Subchapter E of this chapter (relating to Building Requirements);

(2) meets local building ordinances;

(3) is approved by the local fire authority;

(4) meets the standards of the Life Safety Code and the requirements in Subchapter E of this chapter; and

(5) meets the requirements of this chapter based on an on-site health inspection by HHSC [~~DADS~~].

§550.102. General Application Requirements.

(a) An applicant may apply for a license for a center by submitting an [~~a sworn~~] application to the HHSC [~~from the DADS~~] Licensing and Credentialing Unit through the online portal. [~~An application may be obtained from the HHSC DADS website.~~]

(b) An applicant must complete the application in accordance with the instructions provided in the online portal [~~on the application and the DADS website~~].

(c) An applicant must provide accurate and complete statements on the application and any attachments.

(d) If an applicant decides not to continue the application process for a license after submitting an application and license fee, the applicant must submit a written request to HHSC [~~DADS~~] to withdraw the application. HHSC [~~DADS~~] does not refund the license fee for an application that is withdrawn, except as provided in §550.114 [~~§15.114~~] of this subchapter (relating to Time Periods for Processing All Types of License Applications).

§550.103. Building Approval.

(a) Fire authority. An applicant must receive approval from the local fire authority or, if the jurisdiction does not have a local fire authority, the state fire marshal, for an initial, renewal, change of ownership, relocation, or capacity increase license application. An applicant may submit a license application to HHSC through the online portal [~~DADS~~] before receiving fire authority approval. An applicant must submit to HHSC [~~DADS~~] a copy of a signed and dated written approval for occupancy by the local fire authority or state fire marshal that describes the center by name and address by uploading a copy through the online portal.

(b) Local health authority. An applicant for an initial, change of ownership, relocation, or capacity increase license must submit to HHSC, by uploading through the online portal, [~~DADS~~] a copy of a dated written notification to the local health authority that the applicant is submitting a license application to HHSC [~~DADS. DADS sends the local health authority a copy of DADS license renewal notification specifying the expiration date of the center's current license~~]. A local health authority may provide an evaluation to HHSC [~~DADS~~] regarding the status of the center's compliance with local codes, ordinances, or regulations. The local health authority may also recommend that HHSC [~~DADS~~] issue or deny a license to the center, but HHSC [~~DADS~~] makes the final decision regarding licensure of the center.

§550.104. Applicant Disclosure Requirements.

(a) A person that submits an initial, renewal, change of ownership, relocation, or increase in capacity license application through the online portal must follow the instructions for that application; and[~~:~~]

(1) identify the location of the place of business for which the license is sought;

(2) include documentation, signed by the appropriate local government official, stating that the center's place of business and the use of the center meet local zoning requirements;

(3) provide the name, address, and social security number of, and background and criminal history check information for:

(A) the applicant;

(B) the administrator;

(C) the financial officer; and

(D) each controlling person of the applicant;

(4) provide the federal employer identification number or taxpayer identification number of the applicant and of each controlling person, if an applicant or controlling person is not an individual;

(5) state the assumed name under which the center will be doing business;

(6) state the maximum capacity requested for the center; and

(7) include a sworn affidavit that the applicant has complied with this chapter.

(b) For an initial license and change of ownership application, an applicant must follow the instructions for that application; and[~~:~~]

(1) submit to HHSC [~~DADS~~] evidence of the right to possess or occupy the center at the time the application is submitted, which may include:

(A) a lease agreement; or

(B) a deed; and

(2) disclose to HHSC [~~DADS~~] the name and address of the owner of the real property, including the owner of the buildings and grounds appurtenant to the center.[~~:~~]

[~~(3) submit to DADS a certificate of account status issued by the Comptroller of Public Accounts; and~~]

[~~(4) submit to DADS a certificate of incorporation issued by the Secretary of State for a corporation or a copy of the partnership agreement for a partnership.~~]

[~~(c) For a renewal application, an applicant must submit to DADS a certificate of account status issued by the Comptroller of Public Accounts.~~]

(c) [~~(d)~~] An applicant or license holder must provide to HHSC, through the online portal, [~~DADS~~] any additional information requested by HHSC [~~DADS~~] no later than 30 days after the date of the HHSC [~~DADS~~] request.

(d) [~~(e)~~] HHSC [~~DADS~~] may require an applicant to disclose information relating to the fiduciary-appointed administrator of the center.

§550.105. Initial License Application Procedures and Issuance.

(a) The center's administrator must complete pre-licensing program training before an applicant may submit an initial application for a license.

(b) An applicant for an initial license must submit to HHSC through the online portal:

(1) a complete and correct application including all documents and information that HHSC requires as part of the application process;

(2) the correct license fee established in §550.112 [~~§15.112~~] of this subchapter (relating to Licensing Fees);

(3) a letter of credit for $250,000 from a bank that is insured by the Federal Deposit Insurance Corporation, or other documentation acceptable to HHSC, to demonstrate an applicant's financial viability; and

(4) all other documents described in the instructions provided on the application and on the HHSC website.

(c) After HHSC receives an application for an initial license and the correct license fee, HHSC reviews the application and notifies the applicant if additional information is needed to complete the application.

(d) An applicant must submit written notice to HHSC that the center is ready for a Life Safety Code inspection by uploading the notification through the online portal.

(1) The written notice must be submitted:

(A) with the application; or

(B) no later than 120 days after the HHSC Licensing and Credentialing Section receives the application.

(2) After HHSC receives the written notice for a Life Safety Code inspection and an applicant has satisfied the application submission requirements, HHSC staff conducts an on-site Life Safety Code inspection.

(e) The center must meet the building requirements described in Subchapter E of this chapter (relating to Building Requirements). If a center fails to meet the building requirements and fails to implement an approved written plan of correction no later than 120 days after the initial Life Safety Code inspection, HHSC Licensing proposes to deny [~~denies~~] the license application.

(f) If a center meets the building requirements in Subchapter E of this chapter, the center may admit no more than three minors. After a [~~If the~~] center admits one [~~a~~] minor, the applicant must send written notice to HHSC indicating the center is ready for a health inspection by uploading the notice through the online portal. The center must submit the request for the [~~The~~] health inspection [~~request must be submitted~~] no later than 120 days after the date the center meets the building requirements.

(1) After HHSC receives the request for the health inspection, HHSC conducts an on-site health inspection to determine compliance with this chapter.

(2) If the center fails to comply with this chapter and fails to implement an approved written plan of correction no later than 120 days after the date of the initial health inspection, HHSC Licensing proposes to deny [~~denies~~] the license application.

(g) If an applicant receives a notice from HHSC that some or all of the information is missing or incomplete, an applicant must submit the requested information no later than 30 days after the date of the notice. If the applicant fails to timely submit the requested information, HHSC Licensing proposes to deny [~~denies~~] the application. If HHSC Enforcement denies the application, HHSC does not refund the license fee.

(h) HHSC issues an initial license if it determines that an applicant has met the provisions of this chapter and THSC Chapter 248A.

(i) The issuance of an initial license constitutes notice from HHSC to the center of the approval of the application.

(j) HHSC issues a center license to the license holder named on the license at the place of business listed on the license. The license is not transferable or assignable.

(k) The license includes:

(1) the license holder's name;

(2) the name of the center;

(3) the center's place of business;

(4) the center's licensed capacity; and

[~~(5) a statement that the center provides services to minors for 12 hours or less in a 24-hour period but no overnight care; and~~]

(5) [~~(6)~~] the effective date of the license.

(l) HHSC Licensing may propose to deny an application for an initial license if the applicant, a controlling person, or a person required to submit background and qualification information fails to meet the criteria for a license established in §550.101 [~~§15.101~~] of this subchapter (relating to Criteria and Eligibility for a License) or for any reason specified in §550.115 [~~§15.115~~] of this subchapter (relating to Criteria for Denial of a License).

(m) If HHSC denies an application for an initial license, HHSC sends the applicant written notice of the denial and informs the applicant of the right to request an administrative hearing to appeal the denial. The administrative hearing is held in accordance with 1 Texas Administrative Code [~~TAC~~] Chapter 357, Subchapter I (relating to Hearings Under the Administrative Procedure Act) and Chapter 110 [~~91~~] of this title (relating to Hearings Under the Administrative Procedure Act).

(n) An initial license expires on the third anniversary after the effective date of the initial license.

§550.106. Renewal License Application Procedures and Issuance.

(a) A center license expires on the third anniversary after the effective date on the license. To renew a license, a license holder must submit a renewal application to HHSC through the online portal before the expiration date of the current license. HHSC sends written notice of expiration of a license to the license holder through the online portal at least 120 days before the expiration date of a license. [~~The written notice includes instructions for completing the renewal application.~~]

(b) A license holder must comply with the requirements in §550.102 [~~§15.102~~] of this subchapter (relating to General Application Requirements) and §550.114 [~~§15.114~~] of this subchapter (relating to Time Periods for Processing All Types of License Applications) to renew a license.

(c) In accordance with Texas Government Code, §2001.054, HHSC considers that a license holder meets the renewal application submission deadline if the license holder submits through the online portal:

(1) no later than 60 days before the expiration date of the current license:

(A) a complete application for renewal or an incomplete application for renewal with a letter explaining the circumstances that prevented the inclusion of the missing information; and

(B) the correct license fee established in §550.112 [~~§15.112~~] of this subchapter (relating to Licensing Fees); or

(2) during the 60-day period ending on the date the current license expires:

(A) a complete application for renewal or an incomplete application with a letter explaining the circumstances that prevented the inclusion of the missing information;

(B) the correct license fee established in §550.112 [~~§15.112~~] of this subchapter; and

(C) the late fee established in §550.112 [~~§15.112~~] of this subchapter.

(d) HHSC reviews a renewal application and notifies the license holder if additional information is needed to complete the application.

(e) It is the license holder's responsibility to ensure that the application is timely received by HHSC. Failure to submit a timely and sufficient renewal application with the correct license fee through the online portal will result in the expiration of the license.

(f) If a license holder submits a renewal application to HHSC through the online portal [~~that is postmarked~~] after the expiration date of the license, HHSC denies the renewal application and does not refund the renewal license fee. The license holder is not eligible to renew the license and must cease operation on the date the license expires. A license holder whose license expires must apply for an initial license in accordance with §550.105 [~~§15.105~~] of this subchapter (relating to Initial License Application Procedures and Issuance).

(g) HHSC issues a renewal license after determining that an applicant and the center have met the provisions of THSC §248A.002 and this chapter.

(h) The issuance of a renewal license constitutes notice from HHSC to the center that the application is approved.

(i) A renewal license issued in accordance with this chapter expires on the third anniversary after the effective date on the license.

(j) HHSC may pend action on an application for the renewal of a license for up to six months if the center is not in compliance with THSC §248A.002 and this chapter based on an on-site inspection.

(k) HHSC Licensing may propose to deny an application for the renewal of a license if an applicant, controlling person, or any person required to submit background and qualification information fails to meet the criteria for a license established in §550.101 [~~§15.101~~] of this subchapter (relating to Criteria and Eligibility for a License) or for any reason specified in §550.115 [~~§15.115~~] of this subchapter (relating to Criteria for Denial of a License).

(l) Before denying a license renewal application, HHSC Enforcement gives the license holder:

(1) notice by personal service or by registered or certified mail of the facts or conduct alleged to warrant the proposed action; and

(2) an opportunity to show compliance with all the requirements of THSC Chapter 248A and this chapter to retain the license.

(m) To request an opportunity to show compliance, the license holder must send a written request to HHSC. The request must:

(1) be postmarked no later than 10 days after the date of notice from HHSC of the proposed action and received by HHSC no later than 10 days after the date of the postmark; and

(2) contain documentation that refutes HHSC allegations specifically.

(n) The opportunity to show compliance is limited to a review of documentation submitted by the license holder and information HHSC used as the basis for the proposed action. The opportunity to show compliance is not an administrative hearing. HHSC gives the license holder a written affirmation or reversal of the proposed action.

(o) If HHSC Enforcement denies an application for a renewal license, HHSC sends the license holder a written notice of the denial and informs the license holder of the right to request an administrative hearing to appeal the denial. The administrative hearing is held in accordance with 1 Texas Administrative Code [~~TAC~~] Chapter 357, Subchapter I (relating to Hearings Under the Administrative Procedure Act) and HHSC hearing rules found in Chapter 110 [~~91~~] of this title (relating to Hearings Under the Administrative Procedure Act).

§550.108. Change of Ownership License Application Procedures and Issuance and Notice of Changes.

(a) For purposes of this section, a temporary change of ownership license is a temporary license issued to an applicant who proposes to become the new operator of a center that exists on the date the applicant submits a change of ownership license application [~~is submitted~~].

(b) A center license is not assignable or transferable. The applicant (prospective new license holder) must obtain a temporary change of ownership license followed by an initial three-year license in accordance with this section. When HHSC [~~the Texas Health and Human Services Commission (HHSC)~~] approves the change of ownership by issuing a temporary change of ownership license to the applicant (prospective new license holder) [~~new license holder~~], the current license holder's license becomes invalid as of the effective date of the change of ownership indicated in the application. Between the effective date of the change of ownership and the issuance of the temporary change of ownership license, the current license holder remains responsible under its license; however, the applicant may operate a center on behalf of the current license holder during such period of time.

(c) An applicant must submit to HHSC through the online portal:

(1) a complete application for a license in accordance with HHSC instructions and §550.101 of this subchapter (relating to Criteria and Eligibility for a License) or an incomplete application with a letter explaining the circumstances that prevented the inclusion of the missing information;

(2) the application fee, in accordance with §550.112 of this subchapter (relating to Licensing Fees);

(3) a letter of credit for $250,000 from a bank that is insured by the Federal Deposit Insurance Corporation, or other documentation acceptable to HHSC, to demonstrate the applicant's financial viability; and

(4) a signed and notarized Change of Ownership Transfer Affidavit HHSC Form 1092 from the applicant and the center's current license holder of intent to transfer operation of the center from the current license holder to the applicant, beginning on the change of ownership effective date specified on the change of ownership application.

(d) HHSC Licensing may propose to deny issuance of a change of ownership license if the applicant, a controlling person, or

any person disclosed in the application fails to meet the criteria for a license established in §550.101 of this subchapter or for any reason specified in §550.115 of this subchapter (relating to Criteria for Denial of a License).

(e) To avoid a center operating without a license, an applicant must submit all items in subsection (c) of this section in accordance with HHSC instructions at least 30 days before the anticipated date of the change of ownership specified on the change of ownership application [~~in accordance with HHSC instructions~~], unless the 30-day notice requirement is waived in accordance with subsection (f) of this section.

(f) HHSC may waive the 30-day notice required by subsection (e) of this section if:

(1) the applicant presents evidence to HHSC demonstrating that an eviction of the center or a foreclosure of the property from which the center operates is imminent and that circumstances [~~circumstance~~] prevented the timely submission of the items specified in subsection (c) of this section; or

(2) HHSC, in its sole discretion, determines that circumstances are present that threaten a minor's health, safety, or welfare and necessitate waiver of timely submission of the items specified in subsection (c) of this section.

(g) Upon HHSC approval of the items specified in subsection (c) of this section, HHSC issues a temporary change of ownership license to the applicant if HHSC finds that the applicant, all controlling persons, and all persons disclosed in the application satisfy the requirements in §§550.101(a) and (f) of this subchapter, 550.104 of this subchapter (relating to Applicant Disclosure Requirements), and 550.115 of this subchapter.

(1) The issuance of a temporary change of ownership license constitutes [~~HHSC's~~] official written notice by HHSC to the center [~~facility~~] of the approval of the application for a change of ownership.

(2) The effective date of the temporary change of ownership license is the date requested in the application and cannot precede the date the application is received by HHSC through the online portal.

(h) A temporary change of ownership license expires on the earlier of:

(1) 90 days after its effective date or the last day of any extension HHSC provides in accordance with subsection (i) of this section; or

(2) the date HHSC issues a three-year license in accordance with subsection (l) of this section.

(i) HHSC, in its sole discretion, may extend the term of a temporary change of ownership license by 90 days based upon extenuating circumstances.

(j) HHSC conducts an on-site health inspection to verify compliance with the licensure requirements after issuing a temporary change of ownership license. HHSC may conduct a desk review instead of an on-site health inspection after issuing a temporary change of ownership license if:

(1) less than 50 percent of the direct or indirect ownership interest in the former license holder changed, when compared to the new license holder; or

(2) every person with a disclosable interest in the new license holder had a disclosable interest in the former license holder.

(k) HHSC, in its sole discretion, may conduct an on-site Life Safety Code inspection after issuing a temporary change of ownership license.

(l) If an applicant and all other persons disclosed in the application satisfy the requirements of §§550.101(a) and (f), 550.104, and 550.115 of this subchapter for a license, and the center passes the change of ownership health inspection as described in subsection (j) of this section, HHSC issues a three-year license. The effective date of the three-year license is the same date as the effective date of the change of ownership and cannot precede the date the application for a license was received through the online portal.

(m) If a license holder changes its name but does not undergo a change of ownership, the license holder must notify HHSC and submit documentation evidencing a legal name change by submitting an application through the online portal. On receipt of the notice and documentation, HHSC reissues the current license in the license holder's new name.

(n) If a license holder adds an owner with a disclosable interest, but the license holder does not undergo a change of ownership, the license holder must notify HHSC of the addition no later than 30 days after the addition of the owner by submitting an application through the online portal.

§550.109. Increase in Capacity.

(a) A license holder must not increase a center's licensed capacity without approval from HHSC [~~DADS~~].

(b) The license holder must submit an application for an increase in capacity in accordance with §550.102 [~~§15.102~~] of this subchapter (relating to General Application Requirements) and the correct fee required in §550.112 [~~§15.112~~] of this subchapter (relating to Licensing Fees) through the online portal.

(c) The license holder must:

(1) arrange for an inspection of the center by the local fire marshal or the state fire marshal; and

(2) submit written evidence of the fire marshal's approval to HHSC that describes the center by name and address by uploading a copy through the online portal.

[~~(c) The license holder must arrange for an inspection of the center by the local fire marshal and provide written evidence of the fire marshal's approval to DADS.~~]

(d) An applicant must send written notice to HHSC [~~DADS~~] indicating that the center is ready for a Life Safety Code inspection by uploading the notice through the online portal.

(1) The written notice must be submitted:

(A) with the application; or

(B) no later than 120 days after HHSC [~~DADS~~] Licensing and Credentialing Unit receives the application.

(2) After HHSC [~~DADS~~] receives the written notice for a Life Safety Code inspection and an applicant has satisfied the application submission requirements, HHSC [~~DADS~~] staff conducts an on-site Life Safety Code inspection.

(e) If an applicant receives a notice from HHSC [~~DADS~~] that some or all of the information is missing or incomplete, an applicant must submit the requested information no later than 30 days after the date of the notice. If an applicant fails to submit the requested information no later than 30 days after the notice date, HHSC [~~DADS~~] considers the application incomplete and proposes to deny [~~denies~~] the appli-

cation. If HHSC [DADS] denies the application, HHSC [DADS] does not refund the license fee.

(f) The center must meet the building requirements described in Subchapter E of this chapter (relating to Building Requirements). If a center fails to meet the building requirements and fails to implement an approved written plan of correction no later than 120 days after the initial Life Safety Code inspection, HHSC Licensing proposes to deny [DADS denies] the application for a license.

(g) After a center has met Life Safety Code requirements, HHSC [DADS] conducts an on-site health inspection.

(h) HHSC [DADS] issues a new license with an increased capacity if HHSC [DADS] determines that the center is in compliance with this chapter.

(i) If an applicant decides not to continue the application process after submitting the application and correct license fee, an applicant must submit to HHSC [DADS] a written request to withdraw the application. HHSC [DADS] does not refund the license fee.

(j) Before denying an application for an increase in capacity, HHSC Enforcement [DADS] gives the license holder:

(1) notice by personal service or by registered or certified mail of the facts or conduct alleged to warrant the proposed action; and

(2) an opportunity to show compliance with all the requirements of the THSC Chapter 248A and this chapter to retain the license.

(k) To request an opportunity to show compliance, the license holder must send a written request to HHSC [DADS]. The request must:

(1) be postmarked no later than 10 days after the date of the HHSC [DADS] notice of proposed action and received by HHSC [DADS] no later than 10 days after the date of the postmark; and

(2) contain documentation that refutes the [DADS] allegations [superficially].

(l) The opportunity to show compliance is limited to a review of documentation submitted by the license holder and information HHSC [DADS] used as the basis for the proposed action. The opportunity to show compliance is not an administrative hearing. HHSC [DADS] gives the license holder a written affirmation or reversal of the proposed action.

(m) If HHSC [DADS] denies an application for an increase in capacity, HHSC [DADS] sends the license holder a written notice of the denial and informs the license holder of the right to request an administrative hearing to appeal the denial. The administrative hearing is held in accordance with [Texas Health and Human Services Commission rules found at] 1 Texas Administrative Code [TAC] Chapter 357, Subchapter I (relating to Hearings Under the Administrative Procedure Act) and HHSC [DADS] hearing rules found in Chapter 110 [91] of this title (relating to Hearings Under the Administrative Procedure Act).

§550.110. Decrease in Capacity.

(a) A license holder who wishes to decrease the licensed capacity of the center must provide written notification to HHSC by submitting a capacity change application through the online portal [DADS]. The application [written notification] must indicate the new licensed capacity for the center.

(b) After HHSC [DADS] receives the application, HHSC [written notification, DADS] issues a new license with the new licensed capacity [as indicated in the written notification].

§550.111. Relocation.

(a) Relocation is the closing of a center and the movement of its business operations to another location.

(b) A license holder must not relocate a center or provide services to a minor at a new location without prior approval from HHSC [DADS].

(c) The license holder must continue to maintain the license at the current location and must continue to meet all requirements for operation of the center until HHSC approves [DADS has approved] the relocation.

(d) Before a relocation, the license holder must submit a relocation [an] application [for an initial license] for the new location [in accordance with §15.105 of this subchapter (relating to Initial License Application Procedures and Issuance)] and the correct fee for a relocation [an initial license] required in §550.112 [§15.112] of this subchapter (relating to Licensing Fees) through the online portal.

(e) The license holder must:

(1) arrange for an inspection of the center by the local fire marshal or state fire marshal; and

(2) submit written evidence of the fire marshal's approval to HHSC that describes the center by name and address by uploading a copy through the online portal.

[(e) The license holder must arrange for an inspection of the center by the local fire marshal and provide written evidence of the fire marshal's approval to DADS.]

(f) An applicant must send written notice to HHSC [DADS] indicating that the center is ready for a Life Safety Code inspection.

(1) The written notice must be submitted through the online portal:

(A) with the application; or

(B) no later than 120 days after HHSC [DADS] Licensing and Credentialing Unit receives the application.

(2) After HHSC [DADS] receives the written notice for a Life Safety Code inspection and an applicant has satisfied the application submission requirements, HHSC [DADS] staff conducts an on-site Life Safety Code inspection.

(g) If an applicant receives a notice from HHSC [DADS] that some or all of the information is missing or incomplete, an applicant must submit the requested information no later than 30 days after the date of the notice. If an applicant fails to submit the requested information no later than 30 days after the notice date, HHSC Licensing [DADS] considers the application incomplete and proposes to deny [denies] the application. If HHSC Enforcement [DADS] denies the application, HHSC [DADS] does not refund the license fee.

(h) The center must meet the building requirements described in Subchapter E of this chapter (relating to Building Requirements). If a center fails to meet the building requirements and fails to implement an approved written plan of correction no later than 120 days after the initial Life Safety Code inspection, HHSC Licensing proposes to deny [DADS denies] the application for a license.

[(i) After a center has met Life Safety Code requirements, DADS conducts an on-site health inspection.]

(i) [(j)] Following Life Safety Code approval by HHSC [DADS], the license holder must notify HHSC [DADS] of the date the business operations will be relocated.

(j) [~~(k)~~] HHSC [~~DADS~~] issues a license for the new center if the new center meets the requirements in this chapter. The effective date of the license is the date all business operations are relocated.

(k) [~~(l)~~] The issuance of a license constitutes HHSC [~~DADS~~] approval of the relocation.

(l) [~~(m)~~] The license for the current location becomes invalid upon issuance of the new license for the new location.

(m) [~~(n)~~] If an applicant decides not to continue the application process after submitting the application and correct license fee, an applicant must submit to HHSC [~~DADS~~] a written request to withdraw the application. HHSC [~~DADS~~] does not refund the license fee.

(n) [~~(o)~~] Before denying an application for relocation, HHSC Enforcement [~~DADS~~] gives the license holder:

(1) notice by personal service or by registered or certified mail of the facts or conduct alleged to warrant the proposed action; and

(2) an opportunity to show compliance with all the requirements of THSC Chapter 248A and the Chapter to retain the license.

(o) [~~(p)~~] To request an opportunity to show compliance, the license holder must send a written request to HHSC [~~DADS~~]. The request must:

(1) be postmarked no later than 10 days after the date of HHSC [~~DADS~~] notice of proposed action and received by HHSC [~~DADS~~] no later than 10 days after the date of the postmark; and

(2) contain documentation that refutes HHSC [~~DADS~~] allegations specifically.

(p) [~~(q)~~] The opportunity to show compliance is limited to a review of documentation submitted by the license holder and information HHSC [~~DADS~~] used as the basis for the proposed action. The opportunity to show compliance is not an administrative hearing. HHSC [~~DADS~~] gives the license holder a written affirmation or reversal of the proposed action.

(q) [~~(r)~~] If HHSC [~~DADS~~] denies an application for relocation, HHSC [~~DADS~~] sends the license holder a written notice of the denial and informs the license holder of the right to request an administrative hearing to appeal the denial. The administrative hearing is held in accordance with Texas Health and Human Services Commission rules found in 1 Texas Administrative Code [~~TAC~~] Chapter 357, Subchapter I (relating to Hearings Under the Administrative Procedure Act) and HHSC [~~DADS~~] hearing rules found in Chapter 110 [~~91~~] of this title (relating to Hearings Under the Administrative Procedure Act).

§550.112. Licensing Fees.

(a) The schedule of fees for licensure of a center is as follows:

(1) initial license fee (includes changes of ownership and relocation)--$2,625 [~~$2625~~];

(2) renewal license fee--$2,625 [~~$2625~~]; and

(3) increase in capacity--$1,312.50 [~~$1312.50~~].

(b) HHSC does not waive the license fee for a change of ownership application despite a demonstration of the circumstances referenced in §550.108(f) [~~§15.108(f)~~] of this subchapter (relating to Change of Ownership License Application Procedures and Issuance and Notice of Changes). HHSC may waive the timely submission of an application for a change of ownership in accordance with §550.108(f) [~~§15.108(f)~~] of this subchapter.

(c) The late fee established in §550.106 [~~§15.106~~] of this subchapter (relating to Renewal License Application Procedures and Issuance) is $50 per day to a license holder who submits a renewal application after the date as described at §550.106 [~~§15.106~~] of this subchapter, except that the total amount of a late fee may not exceed $500.00.

(d) HHSC does not consider an application as submitted until an applicant pays the correct license fee as required in this section. The fee must accompany the application.

(e) A fee paid to HHSC is not refundable, except as provided by §550.114 [~~§15.114~~] of this chapter (relating to Time Periods for Processing All Types of License Applications).

(f) HHSC accepts payment according to methods described in the application instructions [~~provided on the HHSC website~~].

§550.113. Plan Review Fees.

(a) A center must pay a fee to HHSC [~~DADS~~] for its review of plans for new buildings, additions, conversion of buildings not licensed by HHSC [~~DADS~~], or remodeling of existing licensed facilities as described on the HHSC [~~DADS~~] website.

(b) The fee schedule follows:

(1) facilities--new construction:

(A) single-story facilities--$2,000; and

(B) multiple-story facilities--$2,500; and

(2) additions or remodeling of existing licensed facilities--2 percent of construction cost with a $500 minimum fee and a maximum not to exceed $2,000.

§550.114. Time Periods for Processing All Types of License Applications.

(a) The date of an application is the date the HHSC [~~DADS~~] Licensing and Credentialing Unit receives the application and the correct license fee as required in §550.112 [~~§15.112~~] of this subchapter (relating to Licensing Fees).

(b) HHSC [~~DADS~~] considers an application for an initial license complete when HHSC [~~DADS~~] accepts the information described in §550.105 [~~§15.105~~] of this subchapter (relating to Initial License Application Procedures and Issuance).

(c) HHSC [~~DADS~~] considers an application for a renewal license complete when HHSC [~~DADS~~] accepts the information described in §550.106 [~~§15.106~~] of this subchapter (relating to Renewal License Application Procedures and Issuance). A center may continue to operate during the renewal application process in accordance with §550.106 [~~§15.106~~] of this subchapter.

(d) HHSC [~~DADS~~] considers an application for a change of ownership license complete when HHSC [~~DADS~~] accepts the information described in §550.108 [~~§15.108~~] of this subchapter (relating to Change of Ownership License Application Procedures and Issuance and Notice of Changes).

(e) HHSC [~~DADS~~] reviews an application for a license no later than 45 days after the date the HHSC [~~DADS~~] Licensing and Credentialing Unit receives the application.

(f) If an applicant receives a notice through the online portal from HHSC [~~DADS~~] that some or all of the information required by this chapter is missing or incomplete, an applicant must submit the required information through the online portal no later than 30 days after the date of the notice. If an applicant fails to submit the required information no later than 30 days after the notice date, HHSC Licensing [~~DADS~~] considers the application incomplete and proposes to deny [~~denies~~] the application. If HHSC Enforcement [~~DADS~~] denies the application, HHSC Licensing [~~DADS~~] does not refund the license fee.

(g) HHSC Licensing proposes to deny [~~DADS denies~~] an application that remains incomplete 120 days after the date that the HHSC [~~DADS~~] Licensing and Credentialing Unit receives the application.

(h) HHSC [~~DADS~~] issues a license no later than 30 days after HHSC [~~DADS~~] determines that an applicant and the center have met all licensure requirements referenced in §550.105 [~~§15.105~~] and §550.106 [~~§15.106~~] of this subchapter, as applicable.

(i) If HHSC [~~DADS~~] does not process an application in the time period described in subsections (e) and (h) of this section, an applicant may request reimbursement of the license fee paid. The applicant must submit the reimbursement request through the online portal [~~following the instructions on the DADS website~~].

(j) If HHSC [~~DADS~~] does not agree that the established time period for processing an application described in subsection (e) of this section has been violated or finds that good cause existed for exceeding the established time period, HHSC denies [~~DADS will deny~~] the request.

(k) Good cause for exceeding the established time period exists if:

[~~(1) DADS receives an application during the time period of September 1, 2014 through June 30, 2015;~~]

(1) [~~(2)~~] the number of applications to be processed exceeds by 15 percent or more the number processed in the same fiscal quarter of the preceding year [~~effective when DADS has obtained and published two quarters of application data~~];

(2) [~~(3)~~] HHSC [~~DADS~~] must rely on another public or private entity to process all or a part of the application received by HHSC [~~DADS~~], and the delay is caused by that entity; or

(3) [~~(4)~~] other conditions existed giving good cause for exceeding the established time period.

(l) If HHSC [~~DADS~~] denies the request for reimbursement, an applicant may request that the executive [~~DADS~~] commissioner resolve the dispute. An applicant must send a written statement to the executive [~~DADS~~] commissioner describing the request for reimbursement and the reason for the request. The executive [~~DADS~~] commissioner reviews [~~will review~~] the request and notifies [~~notify~~] an applicant in writing of the decision.

§550.115. Criteria for Denial of a License.

(a) HHSC [~~DADS~~] may deny an application for an initial center license or for renewal of a license for:

(1) a violation of the THSC Chapter 248A or a standard in this chapter committed by the license holder, applicant, or a person listed on the application;

(2) an intentional or negligent act by the center or an employee of the center that HHSC [~~DADS~~] determines significantly affects the health or safety of a minor served at the center;

(3) use of drugs or intoxicating liquors to an extent that affects the license holder's or applicant's professional competence;

(4) a felony conviction, including a finding or verdict of guilty, an admission of guilt, or a plea of nolo contendere, in this state or in any other state of any person required by this chapter to undergo a background and criminal history;

(5) fraudulent acts, including acts relating to Medicaid fraud and obtaining or attempting to obtain a license by fraud or deception, committed by any person listed on the application;

(6) a license revocation, suspension, or other disciplinary action taken in Texas or another state against the license holder or any person listed on the application;

(7) criteria described in Chapter 560 [~~99~~] of this title (relating to Denial or Refusal of License) that applies to any person required by this chapter to undergo a background and criminal history check;

(8) aiding, abetting, or permitting a substantial violation described in paragraph (1) of this subsection about which a person listed on the application had or should have had knowledge;

(9) a license holder or applicant's failure to provide the required information as requested on the application or in follow-up to the review of the application;

(10) a license holder or applicant who knowingly:

(A) submits false or intentionally misleading statements to HHSC [~~DADS~~] on an application;

(B) uses subterfuge or other evasive means of filing an application;

(C) engages in subterfuge or other evasive means of filing an application on behalf of another who is unqualified for licensure; or

(D) conceals a material fact on an application;

(11) a person listed on the application failing to pay the following fees, taxes, and assessments when due:

(A) licensing fees as described in §550.112 [~~§15.112~~] of this subchapter (relating to Licensing Fees);

(B) franchise taxes, if applicable; and

(C) federal taxes, as applicable; or

(12) a person listed on the application having a history of any of the following actions during the five-year period preceding the date of the application:

(A) operation of a facility in Texas or another state or jurisdiction that has been decertified or had its contract canceled under the Medicare or Medicaid program;

(B) federal or state Medicare or Medicaid sanctions or penalties;

(C) an unsatisfied final court judgment;

(D) eviction in Texas or another state or jurisdiction involving any property or space used as a center; or

(E) suspension in Texas or another state or jurisdiction of a license to operate a health facility, long-term care facility, assisted living facility, or a similar facility, or a center.

(b) HHSC [~~DADS~~]:

(1) denies a license to an applicant to operate a center if an applicant has on the date of the application:

(A) a debarment or exclusion from the Medicare or Medicaid programs by the federal government or a state; or

(B) a court injunction prohibiting an applicant or manager from operating a center; and[~~.~~]

(2) may deny a license to an applicant to operate a new center if an applicant has a history of any of the following actions at any time preceding the date of the application:

(A) revocation of a license to operate a health care facility, long-term care facility, assisted living facility or similar facility, or center in any state;

(B) surrender of a license in lieu of revocation or while a revocation hearing is pending;

(C) expiration of a license while a revocation action is pending and the license is surrendered without an appeal of the revocation or an appeal is withdrawn; or

(D) probation period placed on a license to operate a center.

(c) HHSC [~~DADS~~] may consider exculpatory information provided by any person described in §550.101(f) [~~§15.101(f)~~] of this subchapter (relating to Criteria and Eligibility for a License) and grant a license if HHSC [~~DADS~~] finds that person able to comply with THSC Chapter 248A and this chapter.

(d) In determining the denial of a license, HHSC [~~DADS~~] considers all final actions taken against an applicant or license holder whether issued by HHSC [~~DADS~~] or another state or federal agency. An action is final when administrative and judicial remedies are exhausted. All actions, whether pending or final, must be disclosed.

(e) If an applicant owns multiple centers or other facility types, HHSC [~~DADS~~] examines the overall record of compliance in all of the centers or other facilities [~~types~~] and agencies. An overall record poor enough to deny issuance of a new license does [~~will~~] not preclude the renewal of licenses of individual centers with satisfactory records.

(f) If HHSC [~~DADS~~] denies an application for a license, HHSC sends [~~or refuses to issue a renewal of a license,~~] an applicant written notice of the denial and informs the applicant of the right to [~~or license holder may~~] request an administrative [a] hearing to appeal the denial. The administrative hearing is held in accordance with [~~by complying with the Texas Health and Human Services Commission's rules for hearings found in~~] 1 Texas Administrative Code [~~TAC~~] Chapter 357, Subchapter I (relating to Hearings Under the Administrative Procedure Act) and [~~DADS rules for hearings found in~~] Chapter 110 [~~91~~] of this title (relating to Hearings Under the Administrative Procedure Act). [~~An administrative hearing is conducted in accordance with Texas Government Code, Chapter 2001; 1 TAC Chapter 357, Subchapter I; and Chapter 91 of this title.~~]

§550.118. Reporting Changes in Application Information.

If certain information provided on an initial or renewal application changes after HHSC [~~DADS~~] issues the license, a center must report the change to HHSC [~~DADS~~] by submitting a change application through the online portal [~~following the instructions on the DADS website for reporting a change~~]. For requirements on reporting a change regarding:

(1) the administrator, chief financial officer, and controlling person, a center must comply with §550.119 [~~§15.119~~] of this subchapter [~~division~~] (relating to Notification Procedures for a Change in Administration and Management) and §559.302 [~~§15.302~~] of this chapter (relating to Organizational Structure and Lines of Authority);

(2) the center's contact information, a center must comply with §550.120 [~~§15.120~~] of this subchapter (relating to Notification Procedures for a Change of [~~in~~] Contact Information);

(3) the center's operating hours, a center must comply with §550.121 [~~§15.121~~] of this subchapter (relating to Notification Procedures for a Change in Operating Hours); and

(4) name (legal entity or doing business as), a center must comply with §550.122 [~~§15.122~~] of this subchapter (relating to Notification Procedures for a Name Change).

§550.119. Notification Procedures for a Change in Administration and Management.

(a) If a change occurs in the following management staff, a center must report the change to HHSC by submitting notification through the application in the online portal [~~submit written notice to DADS~~] no later than seven days after the date of a change in:

(1) administrator;

(2) chief financial officer; or

(3) controlling person, as defined in §550.5 [~~§15.5~~] of this chapter (relating to Definitions), including:

(A) a change of five percent or more of the controlling interest of a limited partner in a limited partnership or the addition of a controlling person to the limited partnership; or

(B) a change of five percent or more of the controlling interest in a for-profit corporation or limited liability company.

(b) A change in the management staff listed in subsection (a) of this section requires HHSC review [~~DADS evaluation~~] and approval. HHSC [~~DADS~~] reviews the required documents and information submitted. HHSC [~~DADS~~] provides notification to a center through the application in the online portal if a person listed in subsection (a) [~~(a)(1) - (6)~~] of this section does not meet the required qualifications described in §550.101 of this chapter (relating to Criteria and Eligibility for a License).

§550.120. Notification Procedures for a Change of Contact Information.

A center must report a change in contact information [~~submit written notice~~] to HHSC by submitting a change application through the online portal [~~DADS~~] no later than seven days after a change in the center's:

(1) telephone number; or

(2) mailing address, if different from the physical location.

§550.121. Notification Procedures for a Change in Operating Hours.

A center must report a change in operating hours [~~submit written notice~~] to HHSC by submitting a change application through the online portal [~~DADS~~] no later than seven days after a change in the center's operating hours.

§550.122. Notification Procedures for a Name Change.

(a) If a center intends to change the name of its legal entity or assumed name, but does not undergo a change of ownership as defined in §550.107 [~~§15.107~~] of this subchapter (relating to Change of Ownership), the center must report the name change to HHSC by submitting a change application through the online portal [~~DADS~~] no later than seven days after the effective date of the name change.

(b) If a center changes its name but does not undergo a change of ownership, the license holder must notify HHSC through submission of a change application through the online portal [~~DADS~~] and submit a copy of a certificate of amendment from the Office of the Secretary of State. After HHSC [~~DADS~~] receives the certificate of amendment and approves the change application, a license is issued in the license holder's new name.

§550.123. Request and Issuance of Temporary License.

(a) An applicant for an initial license under §550.105 [~~§15.105~~] of this subchapter (relating to Initial License Application Procedures and Issuance) may request that HHSC [~~DADS~~] issue a temporary license pending review by HHSC [~~DADS review~~] of the applicant's application for an initial license.

(b) To request a temporary license, the applicant must submit an application for a temporary license to the HHSC Licensing and Credentialing [~~DADS Provider Licensure and Certification~~] Unit through the online portal [~~a written request for a temporary license~~] and upload a copy of the applicant's policies, procedures and staffing plans that demonstrate compliance with the licensing standards of this chapter.

(c) HHSC [~~DADS~~] issues a temporary license to an applicant who has requested a temporary license if HHSC [~~DADS~~]:

(1) determines that the applicant has submitted an application for an initial license in accordance with §550.105 [~~§15.105~~] of this subchapter;

(2) determines that the applicant meets the building requirements of Subchapter E of this chapter; and

(3) approves the applicant's policies, procedures and staffing plans submitted in accordance with subsection (b) of this section.

(d) If HHSC [~~DADS~~] issues a temporary license, the center may admit no more than six minors to the center until the temporary license expires or terminates.

(e) The issuance of a temporary license constitutes HHSC [~~DADS~~] notice to the applicant of the approval of the temporary license request.

(f) A temporary license expires on the earlier of:

(1) 90 days after HHSC [~~DADS~~] issues the temporary license or the last day of any extension HHSC [~~DADS~~] grants in accordance with subsection (g) of this section; or

(2) the date HHSC [~~DADS~~] issues an initial license.

(g) A temporary license holder may request that HHSC [~~DADS~~] extend the term of a temporary license by 90 days. To request an extension, the license holder must submit to the HHSC [~~DADS~~] Provider License and Certification Unit, a [~~written~~] request for an extension through the online portal. If HHSC [~~DADS~~] receives the request at least 30 days before the date the temporary license expires, HHSC [~~DADS~~] extends the term of the license for 90 days and notifies the temporary license holder of the extension in writing. HHSC [~~DADS~~] grants an applicant only one temporary license extension for a center.

(h) A temporary license holder must comply with the requirements of THSC Chapter 248A and the licensing standards of this chapter for the term of the temporary license. HHSC [~~DADS~~] may take the enforcement action described in Subchapter G of this chapter (relating to Enforcement) if the temporary license holder does not comply with THSC Chapter 248A or this chapter.

(i) HHSC [~~DADS~~] may visit or conduct an investigation or inspection of a center owned or operated by a temporary license holder, as described in Subchapter F of this chapter (relating to Inspections and Visits).

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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Karen Ray
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Health and Human Services Commission
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SUBCHAPTER C. GENERAL PROVISIONS
DIVISION 1. OPERATIONS AND SAFETY PROVISIONS

26 TAC §§550.202, 550.203, 550.205 - 550.207, 550.210, 550.211

STATUTORY AUTHORITY

The amendments are authorized by Texas Government Code §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of services by the health and human services agencies, and Texas Human Resources Code §103.004 and §103.005, which respectively provide that the Executive Commissioner of HHSC shall adopt rules for implementing Chapter 103 and adopt rules for licensing and setting standards for facilities licensed under Chapter 103.

The amendments implement Texas Government Code §531.0055 and Texas Human Resources Code, Chapter 103.

§550.202. Suspension of Operations.

(a) Suspension of operations occurs when a center suspends its normal business operations for five or more consecutive days due to:

(1) a scheduled closing of the center when a center has at least 45 days advance notice of the need to close the center; or

(2) an unscheduled closing of the center when a center has less than 45 days but more than 15 days advance notice of the need to close the center.

(b) A suspension of operations may not exceed the expiration date of the licensure period.

(c) If a center suspends operations due to a scheduled closing of the center, the center must:

(1) provide written notification to an adult minor or a minor's parent at least 30 days before the suspension of operations begins that includes:

(A) the start and end date of the suspension;

(B) instructions for obtaining a minor's medical records before and during the suspension for all services provided at the center; and

(C) information about the available options to transfer, discharge, or put a minor's services on hold depending on the needs of the minor;

(2) assist a parent or an adult minor with finding alternative services during the suspension;

(3) discharge, transfer or put a minor's services on hold in accordance with §550.608 [~~§15.608~~] of this subchapter [~~chapter~~] (relating to Discharge or Transfer Notification);

(4) ensure coordination of services for the minor's other service providers;

(5) notify the minor's physician at least 30 days before the suspension of operations begins;

(6) provide written notification to HHSC through the online portal [~~DADS~~] at least 30 days before the suspension of operations begins; [~~and~~]

(7) post a notice, in a location visible outside of the center for the duration of the suspension, that provides information about the suspension of operations, including:

(A) the start and end date of the suspension; and

(B) how to obtain a minor's records during the suspension;

(8) leave an outgoing message, on the center's answering machine or other similar electronic mechanism or with an answering service, that provides the information in paragraph (7) of this subsection; and

(9) notify HHSC [~~DADS~~] in writing within seven days after resuming normal business operations.

(d) If a center suspends operations due to an unscheduled closing of the center, the center must:

(1) provide oral and written notification to a minor's parent no later than 15 days before the suspension of operations begins that includes:

(A) the start and estimated end date of the suspension;

(B) instructions for obtaining a minor's medical records before and during the suspension for all services provided at the center; and

(C) information about the available options to transfer, discharge, or put a minor's services on hold depending on the needs of the minor;

(2) assist a parent or an adult minor with finding alternative services during the suspension;

(3) discharge, transfer or put the minor's services on hold in accordance with §550.608 [~~§15.608~~] of this subchapter [~~chapter~~];

(4) ensure coordination of services with the minor's other service providers;

(5) notify the minor's physician no later than 15 days before the suspension of operations begins;

(6) provide written notification to HHSC [~~DADS~~] no later than 15 days before the suspension of operations begins;

(7) post a notice, in a location visible outside of the center, for the duration of the suspension that provides information about the suspension of operations, including:

(A) the start and estimated end date of the suspension; and

(B) how to obtain a minor's records during the suspension;

(8) leave an outgoing message, on the center's answering machine or other similar electronic mechanism or with an answering service, that provides the information in paragraph (7) of this subsection; and

(9) notify HHSC [~~DADS~~] in writing within seven days after resuming normal business operations.

(e) If the center must close with less than 15 days advance notice, the center must follow the requirements in §550.209 [~~§15.209~~] of this division (relating to Emergency Preparedness Planning and Implementation).

§550.203. Financial Solvency and Business Records.

(a) A center must have the financial ability to carry out its functions.

(b) A center must make available to HHSC [~~DADS~~], upon request, business records relating to its ability to carry out its functions. HHSC [~~DADS~~] may conduct a more extensive review of the records if there is a question relating to the accuracy of the records or the center's financial ability to carry out its functions.

(c) A center must maintain business records in their original state. Each entry must be accurate and include the date of entry. Correction fluid or tape may not be used in the record. Corrections must be made in accordance with standard accounting practices.

§550.205. Safety Provisions.

(a) A center must ensure that the local fire marshal's office or the state fire marshal inspects the center annually. The center must keep a copy of the annual fire inspection report on file at the center for two years after the date of inspection.

(b) A center must prepare a fire drill plan and conduct a fire drill at least once every month.

(1) The center's administrator and nursing director must participate in the monthly fire drill.

(2) The center must conduct fire drills at various times of the day.

(3) The center must document a drill on the HHSC [~~DADS~~] Fire Drill Report Form.

(c) The center's administrator and nursing director must:

(1) review the center's fire drill plan;

(2) evaluate the effectiveness of the plan after each fire drill;

(3) review any problems that occurred during each drill and take corrective action, if necessary; and

(4) maintain documentation to support the requirements of this subsection.

(d) A center must have a working telephone available at all times at the center. Coin operated telephones or cellular telephones are not acceptable for this purpose. If the center has multiple buildings, a working telephone must be located in each of the buildings.

(e) A center must post at or near the immediate vicinity of all telephones:

(1) emergency telephone numbers including:

(A) the HHSC [~~DADS~~] abuse, neglect, and exploitation hotline;

(B) poison control;

(C) 911 or the local fire department, ambulance, and police in communities where a 911 management system is unavailable; and

(D) an emergency medical facility; and

(2) the center's address.

(f) A center must adopt and enforce written policies and procedures for a minor's medical emergency. The policy must include:

(1) a requirement that each minor has an emergency plan, developed in collaboration with a minor's parent, that:

(A) includes instructions from a minor's prescribing physician, as applicable;

(B) includes coordination with other health care providers, including hospice; and

(C) is updated and reviewed at least yearly or more often as necessary to meet the needs of a minor;

(2) a requirement that staff receive training for medical emergencies;

(3) a requirement that staff receive training in the use of emergency equipment; and

(4) procedures that staff follow when a minor's parent cannot be contacted in an emergency.

(g) If a minor must be transported to an emergency medical facility while at the center, the staff must immediately notify a minor's parent and hospice provider, if applicable. If a parent cannot be contacted, the center must ensure that an individual authorized by the parent or center staff meets a minor at the emergency facility.

(h) The center must prepare a medical emergency transfer form to give to the emergency transportation provider when transporting a minor to an emergency medical facility. The transfer form must include:

(1) the minor's name and age;

(2) the minor's diagnoses, allergies, and medication;

(3) the minor's parent name and contact information;

(4) the minor's prescribing physician name and contact information;

(5) the center's name and contact information; and

(6) the name of the administrator or nursing director.

(i) A center must maintain a first aid kit with unexpired supplies and an automated external defibrillator for minors served at the center that is easily accessible but not within reach of minors.

(j) A center must adopt and enforce written policies and procedures for the verification and monitoring of visitors, including service providers at a center. The policies and procedures must include:

(1) verification of a visitor's identity;

(2) verification of a visitor's authorization to enter a center;

(3) the recording of a visitor's name, organization, purpose of the visit, and the date and time a visitor entered and exited a center;

(4) the center's awareness of a visitor while in a center; and

(5) documentation of the requirements in this subsection.

(k) A center must adopt and enforce written policies and procedures for the release of a minor. The policy must include:

(1) procedures to verify the identity of a person authorized to pick up a minor from the center; and

(2) procedures for the release of a minor when transported by the center in accordance with Subchapter D of this chapter (relating to Transportation).

(l) A center must adopt and enforce written policies and procedures to ensure that no minor is left unattended at the center. The policy must include procedures for:

(1) a minor who arrives at the center;

(2) a minor who remains at the center during operating hours;

(3) a minor who leaves the center; and

(4) staff to conduct daily visual checks at the center at the close of business.

(m) A center must maintain daily records and documentation of the visual check at the end of each day to ensure no minor is left at the center. The documentation must include:

(1) the date and time; and

(2) the signature of the staff member conducting the daily visual checks at the center at the close of business.

(n) Except as otherwise provided in this section, a center must meet the provisions applicable to the health care occupancy chapters of the 2000 edition of the LSC of the National Fire Protection Association (NFPA) and the requirements in Subchapter E of this chapter (relating to Building Requirements). Roller latches are prohibited on corridor doors.

(o) Notwithstanding any provisions of the 2000 edition of the Life Safety Code, NFPA 101, to the contrary, a center may place alcohol-based hand-rub dispensers at the center if:

(1) use of alcohol-based hand-rub dispensers does not conflict with any state or local codes that prohibit or otherwise restrict the placement of such dispensers in health care facilities;

(2) the dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(3) the dispensers are installed in a manner or location out of reach of a minor; and

(4) the dispensers are installed in accordance with Chapter 18.3.2.7 or Chapter 19.3.2.7 of the 2000 edition of the LSC, as amended by NFPA Temporary Interim Amendment 00-1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004.

(p) A center's environment must be free of health and safety hazards to reduce risks to minors. The center must:

(1) use childproof electrical outlets or childproof covers on unused electrical outlets in all rooms to which minors have access at the center;

(2) use safety precautions for strings and cords, including those used on window coverings, and keep them out of the reach of minors;

(3) use safety precautions for all furnishings including cabinets, shelves, and other furniture items that are not permanently attached to the center; and

(4) use play material and equipment that is safe and free from sharp or rough edges and toxic paints.

(q) A center must adopt and enforce a written policy describing whether a center is a weapons-free location. A center must:

(1) provide a copy of the policy to staff, individuals providing services on behalf of a center, an adult minor, and a minor's parent; and

(2) provide a copy of the policy to any person who requests it.

(r) If a center is weapons-free, a center must post a visible and readable sign at the entrance of the center indicating the center is a weapons-free location.

(s) A center must adopt and enforce a written policy prohibiting the use of tobacco in any form, the use of alcohol, and the possession of illegal substances and potentially toxic substances at a center.

§550.206. Person-Centered Direction and Guidance.

(a) A center must adopt and enforce written policies and procedures for the use of person-centered direction and guidance by individuals providing services to minors at the center. The policy must include:

(1) the implementation of a system-wide, person-centered direction and guidance program for minors that includes:

(A) the teaching of successful behavior and coping skills;

(B) proactive strategies to identify and manage a minor's behaviors before they escalate; and

(C) the monitoring and evaluation of the effectiveness of direction and guidance used with a minor by a committee as described in this section;

(2) procedures for ensuring consistent language, practices, and application of direction and guidance by individuals providing services at a center; and

(3) procedures for documenting and providing to a minor's parent a daily report of the minor's behavior.

(b) A center must ensure that only person-centered strategies and techniques that encourage self-esteem, self-control, and self-direction are used for the purposes of direction and guidance of a minor at a center. A center must not use a restraint as part of person-centered direction and guidance.

(c) Person-centered direction and guidance must be:

(1) individualized and consistent for each minor;

(2) differentiated in both nature and intensity based on a minor's level of behavior;

(3) appropriate to the minor's level of understanding and functional or educational development; and

(4) directed toward teaching the minor successful behavior, awareness of behavior triggers and self-control, including:

(A) encouraging a minor to develop positive behavior in accordance with a minor's individualized psychosocial program;

(B) redirecting behavior using positive statements; and

(C) teaching the minor to use effective behavior management techniques.

(d) A center must ensure that quiet time, if used, is:

(1) in accordance with the minor's psychosocial program and plan of care;

(2) brief and under continuous face-to-face observation by center staff;

(3) appropriate for the minor's age and development;

(4) limited to no more than one minute per year of the minor's developmental age; and

(5) does not place a minor alone in a room.

(e) A center must ensure the protection of minors at the center from harsh, cruel, or unusual treatment. Negative discipline is considered punishment and abuse and is prohibited at a center, including:

(1) corporal punishment or threats of corporal punishment;

(2) punishment associated with food, naps, or toilet training;

(3) pinching, shaking, or biting a minor;

(4) hitting a minor with a hand or object;

(5) putting anything in or on a minor's mouth;

(6) humiliating, ridiculing, rejecting, or yelling at a minor;

(7) subjecting a minor to harsh, abusive, or profane language;

(8) placing a minor alone in a locked or darkened room, bathroom, or closet without windows; and

(9) requiring a minor to remain silent or inactive for inappropriately long periods of time for the minor's developmental age.

(f) The center must establish a person-centered direction and guidance committee to review the techniques and strategies used at a center to:

(1) determine whether the individualized direction and guidance used as established in a plan of care is consistently applied for each minor in accordance with center policy; and

(2) evaluate the frequency and outcomes of strategies and techniques used with a minor to:

(A) determine the impact of the direction and guidance on a minor's ability to achieve progress in goals;

(B) determine effectiveness of the minor's program; and

(C) recommend the use of new strategies and techniques when current strategies and techniques are determined to be ineffective.

(g) The committee must include:

(1) the center's administrator;

(2) the center's nursing director or designee;

(3) an individual providing psychosocial treatment and services on behalf of a center; and

(4) a parent or an individual from a parent council or support group for minors receiving services at the center.

(h) The center is not required to include a parent or individual from a parent council or support group if, after a good faith effort, the center is unable to include a parent or individual in a committee meeting. The center must document, for review by HHSC [~~DADS review~~], a good faith effort to include a parent or individual from a parent council or support group at each meeting.

(i) The center must adopt and enforce written policies and procedures for the frequency, format, and documentation of committee meetings.

(j) A center must provide its written person-centered direction and guidance policy to all parents, employees, volunteers, and contractors. The center must maintain documentation of acknowledgment of the written policy from all employees, volunteers, and contractors.

§550.207. Protective Devices and Restraints.

(a) Protective Devices. A center must ensure that a protective device is used only as ordered by a minor's prescribing physician, as agreed to by an adult minor or a minor's parent, and in accordance with the minor's plan of care.

(1) A center may use a protective device only in the following circumstances:

(A) as part of a therapeutic regimen of basic services for a minor's physical health and development;

(B) during medical, nursing, diagnostic, and dental procedures as prescribed by a physician's order and to protect the health and safety of a minor; or

(C) in a medical emergency to protect the health and safety of a minor.

(2) A center must adopt and enforce written policies and procedures requiring a protective device to be used as described in this subsection and in accordance with a minor's plan of care.

(3) A center must not implement a physician's order for the use of a protective device on a pro re nata (PRN) or as-needed basis.

(4) A center must ensure a physician's order is obtained before using a protective device at the center. The physician's order must include:

(A) the circumstances under which a protective device may be used at the center;

(B) instructions on how long a protective device may be used at the center; and

(C) any individualized, less restrictive interventions described in the minor's plan of care that must be used before using a protective device.

(5) A center must ensure that in implementing a physician's order for a protective device that an RN, with input from an adult minor, a minor's parent, and the IDT:

(A) conducts an assessment of a minor's current and ongoing need for a protective device at a center;

(B) reviews the physician's order for a protective device, as described in paragraph (4) of this subsection; and

(C) obtains and documents in a minor's medical record the written consent of an adult minor or a minor's parent to use a protective device at the center.

(6) Before using a protective device for the first time with a minor, the center must ensure an RN provides oral and written notification to the adult minor or the minor's parent of the right at any time to withdraw consent and discontinue use of a protective device at the center.

(7) The center must ensure that a staff member who will apply a protective device has been properly trained in the use of a protective device, as ordered in the minor's plan of care, in accordance with this subsection, and in accordance with §550.415(b)(8)(F) [~~§15.415(b)(8)(F)~~] of this subchapter (relating to Staffing Policies for Staff Orientation, Development, and Training).

(8) If a protective device is used for a minor, the center must ensure:

(A) the minor is assessed by an RN, in accordance with the physician's order but no less than once every hour to determine if the protective device must be repositioned or discontinued;

(B) except for sedation, the protective device is removed to conduct the RN assessment described in subparagraph (A) of this paragraph and removed more frequently as determined necessary by the RN's assessment;

(C) center staff replaces the protective device, if necessary, after the assessment, in accordance with the physician's order;

(D) a minor's physician is notified immediately if an assessment determines a change in the minor's condition or a negative reaction to the protective device has occurred, including notification of:

(i) the minor's psychosocial condition;

(ii) the minor's reaction to the protective device;

(iii) the minor's medical condition; and

(iv) the need to continue or discontinue the use of the protective device;

(E) the type and frequency of use of the protective device is documented in the minor's medical record;

(F) the effects of a protective device on the minor's health and welfare are evaluated and documented in the medical record; and

(G) an RN, an adult minor, a minor's parent, and the IDT, at least every 180 days, or as the minor's needs change, review, with input and direction from the minor's prescribing physician, the use of a protective device to determine its effectiveness and the need to continue the use of the protective device.

(b) Restraints. A center may use a restraint only in a behavioral emergency when the immediate health and safety of the minor or another minor are at risk. A center must not use a chemical or mechanical restraint. [~~A center may use only the following restraints:~~]

(1) The center must adopt and enforce a written policy and procedures regarding the use of restraints in a behavioral emergency, including whether a center is a restraint-free environment.

(2) A center must ensure that the use of a restraint at a center must not be in a manner that:

(A) obstructs a minor's airway, including the placement of anything in, on, or over the minor's mouth or nose;

(B) impairs the minor's breathing by putting pressure on the minor's torso;

(C) interferes with the minor's ability to communicate;

(D) extends muscle groups away from each other;

(E) uses hyperextension of joints; or

(F) uses pressure points or pain.

(3) A center must ensure that a restraint is not used for:

(A) controlling a minor's behavior in a non-emergency;

(B) negative discipline as described in §550.206 [~~§15.206~~] of this division (relating to Person-Centered Direction and Guidance);

(C) convenience;

(D) coercion or retaliation; or

(E) as part of a behavior component of a minor's psychosocial program.

(4) A center must not implement a physician's order for the use of a restraint on a pro re nata (PRN) or as-needed basis.

(5) A center must ensure that a staff member whose job responsibilities will include the use or application of a restraint during a behavioral emergency has been properly trained in the use of a restraint for minors served at the center, in accordance with this section, and in accordance with §550.415(b)(8)(G) [~~§15.415(b)(8)(G)~~] of this subchapter [~~(relating to Staffing Policies for Staff Orientation, Development, and Training)~~].

(6) If a center restrains a minor due to a behavioral emergency, the center must ensure:

(A) all less restrictive options available are exhausted before using a restraint;

(B) the restraint is limited to the use of such reasonable force as is necessary to address the emergency;

(C) the restraint is discontinued immediately at the point when the emergency no longer exists but no more than 15 minutes after the restraint was initiated;

(D) the restraint is implemented in such a way as to protect the health and safety of the minor and others;

(E) immediately after the restraint is discontinued, the minor is assessed by an RN;

(F) immediately following an RN assessment, medical attention is provided for the minor if determined necessary by the RN assessment;

(G) within three days after the use of the restraint, an assessment is conducted by an RN as described in §550.504 [~~§15.504~~] of this subchapter [~~chapter~~] (relating to Psychosocial Treatment and Services) to determine if the development and implementation of a psychosocial treatment and services program is needed for the minor to address the minor's behavior and reduce the occurrence of future behavioral emergencies; and

(H) within three days after the use of the restraint, an RN reviews and updates a minor's plan of care and psychosocial treatment and services program as determined appropriate.

(7) If a center restrains a minor due to a behavioral emergency, the center must ensure the following documentation and notifications occur:

(A) immediately after the restraint is discontinued, information about the restraint is documented, including:

(i) the name of the individual who administered the restraint;

(ii) the date and time the restraint began and ended;

(iii) the location of the restraint;

(iv) the nature of the restraint;

(v) a description of the setting and activity in which the minor was engaged immediately preceding the use of the restraint;

(vi) the behavior that prompted the restraint;

(vii) the efforts made to de-escalate the situation and the less restrictive alternatives attempted before the restraint; and

(viii) the minor's condition after the restraint was discontinued;

(B) within 24 hours after the use of the restraint, written documentation regarding the use of the restraint and the RN assessment conducted immediately after the use of the restraint is included in a minor's medical record;

(C) documentation of nursing director and administrator oral and written notifications as described in subparagraphs (E) and (I) of this paragraph, including nursing director and administrator signatures acknowledging receipt of notifications must be included in the minor's medical record;

(D) documentation of parent oral and written notifications as described in subparagraphs (F) and (J) of this paragraph, including a parent signature acknowledging receipt of notifications must be included in the minor's medical record;

(E) immediately after the restraint is used, the administrator and director of nursing are notified orally that the restraint occurred;

(F) on the day the restraint is used, the minor's parent is notified orally that the restraint occurred;

(G) on the day the restraint is used, the center's staff responsible for psychosocial treatment and services is notified orally that the restraint occurred;

(H) immediately after the RN assessment is conducted in accordance with paragraph (6)(E) of this subsection, if the assessment determines a change in the minor's condition or a negative reaction to the restraint has occurred, the minor's physician is notified of the restraint and the minor's condition, including:

(i) the minor's medical condition;

(ii) the minor's reaction to the restraint; and

(iii) the minor's psychosocial condition;

(I) within one hour after the use of the restraint, the administrator and director of nursing are notified in writing of the restraint, including the information in subparagraph (A) of this paragraph; and

(J) within one day after the use of the restraint, the minor's parent is notified in writing, in a language and format the parent understands, of the restraint, including the information in subparagraph (A) of this paragraph. [~~;~~]

(8) The IDT must review, on an annual basis or more frequently as needed, all behavioral emergencies that occurred at the center during the time period being reviewed to determine the appropriateness of the center's response and to identify strategies for reducing behavioral emergencies at the center.

(9) A center must maintain documentation of compliance with this section.

§550.210. Sanitation, Housekeeping, and Linens.

(a) A center must ensure a sanitary environment by following accepted standards of practice and maintain a safe physical environment free of hazards for minors, staff, and visitors.

(b) A center must ensure that the following conditions are met.

(1) Wastewater and sewage must be discharged into a state-approved municipal sewage system. An on-site sewage facility must be approved by the Texas Commission on Environmental Quality (TCEQ) or authorized agent.

(2) The water supply must be from a system approved by the Public Drinking Water Section of the TCEQ, or from a system regulated by an entity responsible for water quality in the jurisdiction where the center is located as approved by the Public Drinking Water Section of the TCEQ.

(3) Waste, trash, and garbage must be disposed of from the premises at regular intervals in accordance with state and local prac-

tices. Excessive accumulations are not permitted. Outside containers must have tight-fitting lids left in closed position. Containers must be maintained in a clean and serviceable condition.

(4) Center grounds must be well kept and the exterior of the building, including sidewalks, steps, porches, ramps, and fences, must be in good repair.

(5) The interior of the center's buildings including walls, ceilings, floors, windows, window coverings, doors, plumbing, and electrical fixtures must be in good repair.

(6) Pest control must be provided by a licensed structural pest control applicator with a license category for pests. The center must maintain documented evidence of routine efforts to remove rodents and insects.

(7) The center must be kept free of offensive odors, accumulations of dirt, rubbish, dust, and hazards. Storage areas, attics, and cellars must be free of refuse and extraneous materials.

(c) A center must adopt and enforce a written work plan for housekeeping operations, with categorization of cleaning assignments as daily, weekly, monthly, or annually within each area of the center.

(d) A center must ensure the provision of housekeeping and maintenance of the interior, exterior, and grounds of the center in a safe, clean, orderly, and attractive manner. The center must provide housekeeping and maintenance staff with equipment and supplies if needed. A center must designate staff to be responsible for overseeing the housekeeping services.

(e) A center must develop procedures for the selection, use, and disposal of housekeeping and cleaning products and equipment. The center must ensure:

(1) the use of Environmental Protection Agency-approved [~~EPA approved~~] cleaning products appropriate for the application and materials to be sanitized;

(2) the following of manufacturer instructions for use and disposal of cleaning products;

(3) all bleaches, detergents, disinfectants, insecticides, and other poisonous substances are kept in a safe place accessible only to staff; and

(4) all products are labeled.

(f) A center must ensure a sufficient supply of clean linens is available to meet the needs of minors. Clean laundry must be provided in-house by the center, through a contract with another health care center, or with an outside commercial laundry service.

(g) A center must ensure:

(1) linens are handled, stored, and processed so as to control the spread of infection;

(2) linens are maintained in good repair;

(3) linens are washed, dried, stored, and transported in a manner which will produce hygienically clean linen;

(4) the washing process has a mechanism for removing soil and killing bacteria;

(5) clean linens are stored in a clean linen area easily accessible to the staff;

(6) soiled linens and clothing are stored separately from clean linen and clothing;

(7) soiled linens and clothing are stored in well-ventilated areas, and are not permitted to accumulate at the center;

(8) soiled linens and clothing are transported in accordance with procedures consistent with universal precautions;

(9) soiled linens are not sorted, laundered, rinsed, or stored in bathrooms, corridors, food preparation area, or food storage areas;

(10) a minor's clothing stored at the center is cleaned after each use; and

(11) staff wash their hands both after handling soiled linen and before handling clean linen.

§550.211. Infection Prevention and Control Program and Vaccinations Requirements.

(a) A center must establish and maintain an infection prevention and control program (IPCP) designed to provide a safe, sanitary, and comfortable environment by preventing the development and transmission of disease and infection. Under the IPCP, the center must:

(1) investigate, prevent, and control infections at the center;

(2) decide what procedures, such as isolation, should be applied to an individual minor;

(3) address vaccine preventable diseases in accordance with THSC, Chapter 224;

(4) address hepatitis B vaccinations in accordance with Occupational Safety and Health Administration;

(5) address tuberculosis requirements; and

(6) maintain a record of incidents and corrective actions relating to infections.

(b) A center must provide IPCP information to employees, contractors, volunteers, parents, health care providers, other service providers, and visitors.

(c) A center's IPCP must include written policies and procedures for admissions and attendance of minors who are at risk for infections or present a significant risk to other minors. The policy must include that a minor is accepted only:

(1) as authorized by a minor's prescribing physician:

(2) as determined by the center's medical director's assessment of the risk;

(3) as determined by the medical and nursing director review, on a case-by-case basis, to determine appropriateness of admission to or attendance at the center; and

(4) in accordance with Centers for Disease Control (CDC) guidelines.

(d) The center's IPCP must include written policies and procedures for preventing the spread of infection.

(1) If the center determines, in accordance with its IPCP, that a minor must be isolated to prevent the spread of infection, the center must isolate a minor.

(A) The center must maintain an isolation room with a glass window for observation of a minor. The isolation room must be equipped with emergency outlets and equipment as necessary to provide care to a minor. The isolation room must have a dedicated bathroom not accessible to the center's other rooms if appropriate to control the spread of infectious disease.

(B) The center must ensure that all equipment is thoroughly cleaned and disinfected before being placed in the isolation room and before being removed from the room.

(C) The center's procedures must address:

(i) notification to a minor's parent of the minor's condition and the center's recommendation of isolation or removal based on the minor's risk assessment;

(ii) the arrangement of transportation if the minor must be removed from the center; and

(iii) the return of a minor to the center, as determined by a reassessment conducted by a nurse that the minor no longer poses a risk to other minors.

(2) The center must prohibit employees, volunteers, and contractors with an infectious disease or infected skin lesions from direct contact with minors or food, if direct contact will transmit the disease.

(3) The center's infection control policy must provide that staff, volunteers, and contractors wash their hands between each treatment and care interaction with a minor.

(4) The center must immediately report the name of any minor with a reportable disease as specified in 25 Texas Administrative Code [~~TAC~~] Chapter 97, Subchapter A (relating to Control of Communicable Diseases) to the city health officer, county health officer, or health unit director having jurisdiction, and implement appropriate infection control procedures as directed by the local health authority or the Texas Department of State Health Services.

(e) The center must assign a crib, bed, or sleep mat for a minor's exclusive use each day. A center must label cribs, beds, and sleep mats with the minor's name.

(f) A center must place liquid soap, disposable paper towels, and trash containers at each sink.

(g) The center must adopt and enforce written policies and procedures for the control of communicable diseases for employees, contractors, volunteers, parents, health care providers, other service providers, and visitors and must maintain evidence of compliance.

(h) The center must adopt and enforce written policies and procedures for the control of an identified public health disaster.

(1) If a center determines or suspects that an employee, volunteer, or contractor providing services has been exposed to, or has a positive screening for, a communicable disease, the center must respond according to current CDC guidelines and keep documentation of the action taken.

(2) If the center determines that an employee, volunteer, or contractor providing services has been exposed to a communicable disease, the center must conduct and document a reassessment of the risk classification. The center must conduct and document subsequent screenings based upon the reassessed risk classification.

(3) If the center determines that an employee, volunteer, or a contractor providing services at the center is suspected of having a communicable disease, the individual must not return to the center until the individual no longer poses a risk of transmission as documented by a written physician's statement.

(i) The center must conduct and document an annual review that assesses the center's current risk classification according to the current CDC Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health Care Settings and 25 Texas Administrative Code [~~TAC~~] Chapter 97, Subchapter A.

(1) The center must have a system in place to screen all individuals providing services at the center.

(2) The center must require employees, volunteers, and contractors providing services to provide evidence of current tuberculosis screening before providing services at the center. The center must maintain evidence of compliance.

(3) Any employee, volunteer, or contractor providing services at a center with positive results must be referred to the person's personal physician, and if active tuberculosis is suspected or diagnosed, the person must be excluded from work until the physician provides written approval to return to work.

(j) A center must adopt and enforce written policies and procedures to protect a minor from vaccine preventable diseases, in accordance with THSC[~~,~~] Chapter 224.

(1) The policy must:

(A) require an employee, volunteer, or contractor providing direct care to receive vaccines for the vaccine preventable diseases specified by the center based on the level of risk the employee, volunteer, or contractor, presents to minors by the employee's, volunteer's, or contractor's routine and direct exposure to minors;

(B) specify the vaccines an employee, volunteer, or contractor who provides direct care is required to receive in accordance with subsection (i) of this section;

(C) include procedures for the center to verify that an employee, volunteer, or contractor who provides direct care has complied with the policy;

(D) include procedures for the center to exempt an employee, volunteer, or contractor who provides direct care from the required vaccines for the medical conditions identified as contraindications or precautions by the CDC;

(E) include procedures, including using protective equipment such as gloves and masks, to protect minors from exposure to vaccine preventable diseases, based on the level of risk the employee, volunteer, or contractor presents to minors by the employee's, volunteer's, or contractor's routine and direct exposure to minors;

(F) prohibit discrimination or retaliatory action against an employee, volunteer, or contractor who provides direct care and who is exempt from the required vaccines for the medical conditions identified as contraindications or precautions by the CDC, except that required use of protective medical equipment, such as gloves and masks, will not be considered retaliatory action;

(G) require the center to maintain a written or electronic record of each employee's, volunteer's, or contractor's compliance with or exemption from the policy; and

(H) include disciplinary actions the center may take against an employee, volunteer, or contractor providing direct care who fails to comply with the policy.

(2) The center must have a written policy describing whether it will exempt an employee, volunteer, or contractor providing direct care:

(A) from the required vaccines based on reasons of conscience, including a religious belief; and

(B) prohibit an employee, volunteer, or contractor providing direct care who is exempt from the required vaccines from having contact with minors during a public health disaster.

(k) The center must adopt and enforce written policies and procedures to identify employees, volunteers, or contractors at risk of directly contacting blood or other potentially infectious materials in accordance with the Occupational Safety and Health Standards in [~~Administration (OSHA),~~] 29 Code of Federal Regulations §1910.1030 [~~Part 1910.1030 and Appendix A~~] relating to Bloodborne pathogens [~~Pathogens~~].

(l) A center must ensure that its employees, volunteers, and contractors comply with:

(1) the center's IPCP;

(2) the Communicable Disease Prevention and Control Act, THSC Chapter 81; and

(3) THSC Chapter 85, Subchapter I, concerning the prevention of the transmission of human immunodeficiency virus and hepatitis B virus.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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Health and Human Services Commission
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DIVISION 2. ADMINISTRATION AND MANAGEMENT

26 TAC §§550.301, 550.303 - 550.306, 550.308 - 550.311

STATUTORY AUTHORITY

The amendments are authorized by Texas Government Code §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of services by the health and human services agencies, and Texas Human Resources Code §103.004 and §103.005, which respectively provide that the Executive Commissioner of HHSC shall adopt rules for implementing Chapter 103 and adopt rules for licensing and setting standards for facilities licensed under Chapter 103.

The amendments implement Texas Government Code §531.0055 and Texas Human Resources Code, Chapter 103.

§550.301. License Holder's Responsibilities.

(a) The license holder is responsible for the conduct of the center and for the adoption, implementation, and enforcement of the written policies required throughout this chapter. The license holder is also responsible for ensuring that these policies comply with THSC Chapter 248A and the applicable provisions of this chapter and are administered to provide safe, professional, and quality health care.

(b) The persons described in §550.101(f) [~~§15.101(f)~~] of this chapter (relating to Criteria and Eligibility for a License) must not have been convicted of an offense described in §560.2 [~~§99.2~~] of this title (relating to Convictions Barring Licensure), during the time frames described in that chapter.

(c) The license holder must ensure that all documents submitted to HHSC [~~DADS~~] or maintained by the center as required by this chapter are accurate and do not misrepresent or conceal a material fact.

(d) The license holder must comply with an order of the executive [~~DADS~~] commissioner or other enforcement orders that may be imposed on the center in accordance with THSC Chapter 248A and this chapter.

(e) The license holder of the center must have full legal authority and responsibility for the operation of the center.

(f) A license holder must designate in writing an individual who meets the qualifications and conditions set out in §550.303 [~~§15.303~~] of this division [~~subchapter~~] (relating to Administrator and Alternate Administrator Qualifications and Conditions) to serve as the administrator of the center.

(g) A license holder must designate in writing an alternate administrator who meets the qualifications and conditions of an administrator set out in §550.303 [~~§15.303~~] of this division [~~subchapter~~] to act in the absence of the administrator or when the administrator is unavailable to the staff during the center's operating hours.

(h) A license holder must ensure the position and designation of an administrator or alternate administrator is filled with a qualified staff.

(i) A license holder must ensure maintenance of documentation of efforts to ensure a vacancy in the position of an administrator or alternate administrator does not last more than 30 days.

(j) A license holder must ensure all written notices to HHSC [~~DADS~~] required by this chapter, unless otherwise specified in this chapter, are submitted through the online portal [~~as described in the instructions provided on the DADS website~~].

§550.303. Administrator and Alternate Administrator Qualifications and Conditions.

(a) The administrator and alternate administrator of a center must have two years of experience in supervision and management in a pediatric health care setting and meet one of the following criteria:

(1) be a physician licensed in Texas to practice medicine in accordance with Texas Occupations Code, Chapter 155;

(2) be an RN with a master's or baccalaureate degree in nursing and be licensed under the Nursing Practice Act, Texas Occupations Code, Chapter 301, with no disciplinary actions;

(3) be a college graduate with a bachelor's degree with one additional year of supervision or management experience in a health care setting;

(4) have an associate [~~associate's~~] degree in health care or administration with two additional years of supervision or management experience in a health care setting; or

(5) have an associate [~~associate's~~] degree in nursing and currently licensed under the Nursing Practice Act, Texas Occupations Code, Chapter 301, with no disciplinary action with two additional years of supervision or management experience in a health care setting.

(b) The administrator and the alternate administrator of a center must be at least 25 years of age.

(c) An administrator and alternate administrator of a center must meet the initial training requirements specified in §550.305 [~~§15.305~~] of this division (relating to Initial Training in Administration) and the continuing training requirements specified in §550.306

[§15.306] of this division (relating to Continuing Training in Administration).

(d) A person is not eligible to be the administrator or alternate administrator of a center if the person was the administrator of a center cited with a violation that resulted in HHSC [DADS] taking enforcement action against the center while the person was the administrator of the cited center.

(1) This subsection applies for 12 months after the date of the enforcement action.

(2) For purposes of this subsection, enforcement action means license suspension, licensure revocation, emergency suspension of a license, denial of an application for a license, or the issuance of an injunction. Enforcement action does not include administrative or civil penalties.

(e) An administrator or alternate administrator must not be convicted of an offense described in §560.2 [§99.2] of this title (relating to Convictions Barring Licensure) during the time frames described in that chapter.

(f) The designated administrator and alternate administrator of a center must be full-time employees of the center.

(g) The designated administrator or alternate administrator may serve as the nursing director or alternate nursing director if the administrator or alternate administrator meets the nursing director qualifications as described in §550.309 [§15.309] of this division (relating to Nursing Director and Alternate Nursing Director Qualifications and Conditions).

(h) The designated administrator or alternate administrator may be included in the center's staffing ratio if:

(1) the administrator or alternate administrator is a licensed nurse or meets the qualifications in §550.409 [§15.409] of this subchapter (relating to Direct Care Staff Qualifications); and

(2) the center's actual census is less than four minors.

(i) The designated administrator or alternate administrator must not be included in the center's staffing ratios when functioning as the nursing director or alternate nursing director.

(j) The designated administrator must manage only one center.

§550.304. Administrator Responsibilities.

(a) An administrator of a center must be responsible for implementing and supervising the administrative policies and operations of the center and for administratively supervising the provision of all services to minors on a day-to-day basis.

(b) A center's administrator must:

(1) ensure that the center complies with applicable federal, state, and local laws, rules, and regulations;

(2) manage the daily operations of the center;

(3) organize and direct the center's ongoing functions;

(4) ensure the availability of qualified staff and ancillary services to ensure the health, safety, and proper care of each minor;

(5) ensure criminal history [ehecks], employee misconduct registry, [and] nurse aide registry, and medication aide registry checks are conducted for required staff before employment;

(6) ensure the implementation of the center's training program policies and procedures;

(7) familiarize staff with regulatory issues, as well as the center's policies and procedures;

(8) ensure that the documentation of services provided is accurate and timely;

(9) manage census records, including daily, actual, and total, in accordance with §550.803 [§15.803] of this chapter (relating to Census);

(10) ensure that the center immediately notifies a minor's parent of any and all accidents or unusual incidents involving their minor or that had the potential to cause injury or harm to a minor;

(11) ensure that the center provides written notice to the parent of accidents or unusual incidents involving their minor on the day of occurrence;

(12) maintain a record of accidents or unusual incidents involving a minor or staff member that caused, or had the potential to cause, injury or harm to a person or property at the center;

(13) maintain a copy of current contractor agreements with third party providers contracted by the center;

(14) maintain a copy of current written agreements with each contractor;

(15) ensure adequate staff education and evaluations according to requirements in §550.415 [§15.415] of this subchapter (relating to Staffing Policies for Staff Orientation, Development, and Training);

(16) maintain documented development programs for all staff;

(17) ensure the accuracy of public information materials and activities made available and presented on behalf of the center;

(18) ensure implementation of an effective budgeting and accounting system consistent with good business practice that promotes the health and safety of the center's minors; and

(19) supervise the annual distribution and evaluation of the responses to the parent-satisfaction surveys on all minors served.

§550.305. Initial Training in Administration.

(a) This section applies to an administrator and alternate administrator designated as an administrator or alternate administrator of a center.

(b) Before designation, an administrator or alternate administrator must complete the HHSC [DADS] pre-licensing program training titled Overview of Prescribed Pediatric Extended Care Center Licensing Standards in Texas.

(c) An administrator and alternate administrator of a center must complete a total of 12 clock hours of training in the administration of a center before the end of the first 12 months after designation to the position.

(d) The initial 12 clock hours of training must address:

(1) information on state and federal laws applicable to a center, including:

(A) the Americans with Disabilities Act;

(B) the Civil Rights Act of 1991;

(C) the Rehabilitation Act of 1973;

(D) the Family and Medical Leave Act of 1993;

(E) Public Law 111-148 Patient Protection and Affordable Care Act; and

(F) Occupational Safety and Health Administration requirements; and [.]

(2) information regarding the prevention, detection and reporting of fraud, waste, and abuse;

(3) legal issues regarding advance directives;

(4) infection control;

(5) communicable disease reporting;

(6) nutrition;

(7) principles of person-centered direction and guidance; and

(8) provision of services to a minor.

(e) The 12-clock-hour training requirement described in subsection (d) of this section must be met through structured, formalized classes, correspondence courses, competency-based computer courses, training videos, distance learning programs, or off-site training courses. Subject matter that deals with the internal affairs of a center does not qualify for clock hours.

(1) The training must be provided or produced by:

(A) an academic institution;

(B) a recognized state or national organization or association;

(C) a consultant;

(D) an accredited pediatric hospital; or

(E) HHSC [~~DADS~~] or other state agency.

(2) If a consultant provides or produces the training, the training must be approved by a recognized state or national organization or association. The center must maintain documentation of this approval or recognition for review by HHSC [~~DADS~~] inspectors.

(3) An administrator and alternate administrator may apply joint training provided by HHSC [~~DADS~~] toward the 12 clock hours of training required by this section if the joint training meets the training requirements described in subsection (d) of this section.

(f) Documentation of administrator and alternate administrator training must:

(1) be on file at the center; and

(2) contain:

(A) the name of the class or workshop;

(B) course content, including the curriculum;

(C) hours and dates of the training; and

(D) name and contact information of the entity and trainer who provided the training.

(g) An administrator and alternate administrator must not apply the pre-licensing program training as part of the 12 clock hours of training required in this section.

(h) After completing 12 clock hours of initial training during the first 12 months after designation as an administrator and alternate administrator, an administrator and alternate administrator must complete the continuing training requirements as specified in §550.306 [~~§15.306~~] of this division (relating to Continuing Training in Administration) in each subsequent 12-month period after designation.

§550.306. Continuing Training in Administration.

(a) An administrator and alternate administrator must complete 12 clock hours of continuing training within each subsequent 12-month period beginning with the date of designation. The 12 clock hours of continuing training must include at least two of the following topics and may include other topics relating to the duties of an administrator:

(1) any one of the training topics listed in §550.305(d) [~~§15.305(d)~~] of this division (relating to Initial Training in Administration);

(2) development and interpretation of the center policies;

(3) basic principles of management in a licensed health care setting;

(4) ethics;

(5) quality improvement;

(6) risk assessment and management;

(7) financial management;

(8) skills for working with minors, a minor's parent, and other professional service providers;

(9) community resources;

(10) communicable disease reporting; or

(11) marketing.

(b) In addition to the 12 clock hours of training required in this section, an administrator or alternate administrator must complete the Overview of Prescribed Pediatric Extended Care Center Licensing Standards in Texas provided by HHSC [~~DADS~~] every three years from the date of designation to the position.

(c) The center must keep documentation of administrator and alternate administrator continuing training on file at the center and maintain:

(1) the name of the class or workshop;

(2) course content, including the curriculum;

(3) hours and dates of the training; and

(4) name and contact information of the entity and trainer who provided the training.

(d) An administrator or alternate administrator must not apply the pre-licensing program training toward the continuing training requirements in this section.

§550.308. Medical Director Responsibilities.

The medical director must:

(1) review the services provided at the center to ensure a high quality of services;

(2) maintain a liaison role with the medical community in the location of the center's place of business;

(3) participate in the development and implementation of appropriate performance improvement and safety initiatives as directed by the Quality Assessment and Performance Improvement (QAPI) program;

(4) participate in the development of new programs and modifications of existing programs at the center;

(5) designate a physician as defined in §550.5 [~~§15.5~~] of this chapter (relating to Definitions) to provide medical consultation in the event the medical director is unavailable to the center's staff;

(6) serve on committees as defined and required by this chapter and the center's polices;

(7) consult with the center's administrator and nursing director on the health status of the center's staff as it relates to the center's IPCP and on a minor's health and safety or as threats to infection control arise;

(8) review reports of accidents and unusual incidents occurring at the center and identify to the center's administrator hazards to health and safety as directed by the QAPI program;

(9) participate in the development and implementation of policies and procedures for the delivery of emergency services for minors;

(10) participate in the development and implementation of policies and procedures for the use of restraints; and

(11) participate in the development and implementation of policies and procedures for the delivery of physician's services when a minor's prescribing physician or designated alternate is not available.

§550.309. Nursing Director and Alternate Nursing Director Qualifications and Conditions.

(a) A center must designate a nursing director and alternate nursing director who meet the qualifications and conditions set out in this section and who have completed the HHSC [~~Texas Health and Human Services Commission (HHSC)~~] pre-licensing program training titled ["] Overview of Prescribed Pediatric Extended Care Center Licensing Standards in Texas.["]

(b) The nursing director and alternate nursing director must have the following qualifications:

(1) a valid RN license under Texas Occupations Code, Chapter 301, with no disciplinary action;

(2) a valid certification in Pediatric Cardiopulmonary [~~Cardio Pulmonary~~] Resuscitation or Basic Cardiac Life Support; and

(3) a minimum of two years of supervision and management in employment in a pediatric setting caring for a medically or technologically dependent minor or at least two years of supervision in one of the following specialty settings:

(A) pediatric intensive care;

(B) neonatal intensive care;

(C) pediatric emergency care;

(D) center;

(E) home health or hospice agency specializing in pediatric care;

(F) ambulatory surgical center specializing in pediatric care; or

(G) have comparable pediatric unit experience in a hospital for two consecutive years before the person applies for the position of nursing director.

(c) The nursing director and alternate nursing director must meet the requirements of this subsection.

(1) The nursing director must be a full-time employee of the center.

(2) The nursing director or alternate nursing director may serve as the administrator or alternate administrator of the center if the nursing director or alternate nursing director meets the administrator qualifications as described in §550.303 of this division (relating to Administrator and Alternate Administrator Qualifications and Conditions).

(3) A center must designate an alternate nursing director who meets the qualifications as specified in this section who will assume the responsibilities of the nursing director when the nursing director is unavailable during the center's operating hours.

(4) The nursing director must not be included in the center's staffing ratio when the center's actual census is less than four minors and the nursing director is also functioning as the administrator.

(5) The designated alternate nursing director must not be included in the center's staffing ratio when functioning as the nursing director, administrator, or alternate administrator.

§550.310. Nursing Director Responsibilities and Supervision Responsibilities.

The center's nursing director's responsibilities must include, but are not limited to:

(1) supervising all aspects of a minor's plan of care to ensure the minor's plan of care is implemented as ordered;

(2) supervising all activities of the center's professional nursing staff and direct care staff to ensure compliance with current standards of accepted nursing practice;

(3) ensuring compliance with all federal and state laws, rules, and regulations in this chapter;

(4) supervising the daily clinical operations of the center;

(5) ensuring the documentation of the center's actual, daily, and total census in accordance with §550.803 [~~§15.803~~] of this subchapter (relating to Census) and §550.410 [~~§15.410~~] of this subchapter (relating to Nursing Services Staffing Ratio);

(6) ensuring the documentation of the center's staffing ratios in accordance with §559.410 [~~§15.410~~] of this subchapter;

(7) supervising the implementation of staffing policies to ensure that only qualified staff are hired by the center, including verification of licensure and certification before employment and annually thereafter;

(8) ensuring the maintenance of records to support competency of the center's nursing and direct care staff;

(9) ensuring the implementation of the center's policies and procedures that establish and support quality care to a minor;

(10) providing orientation and in-service training to employees and providers of basic services to promote effective basic services and safety to a minor;

(11) performing timely annual performance evaluations for the center's nursing and direct care staff;

(12) ensuring participation in regularly scheduled continuing training for the center's nursing and direct care staff; and

(13) ensuring that the care at the center promotes effective services and the safety of a minor.

§550.311. Prohibition of Solicitation.

(a) A center must adopt and enforce a written policy to ensure compliance of the center and its employees, volunteers, and contractors with Texas Occupations Code, Chapter 102.

(b) HHSC [~~DADS~~] may take enforcement action against a center in accordance with Subchapter G of this chapter (relating to Enforcement) if the center violates Texas Occupations Code, §102.001 or §102.006.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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Karen Ray
Chief Counsel
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DIVISION 3. NURSING AND STAFFING REQUIREMENTS

26 TAC §§550.402 - 550.406, 550.409 - 550.411, 550.413, 550.415, 550.417, 550.418

STATUTORY AUTHORITY

The amendments are authorized by Texas Government Code §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of services by the health and human services agencies, and Texas Human Resources Code §103.004 and §103.005, which respectively provide that the Executive Commissioner of HHSC shall adopt rules for implementing Chapter 103 and adopt rules for licensing and setting standards for facilities licensed under Chapter 103.

The amendments implement Texas Government Code §531.0055 and Texas Human Resources Code, Chapter 103.

§550.402. Registered Nurse Qualifications.

(a) An [~~A~~] RN providing services on behalf of a center must have at least the following qualifications and experience:

(1) a valid RN license under Texas Occupations Code, Chapter 301, with no disciplinary action;

(2) valid certifications in Pediatric Cardiopulmonary [~~Cardio Pulmonary~~] Resuscitation and Basic First Aid; and

(3) one of the following:

(A) one year of pediatric specialty experience with emphasis on medically and technologically dependent minors, obtained within the previous five years; or

(B) sufficient skills to meet the competency and training requirements described in subsection (b) of this section.

(b) A center must adopt and enforce a written policy regarding an RN who qualifies to provide services at the center under subsection (a)(3)(B) of this section. The policy must:

(1) require an RN qualified under subsection (a)(3)(B) of this section to complete a training program that is determined appropriate by the Director of Nursing and conducted by an RN on the RN responsibilities described in §550.403 [~~§15.403~~] of this division (relating to Registered Nurse Responsibilities) and that includes hands-on training;

(2) require, before performing the RN responsibilities described in §550.403 [~~§15.403~~] of this division, an RN qualified under subsection (a)(3)(B) of this section to demonstrate competency in performing the responsibilities described in §550.403 [~~§15.403~~] of this division, as determined by an RN;

(3) describe procedures for increased supervision of an RN qualified under subsection (a)(3)(B) of this section during the training program, competency evaluation, and for three months after completion of the competency evaluation to ensure the health and safety of minors; and

(4) prohibit an RN qualified under subsection (a)(3)(B) of this section from performing the responsibilities in §550.403 [~~§15.403~~] of this division or being included in the nursing services staffing ratio as an RN, as described in §550.410 [~~§15.410~~] of this division (relating to Nursing Services Staffing Ratio), until the RN completes the training program described in paragraph (1) of this subsection and demonstrates competency as described in paragraph (2) of this subsection.

(c) An RN qualified under subsection (a)(3)(B) of this section must meet the requirements in §550.415 [~~§15.415~~] of this division (relating to Staffing Policies for Staff Orientation, Development, and Training) and §550.416 [~~§15.416~~] of this division (relating to Staff Development Program).

§550.403. Registered Nurse Responsibilities.

An RN providing services on behalf of a center must be responsible for the following:

(1) maintaining compliance with the standards of nursing practice and delegation;

(2) developing a minor's plan of care;

(3) providing nursing interventions that includes parental training, information, and education to increase a parent's confidence and competence in caring for a minor;

(4) coordinating services with other service providers;

(5) monitoring the ongoing physical and developmental growth of a minor;

(6) having knowledge of access to available community resources;

(7) participating on the IDT and in the IDT meetings regarding a minor's plan of care and progress;

(8) in accordance with accepted standards of professional practice:

(A) administering medication, intravenous infusions, parenteral feeding, and other specialized treatments; and

(B) monitoring and documenting the effect of medications, therapies, and progress [~~in accordance with accepted standards of professional practice~~];

(9) communicating findings to a minor's prescribing physician and the center's nursing director; and

(10) supervising the center's direct care staff.

§550.404. Licensed Vocational Nurse Qualifications.

(a) An LVN providing services on behalf of a center must have at least the following qualifications and experience:

(1) a valid LVN license [~~licensed~~] under Texas Occupations Code, Chapter 301, with no disciplinary action;

(2) valid certifications in Pediatric Cardiopulmonary [~~Cardio Pulmonary~~] Resuscitation and Basic First Aid; and

(3) one of the following:

(A) one year of pediatric specialty experience with emphasis on medically and technologically dependent minors obtained within the last consecutive five years; or

(B) sufficient skills to meet the competency and training requirements described in subsection (b) of this section. [;]

(b) A center must adopt and enforce a written policy regarding an LVN who qualifies to provide services at the center under subsection (a)(3)(B) of this section. The policy must:

(1) require an LVN qualified under subsection (a)(3)(B) of this section to complete a training program that is determined appropriate by the Director of Nursing and conducted by an RN on the LVN responsibilities described in §550.405 [~~§15.405~~] of this division (relating to Licensed Vocational Nurse Responsibilities) and that includes hands-on training;

(2) require, before performing the LVN responsibilities described in §550.405 [~~§15.405~~] of this division, an LVN qualified under subsection (a)(3)(B) of this section to demonstrate competency in performing the responsibilities described in §550.405 [~~§15.405~~] of this division, as determined by an RN;

(3) describe procedures for increased supervision of an LVN qualified under subsection (a)(3)(B) of this section during the training program, competency evaluation, and for three months after completion of the competency evaluation to ensure the health and safety of minors; and

(4) prohibit an LVN qualified under subsection (a)(3)(B) of this section from performing the responsibilities in §550.405 [~~§15.405~~] of this division or being included in the nursing services staffing ratio as an LVN, as described in §550.410 [~~§15.410~~] of this division (relating to Nursing Services Staffing Ratio), until the LVN completes the training program described in paragraph (1) of this subsection and demonstrates competency as described in paragraph (2) of this subsection.

(c) An LVN must meet the requirements in §550.415 [~~§15.415~~] of this division (relating to Staffing Policies for Staff Orientation, Development, and Training) and §550.416 [~~§15.416~~] of this division (relating to Staff Development Program).

§550.405. Licensed Vocational Nurse Responsibilities.

(a) An LVN providing services on behalf of a center must work under the supervision of an RN and is responsible to provide, within the LVN's level of competence and scope of practice, nursing care to the center's minors as ordered in the plan of care.

(b) An LVN must be responsible for the following:

(1) maintaining compliance with the standards of nursing practice;

(2) providing nursing interventions that includes parental training, information, and education to increase a parent's confidence and competence in caring for a minor;

(3) having knowledge of the availability of community resources;

(4) participating on the IDT and in the IDT meetings regarding a minor's plan of care and progress;

(5) communicating findings to a minor's prescribing physician and an RN; and

(6) in accordance with accepted standards of professional practice:

(A) administering medication, intravenous infusions, parenteral feeding, and other specialized treatments; and

(B) monitoring and documenting the effect of medications, therapies, and progress [~~in accordance with accepted standards of professional practice~~].

§550.406. Student Nurses.

(a) If a center has an agreement with an accredited school of nursing to use the center for a portion of a student nurse's clinical experience, the student nurse may provide care under the following conditions:

(1) the agreement ensures that criminal history checks are conducted for a student nurse in accordance with §550.418 [~~§15.418~~] of this division (relating to Criminal History Checks, Nurse Aide Registry, Medication Aide Registry [~~(NAR)~~], and Employee Misconduct Registry [~~(EMR)~~] Requirements) before a student nurse provides direct care;

(2) a student nurse is not counted in the staffing ratio required in this chapter; and

(3) one of the following:

(A) an instructor from the school is onsite, provides class supervision, and assumes responsibility for all student nursing activities at the center; or

(B) the center:

(i) assumes responsibility for supervision of all student nurses and for all student nursing activities at the center; and

(ii) meets the requirements described in subsection (b) of this section.

(b) The center must adopt and enforce written policy and procedures describing whether the center will assume responsibility for supervision of all student nurses and for all student nursing activities at the center. If a center assumes responsibility for student nurse activity, the center must:

(1) determine the appropriate level of student nurse interaction with a minor, based on the qualifications and experience of the student nurse;

(2) assign an RN to supervise a student nurse;

(3) limit RN supervision to no more than three student nurses at one time; and

(4) based on the outcomes of paragraph (1) of this subsection, determine if it is appropriate to exclude from the staffing ratio the RN assigned to supervise the student nurse activities to ensure the health and safety of minors.

§550.409. Direct Care Staff Qualifications.

(a) Direct care staff providing services on behalf of a center, must have the following qualifications:

(1) be 18 years of age or older;

(2) a high school diploma or a general equivalency degree;

(3) one of the following:

(A) one year of experience employed in a health care setting providing direct care to minors who are medically or technologically dependent;

(B) two years of experience employed in a health care, childcare, or school setting providing direct care to minors who are medically or technologically dependent;

(C) two years of experience employed in a health care setting providing direct care to adults; or

(D) sufficient skills to meet the competency and training requirements described in subsection (b) of this section; and

(4) maintain current certification in Pediatric Cardiopulmonary [~~Cardio Pulmonary~~] Resuscitation and Basic [~~basic~~] First Aid.

(b) A [~~The~~] center must adopt and enforce written policies [~~policy~~] and procedures regarding [~~describing whether~~] direct care staff who qualify to provide services at the center under subsection (a)(3)(D) of this section. The policy must:

(1) require direct care staff who qualify under subsection (a)(3)(D) of this section to complete a training program regarding the provision of direct care to minors that:

(A) is determined appropriate by the nursing director;

(B) is conducted by an RN or LVN; and

(C) includes hands-on training;

(2) require, before providing services to a minor, direct care staff who qualify under subsection (a)(3)(D) of this section to demonstrate competency in the provision of direct care to minors as determined by an RN;

(3) describe procedures for increased supervision of direct care staff who qualify under subsection (a)(3)(D) of this section during the training program and the competency evaluation, and for six months after completion of the competency evaluation, to ensure the health and safety of minors; and

(4) prohibit direct care staff who qualify under subsection (a)(3)(D) of this section from being assigned to a minor or being included in the nursing services staffing ratio as described in §550.410 [~~§15.410~~] of this division (relating to Nursing Services Staffing Ratio) until the direct care staff completes the training program described in paragraph (1) of this subsection and demonstrates competency as described in paragraph (2) of this subsection.

(c) Direct care staff must meet the requirements in §550.415 [~~§15.415~~] of this division (relating to Staffing Policies for Staff Orientation, Development, and Training) and §550.416 [~~§15.416~~] of this division (relating to Staff Development Program).

§550.410. Nursing Services Staffing Ratio.

(a) A center's total staffing for nursing services must be maintained, at a minimum, in the [~~following~~] ratios described in subsection (d)(2) of this section [~~but at no time must there be less than one staff member on duty per three minors receiving nursing services from a center~~]. If only one staff member is on duty, that member must be an RN.

(b) The staffing ratio is based on the number of minors on the center's actual census that are receiving nursing services from the center.

(c) A center must not include direct care staff who qualify under §550.409(a)(3)(D) [~~subsection (b) of §15.409~~] of this division (relating to Direct Care Staff Qualifications) in the staffing ratio until the staff complete the training program and demonstrate competency as described in §550.409(b)(1) and (2) [~~subsection (b)(3) of §15.409~~] of this division.

(d) A center must maintain documentation to support compliance with this section and §550.803 [~~§15.803~~] of this subchapter [~~chapter~~] (relating to Census). Documentation must include:

(1) each change in the number of minors on the center's actual census that are receiving nursing services from the center; and

(2) the increase or decrease in the number of RNs, LVNs, and direct care staff in accordance with this section as changes in the number of minors on the center's actual census that are receiving nursing services from the center occurs.

Figure: 26 TAC §550.410(d)(2)

[~~Figure: 40 TAC §15.410(d)(2)~~]

§550.411. Rehabilitative and Ancillary Professional Staff and Qualifications.

(a) If the following staff provide [~~will be providing~~] services on behalf of a center or supervise [~~supervising~~] services at a center, the staff must have one year of experience in [~~of~~] pediatric care in a health care setting. The staff may be:

(1) an audiologist with a valid license under Texas Occupations Code, Chapter 401;

(2) an occupational therapist with a valid license under Texas Occupations Code, Chapter 454;

(3) an occupational therapist assistant with a valid license under Texas Occupations Code, Chapter 454;

(4) a physical therapist with a valid license under Texas Occupations Code, Chapter 453;

(5) a physical therapist assistant with a valid license under Texas Occupations Code, Chapter 453;

(6) a respiratory therapist with a valid license under Texas Occupations Code, Chapter 604;

(7) a speech-language pathologist with a valid license under Texas Occupations Code, Chapter 401;

(8) a licensed assistant in speech-language pathology with a valid license under Texas Occupations Code, Chapter 401; or

(9) a social worker with a valid license under Texas Occupation Code, Chapter 505.

(b) A center must employ or contract with a qualified dietitian who has a valid license under the laws of the State of Texas to use the title of licensed dietitian or provisional licensed dietitian, or who is a registered dietitian with one year of supervisory experience in dietetic service.

(c) If a center has a qualified pharmacist on a full-time, part-time, or consultant basis, the pharmacist must have a valid license under Texas Occupations Code, Chapter 558.

(d) A rehabilitative professional providing services on behalf of a center or supervising services at a center must be supervised by a center's qualified licensed person who practices under the center's policies and procedures.

(e) A center must not include rehabilitative professionals in the staffing ratios.

§550.413. Contractors.

(a) If a center uses contractors, the center must enter into a contract with each contractor. The contract must be enforced by the center and clearly designate:

(1) that minors are accepted for care only by the center;

(2) the services to be provided by the contractor and how they will be provided, including per visit or per hour;

(3) the necessity of the contractor to conform to all applicable center policies, including staff qualifications;

(4) the contractor's responsibility for participating in developing the plan of care;

(5) the manner in which services will be coordinated and evaluated by the center in accordance with §550.802 [~~§15.802~~] of this subchapter (relating to Coordination of Services); and

(6) the procedures for:

(A) submitting information and documentation by the contractor in accordance with the center's record policies;

(B) scheduling of visits by the contractor or the center; and

(C) periodic evaluation of the minor by the contractor.

(b) A center must establish and maintain a contract management record system to ensure that services provided to each minor by a contractor at the center are completely and accurately documented, readily accessible and systematically organized to facilitate the compilation, retrieval, and review of the information.

(c) The center is not required to maintain a personnel record for contractors. Upon request by HHSC [~~DADS~~], a center must provide documentation at the site of a survey no later than eight working hours after [~~of~~] the request to demonstrate:

(1) that contractors meet the center's written job qualifications for the position and duties performed; and

(2) the center is in compliance with §550.418 [~~§15.418~~] of this division (relating to Criminal History Checks, Nurse Aide Registry, Medication Aide Registry [~~(NAR)~~], and Employee Misconduct Registry [~~(EMR)~~] Requirements).

§550.415. Staffing Policies for Staff Orientation, Development, and Training.

(a) A center must adopt and enforce [~~a~~] written staffing policies and procedures that govern all staff providing services on behalf of the center, including employees, volunteers, and contractors.

(b) A center's written staffing policies must include:

(1) requirements for orientation to the policies, procedures, and objectives of the center;

(2) requirements and procedures for processing criminal history checks;

(3) requirements that staff are current on immunizations;

(4) requirements that an applicant for employment provide written documentation to rule out communicable diseases, including but not limited to tuberculosis;

(5) requirements for direct care staff to demonstrate the necessary skills and competency to meet the direct care needs of a minor to which he or she is assigned and as described in their job description;

(6) requirements for staff to participate in appropriate employee development programs quarterly;

(7) requirements for participation by all staff in job-specific training;

(8) staff training policies that ensure:

(A) staff are properly oriented to tasks performed;

(B) demonstration of competency for tasks when competency cannot be determined through education, license, certification, or experience;

(C) quarterly continuing systemic training for all staff who provide services, including training on infection prevention and control;

(D) staff are informed of changes in techniques, philosophies, organization, minor's rights, ethics and confidentiality, medical record requirements, information relating to minor's development, goals, and products relating to a minor's care;

(E) staff are properly oriented and trained in the proper use of person-centered direction and guidance as outlined in center policy and in accordance with §550.206 [~~§15.206~~] of this subchapter (relating to Person-Centered Direction and Guidance);

(F) staff are properly oriented and trained in the proper use and application of protective devices; and

(G) staff are properly oriented and trained in the proper use and application of restraints in accordance with the following requirements:

(i) all center staff whose job responsibilities include the use of restraint during a behavioral emergency must be trained before assuming direct care responsibilities for a minor;

(ii) all center staff must receive training and demonstrate competency in the following areas:

(I) using any restraint techniques or procedures that are expected or anticipated to be employed;

(II) identifying the underlying causes or functions of threatening behaviors;

(III) understanding how the behavior of staff members affects the behavior of minors;

(IV) using de-escalation, mediation, self-protection, and other techniques, such as quiet time, to prevent or reduce the use of restraint;

(V) applying principles of trauma informed care; and

(VI) recognizing and responding to signs of distress in a minor who is being restrained; and

(iii) all center staff must complete training and demonstrate competence in the use of restraint in a behavioral emergency at least every 12 months following initial training; and

(H) job-specific training is documented with the following information:

(i) the name and qualifications of the trainer;

(ii) the training topics and length; and

(iii) a list of staff who completed the training and demonstrated competence;

(9) a requirement to have a written job description that is a statement of the functions and responsibilities, and job qualifications, including the specific education and training requirements for each position at the center;

(10) procedures for searching the nurse aide registry and the employee misconduct registry for staff in accordance with §550.418 [~~§15.418~~] of this division (relating to Criminal History Checks, Nurse Aid Registry, Medication Aide Registry [~~(NAR)~~], and Employee Misconduct Registry [~~(EMR)~~] Requirements);

(11) a requirement to have annual evaluation of employee and volunteer performance;

(12) a description of employee and volunteer disciplinary action and procedures;

(13) a policy regarding the use of volunteers that is in compliance with §550.414 [~~§15.414~~] of this division (relating to Volunteers); and

(14) a requirement that all staff providing services on behalf of a center sign a statement that the staff have read, understand, and will comply with all applicable center policies.

(c) A center must adopt and enforce written policies and procedures for parent orientation and training programs in accordance with §550.509 [~~§15.509~~] of this subchapter (relating to Parent Training). The policy must:

(1) require orientation be provided to each parent of each minor admitted to the center; and

(2) ensure that orientation includes:

(A) the philosophy of the center;

(B) the basic services as defined in §550.5 of this chapter (relating to Definitions);

(C) on-going parent training needs as determined by the individual needs of the minor;

(D) a minor's parent agreement and disclosure form;

(E) the center attendance policy for minors; and

(F) information about a minor's rights while receiving services at the center.

§550.417. Personnel Records.

(a) A center must maintain a personnel record for an employee and volunteer. A personnel record may be maintained electronically if it meets the same requirements as a paper record. All information must be kept current. A personnel record must include the following:

(1) a signed job description and qualifications for each position accepted or a signed statement that the person read the job description and qualifications for each position accepted;

(2) an application for employment or volunteer agreement;

(3) a record of the immunizations requirements and evaluation of the tuberculosis results;

(4) verification of references, job experience, and educational requirements as conducted by the center to verify qualifications for each position accepted;

(5) verification of licenses, permits, and certifications before employment and annually;

(6) annual performance evaluations and disciplinary actions;

(7) the signed statement about compliance with center policies required by §550.415 [~~§15.415~~] of this division (relating to Staffing Policies for Staff Orientation, Development, and Training); and

(8) for an employee and volunteer:

(A) a printed copy of the results of the initial and annual searches of the nurse aide registry and employee misconduct registry obtained from the HHSC [~~DADS~~] Internet website; and

(B) documentation that the employee, volunteer, or contractor in accordance with §550.418 [~~§15.418~~] of this division (relating to Criminal History Checks, Nurse Aide Registry, Medication Aide Registry [~~(NAR)~~], and Employee Misconduct Registry [~~(EMR)~~] Requirements) received written information about the Employee Misconduct Registry [~~EMR~~].

(b) A center must keep a complete and accurate personnel record for an employee and volunteer at its licensed location.

§550.418. Criminal History Checks, Nurse Aide Registry, Medication Aide Registry ~~(NAR)~~, and Employee Misconduct Registry ~~(EMR)~~ Requirements.

(a) The following words and terms, when used in this section, have the following meanings, unless the context clearly indicates otherwise.

(1) Applicant means any individual applying for a position in a center.

(2) Employee means an individual directly employed by a center, a volunteer, or a contractor.

(b) The provisions in this subsection apply to an applicant and an employee.

(1) A center must conduct a criminal history check authorized by, and in compliance with, THSC Chapter 250 for an applicant for employment and an employee.

(2) A center must not employ an applicant whose criminal history check includes a conviction listed in THSC §250.006 that bars employment or a conviction the center has determined is a contraindication to employment. If an applicant's or employee's criminal history check includes a conviction of an offense that is not listed in THSC §250.006, the center must document its review of the conviction and its determination of whether the conviction is a contraindication to employment.

(3) The center must immediately discharge an employee when the center becomes aware that the employee's criminal history check reveals conviction of a crime that bars employment or that the center has determined is a contraindication to employment.

(c) The provisions in this subsection apply to an applicant and an employee.

(1) Before a center hires an applicant, the center must search the Nurse Aide [~~Aid~~] Registry (NAR), Medication Aide Registry (MAR), and [~~the~~] Employee Misconduct Registry (EMR) using the HHSC [~~DADS~~] website to determine if an applicant or employee is listed in any of these registries [~~either registry~~] as unemployable. The center must not employ an applicant who is listed as unemployable in any of these registries [~~either registry~~].

(2) The center must provide information about the EMR to an employee no later than five business days after hiring an employee. The information must:

(A) be in writing;

(B) state that a person listed in the EMR is not employable by the center; and

(C) include a reference to Chapter 561 [~~93~~] of this title (relating to Employee Misconduct Registry [~~(EMR)~~]) and THSC Chapter 253.

(3) In addition to the initial verification of employability, the center must search the NAR and the EMR to determine if the employee is listed as unemployable in either registry at least every 12 months.

(4) A center must suspend the employment of an employee who HHSC finds has engaged in reportable conduct while the employee

exhausts any applicable appeals process, including informal and formal appeals and any hearing or judicial review, in accordance with THSC §253.004 or §253.005, pending a final decision by an administrative law judge. A center must not reinstate the employee's employment or contract during the course of any applicable appeals process.

(5) [~~(4)~~] The center must immediately discharge an employee when the center becomes aware:

(A) that the employee is designated in the NAR or the EMR as unemployable; or

(B) that the employee's criminal history check reveals conviction of a crime that bars employment or that the center has determined is a contraindication to employment.

(d) Upon request by HHSC [~~DADS~~], a center must provide documentation to demonstrate compliance with subsections (b) and (c) of this section.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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Health and Human Services Commission
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For further information, please call: (512) 438-3161

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DIVISION 4. GENERAL SERVICES

26 TAC §§550.504, 550.506 - 550.508, 550.510, 550.511

STATUTORY AUTHORITY

The amendments are authorized by Texas Government Code §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of services by the health and human services agencies, and Texas Human Resources Code §103.004 and §103.005, which respectively provide that the Executive Commissioner of HHSC shall adopt rules for implementing Chapter 103 and adopt rules for licensing and setting standards for facilities licensed under Chapter 103.

The amendments implement Texas Government Code §531.0055 and Texas Human Resources Code, Chapter 103.

§550.504. Psychosocial Treatment and Services.

(a) A center must ensure the provision of psychosocial treatment based on the needs of a minor, in accordance with a minor's plan of care and as ordered by a minor's prescribing physician.

(b) If psychosocial treatment and services are provided at the center, the center must ensure that the provision of psychosocial treatment and services complies with the requirements of this section, §550.206 [~~§15.206~~] of this subchapter (relating to Person-Centered Direction and Guidance) and §550.207 [~~§15.207~~] of this subchapter (relating to Protective Devices and Restraints) as applicable to a minor's plan of care and physician's order.

(c) The center must ensure psychosocial treatments and services provided at a center are overseen by a physician, RN, or psychologist.

(d) If psychosocial treatments and services are provided in a center, the center must adopt and enforce written policies and procedures relating to the provision of psychosocial treatments to a minor, including:

(1) ensuring the development of interventions to foster normal development;

(2) ensuring the development of interventions to foster psychosocial adaptations;

(3) using person-centered direction and guidance in accordance with §550.206 [~~§15.206~~] of this chapter; and

(4) using restraints in accordance with §550.207 [~~§15.207~~] of this subchapter.

(e) If psychosocial treatments are provided in a center, the center must ensure the initial health assessment of a minor receiving psychosocial treatments includes:

(1) mental status including psychological and behavioral status;

(2) sensory and motor function;

(3) cranial nerve function;

(4) language function; and

(5) any other criteria established by a center's policy.

(f) The center must ensure that an individual providing psychosocial treatment and services in a center:

(1) actively participates in the coordination of a minor's care, in accordance with accepted standards of practice;

(2) participates in ongoing interdisciplinary comprehensive assessments and developing and evaluating the plan of care;

(3) participate as a committee member in the continuous review of the center's person-centered direction and guidance program in accordance with §550.206 [~~§15.206~~] of this subchapter;

(4) provides assistance to a minor's family with the effects of chronic illness and supporting effective relationships within a family; and

(5) develops interventions to foster normal development and psychosocial adaptation.

§550.506. Rehabilitative Services.

(a) A center must ensure the provision of rehabilitative services based on the needs of a minor, in accordance with a plan of care and as ordered by a minor's prescribing physician.

(b) The center must ensure rehabilitative services provided at a center are overseen by a licensed or certified qualified professional staff as specified in §550.411 [~~§15.411~~] of this subchapter (relating to Rehabilitative and Ancillary Professional Staff and Qualifications).

(c) The center must ensure that an individual providing rehabilitative services in a center:

(1) actively participates in the coordination of a minor's care, in accordance with accepted standards of practice; and

(2) participates in ongoing interdisciplinary comprehensive assessments, and in developing and evaluating the plan of care.

§550.507. Functional Developmental Services.

(a) A center must ensure the provision of functional developmental services based on the needs of a minor, in accordance with the minor's plan of care and as ordered by a minor's prescribing physician.

(b) A center must refer a minor to Early Childhood Intervention, within seven days after identification of a developmental delay or risk of developmental delay in accordance with 34 Code of Federal Regulations [~~, Title 34,~~] §303.303 Referral procedures [~~(relating to Referral Procedures)~~].

(c) A center must ensure that each minor has a functional assessment incorporated into the comprehensive assessment to include developmentally appropriate areas.

(d) A minor's functional assessment must include:

(1) measurable goals that enhance independent functioning in daily activities and to promote socialization;

(2) a description of a minor's strengths and present performance level with respect to each goal;

(3) skills areas in priority order; and

(4) planning for specific areas identified as needing development.

§550.508. Educational Developmental Services.

(a) The center must adopt and enforce written policies and procedures to facilitate each minor's access to available early intervention and educational services and programs delivered by an education provider, including a local education agency (LEA), as defined in United States Code, Title 20, §1401(19), [~~§1401(15), (LEA),~~] early childhood intervention agency, or private school, in the least restrictive environment in the community where a minor resides and where the center is located. The center's educational policy must:

(1) be person-centered and parent driven;

(2) be collaborative with the education provider;

(3) ensure that the center does not act as the primary education provider for a minor or accept a delegation of responsibility for the provision of a minor's education from an education provider; and

(4) support a minor's education program as agreed to by a parent and education provider.

(b) The center must not coerce or provide an incentive to an individual or education provider that would result in a minor's removal from a less restrictive educational environment.

(c) The center must not be the primary location for the education provider to deliver services to a minor unless it is determined by the education provider, including the LEA's Admission, Review, and Dismissal (ARD) committee or committee required by Section 504 of the Rehabilitation Act of 1973, in collaboration with a minor's parent and a minor's prescribing physician that the center is the least restrictive environment for a minor to receive educational services.

(d) For a minor who is not receiving services from an education provider, the center must provide a minor and a minor's parent contact information for the LEA where a minor resides.

(e) For a minor receiving services from an education provider, the center must:

(1) not duplicate or provide services that conflict with a minor's education program;

(2) for a minor receiving services from an LEA, not interfere with the compulsory attendance requirements of Texas Education Code §25.085 and §25.086;

(3) when requested by a parent, make available a minor's records to support the minor's education program;

(4) request copies of a minor's education program records to support center care planning activities;

(5) if requested by a parent, participate in planning activities for a minor conducted by the education provider, including an LEA's ARD committee or committee required by Section 504 of the Rehabilitation Act of 1973;

(6) request that a minor's teacher, or other education provider representative, participate as part of the IDT to ensure coordination of a minor's services with the scheduled education component of activities; and

(7) support a minor's education program activities at the center, if needed, by:

(A) providing a well-lighted room, private space or other adequate workspace;

(B) providing functional assistance to a minor;

(C) coordinating with a minor and a minor's parent to ensure special and general supplies and equipment available for a minor if needed; and

(D) providing an area to post education program calendars and information bulletins provided to the center for minors and parents to view.

§550.510. Nutritional Counseling.

(a) A center must ensure the provision of nutritional counseling as defined in §550.5 [~~§15.5~~] of this chapter (relating to Definitions) based on the minor's needs and in accordance with the minor's plan of care.

(b) Nutritional counseling must be overseen by a qualified individual including a dietitian, a nutritionist, or an RN.

§550.511. Dietary Services.

(a) A center must adopt and enforce written policy and procedures to ensure that a minor, while at the center, receives:

(1) a nourishing, well-balanced diet as recommended by the American Academy of Pediatrics or Food and Nutrition Board of the National Research Council, National Academy of Sciences; or

(2) a diet ordered by a minor's prescribing physician.

(b) If a minor's meals and snacks are supplied by an adult minor or a minor's parent, the center's written policy and procedures must:

(1) include a written signed agreement between the center and the adult minor or minor's parent that includes:

(A) a statement that the adult minor or minor's parent is responsible for providing the appropriate meals and snacks for the minor in accordance with this section;

(B) the responsibilities of the center and the responsibilities of the adult minor or minor's parent concerning the provision of meals and snacks; and

(C) actions that may be taken by the center if the adult minor or minor's parent fails to provide meals and snacks for the minor as agreed;

(2) describe the actions that will occur if an adult minor or minor's parent fails to provide the minor's meals and snacks or fails to provide meals and snacks in accordance with the minor's prescribed diet, which must include that the center ensures that the minor receives the meals and snacks as required in this section while at the center; and

(3) ensure an adult minor or minor's parent receives nutritional counseling as described in §550.510 [~~§15.5101~~] of this division (relating to Nutritional Counseling).

(c) If the center provides meals and snacks directly or under contract, the center must employ or contract with a dietitian as described in §550.411(b) [~~§15.411(b)~~] of this subchapter (relating to Rehabilitative and Ancillary Professional Staff and Qualifications).

(1) The dietitian is responsible for the overall operation of the dietary service.

(2) The dietitian must participate in regular conferences with the administrator and nursing director to provide information about approaches to identified nutritional problems.

(3) The dietitian must participate in the development of dietary support staff policies.

(4) The center must employ sufficient dietary support staff who meet the qualifications to carry out the functions of the dietary service.

(5) The dietitian must ensure that a minor has a diet:

(A) that meets the daily nutritional and special dietary needs of a minor, based upon the acuity and clinical needs of a minor; or

(B) as prescribed by a minor's prescribing physician.

(6) The dietitian is required to review a minor's plan of care for any known food allergy and special diet ordered by a minor's prescribing physician as often as necessary for changes to a minor's dietary needs.

(d) If a center provides meals and snacks directly or under contract:

(1) a dietitian must develop a menu that:

(A) is prepared at least one week in advance;

(B) is written for each type of diet; and

(C) varies from week to week, taking the general age-group of minors into consideration;

(2) the center must post the current week's menu in a conspicuous location so an adult minor and a minor's parent may see it; and

(3) the center must retain menus for 30 days.

(e) If a center provides meals and snacks directly, the center must retain records of menus served and food purchased for 30 days. The center must keep a list of minors receiving special diets and a record of the diets in the minors' medical records for at least 30 days.

(f) The center must:

(1) provide tables that allow minors to eat together when possible;

(2) provide assistance to minors, as needed;

(3) serve food on appropriate tableware; and

(4) ensure clean napkins, bibs, dishes, and utensils are available for each use.

(g) A center must coordinate with an adult minor or a minor's parent to ensure special eating equipment and utensils are available for a minor at the center if needed.

(h) An identification system, such as tray cards, must be available to ensure that all food is served in accordance with a minor's diet.

(i) A center must monitor and record food intake of all minors as follows.

(1) Deviations from normal food and fluid intake must be recorded in a minor's medical record.

(2) In-between meal snacks, and supplementary feedings, either as a part of the overall plan of care or as ordered by a minor's prescribing physician, including special diets, must be documented using professional practice standards.

(j) The center must serve a minor meals and snacks as specified in this section and as outlined in a minor's plan of care.

(1) If breakfast is served, a morning snack is not required.

(2) Notwithstanding the provisions of this section, a minor must not go more than three hours without a meal or snack being offered, unless a minor is sleeping.

(3) The center must offer at least one snack to a minor who is served at the center for less than four hours.

(4) The center must offer one meal, or one meal and one snack, equal to one third of a minor's daily food needs to a minor who is served at the center for four to seven hours.

(5) The center must offer two meals and one snack, or two snacks and one meal, equal to one half of a minor's daily food needs to a minor who is served at the center for more than seven hours.

(6) The center must ensure that a supply of drinking water is always available to each minor and is served at every snack, mealtime, and after active play.

(k) The center must:

(1) purchase food from sources approved or considered satisfactory by federal, state, and local authorities;

(2) store, prepare, and serve food under sanitary conditions, as required by the Texas Department of State Health Services food service sanitation requirements; and

(3) dispose of garbage and refuse properly.

(l) The center must provide safe and proper storage and service of a minor's meals and snacks provided by an adult minor and a minor's parent.

(m) Dietary service staff must be in good health and practice hygienic food-handling techniques. Staff with symptoms of communicable diseases or open, infected wounds may not work at the center until the center receives written documentation from a health care professional that the staff member is released to return to work or, the signs and symptoms which relate to the communicable disease are no longer evident.

(n) Dietary service staff must wear clean, washable garments, wear hair coverings or clean caps, and have clean hands and fingernails.

(o) Routine health examinations must meet all local, state, and federal codes for food service staff.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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DIVISION 5. ADMISSION CRITERIA, CONFERENCE, ASSESSMENT, INTERDISCIPLINARY PLAN OF CARE, AND DISCHARGE OR TRANSFER

26 TAC §§550.601 - 550.608

STATUTORY AUTHORITY

The amendments are authorized by Texas Government Code §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of services by the health and human services agencies, and Texas Human Resources Code §103.004 and §103.005, which respectively provide that the Executive Commissioner of HHSC shall adopt rules for implementing Chapter 103 and adopt rules for licensing and setting standards for facilities licensed under Chapter 103.

The amendments implement Texas Government Code §531.0055 and Texas Human Resources Code, Chapter 103.

§550.601. Admission Criteria.

(a) A center may admit a minor if:

(1) the minor's prescribing physician, in consultation with the minor's parent and the minor, recommends admission to a center, taking into consideration the medical, nursing, psychosocial, therapeutic, nutritional, dietary, functional, education, and development needs of the minor in addition to the emotional, psychosocial, and environmental factors;

(2) the minor's prescribing physician issues a prescription ordering care at a center;

(3) the minor is stable for outpatient medical services and requires ongoing nursing care and other basic services;

(4) the adult minor or the minor's parent signs a written agreement and disclosure form consenting to the adult minor's or minor's admission to a center; and

(5) the admission is voluntary.

(b) The center must ensure that its admission criteria are in accordance with §550.211 [~~§15.211~~] of this subchapter (relating to Infection Prevention and Control Program and Vaccinations Requirements).

§550.602. Pre-admission Conference.

(a) If a minor meets the criteria for admission into a center as described in §550.601 [~~§15.601~~] of this division (relating to Admission Criteria), the medical or nursing director must contact the minor's prescribing physician to schedule a pre-admission conference before the minor receives services at the center.

(b) If a minor is hospitalized at the time of referral to a center, the pre-admission conference must include the minor's parent, the minor, the minor's prescribing physician, center staff, relevant hospital staff, including medical, nursing, social services, and developmental staff, and any other individuals requested by the adult minor or the minor's parent, to begin developing the plan of care.

(c) If a minor is not hospitalized at the time of referral to a center, the pre-admission conference must include the minor's parent, the minor, the minor's prescribing physician, center staff, and any other individuals requested by the adult minor or the minor's parent to begin developing the plan of care.

(d) A center must schedule a pre-admission conference no later than three days after the center receives a [~~receipt of the~~] referral. The pre-admission conference must address a minor's:

(1) medical history;

(2) diagnosis;

(3) mental and developmental status;

(4) nutritional status;

(5) dietary requirements;

(6) functional abilities and limitations;

(7) activities permitted and prohibited;

(8) use of assistive devices;

(9) treatment procedures;

(10) use of restraints, if applicable;

(11) medication;

(12) safety measures to protect against injury;

(13) education level and participation in an education program, if applicable;

(14) immunization record;

(15) receipt of services from other service providers; and

(16) other appropriate information.

§550.603. Agreement and Disclosure.

(a) A center must review a written agreement and disclosure form with a minor's parent or with an [~~the~~] adult minor before services are provided at the center.

(b) The agreement and disclosure form must include evidence or attestation that the parent of a minor has the legal authority to consent to the [~~a~~] minor's medical care.

(c) The agreement and disclosure form must document that a center obtained a minor's parent's or an adult minor's written informed consent specifying the services that may be provided on behalf of a center to a minor.

(d) The agreement and disclosure form must document that the center provided the following information orally and in writing to a [~~the~~] minor's parent or the minor, or an adult minor, in a language or format the minor [~~he or she~~] understands:

(1) the notice of rights and responsibilities described in §550.901 [~~§15.901~~] of this subchapter (relating to Rights and Responsibilities);

(2) information on the Advance Directives Act, THSC, Chapter 166;

(3) the extent to which payment for services provided on behalf of the center may be expected from any third-party payment source known to a center, the charges for services not covered by a third-party payment source and charges that a minor's parent or adult minor may have to pay;

(4) a list of the staff who will provide services on behalf of the center;

(5) a list of expected outcomes and any specific limitations or barriers to reaching the outcomes;

(6) the method of supervision and oversight by a center of the services to be provided at the center;

(7) the HHSC [~~DADS~~] toll-free telephone number and its purpose;

(8) the process for directing a grievance to the administrator about services provided at the center and the time frame in which the center must review and resolve a grievance;

(9) the [~~an~~] adult minor's and the minor's [~~a~~] parent's responsibilities;

(10) an emergency plan for a minor; and

(11) notice of the center's policies regarding:

(A) attendance requirements;

(B) implementing an advance directive in accordance with §550.902 [~~§15.902~~] of this subchapter (relating to Advance Directives);

(C) disclosure of the minor's medical record;

(D) person-centered direction and guidance;

(E) restraints;

(F) reporting abuse, neglect, or exploitation of a minor by an employee, volunteer, or contractor;

(G) drug testing of employees in direct contact with a minor in accordance with §550.419 [~~§15.419~~] of this subchapter (relating to Drug Testing Policy); and

(H) management and disposal of medications in the center.

(e) The agreement and disclosure form must be signed by a minor's parent or an adult minor.

(f) A center must provide a signed copy of the agreement and disclosure form to the minor's parent or the adult minor.

(g) The center must keep the signed written agreement and disclosure form in the minor's medical record.

(h) The center must update the agreement and disclosure form if information in the form changes.

(i) The center must comply with the terms of the agreement.

§550.604. Admission Procedures.

(a) A center's administrator, nursing director, or designee must conduct an interview with a minor's parent or an adult minor before or at a minor's admission to the center that addresses the following:

(1) the adult minor's and minor's parent's rights and responsibilities;

(2) the center's policies and procedures;

(3) basic services;

(4) the center's dietary services;

(5) the center's transportation services;

(6) the center's operating hours and contact information;

(7) the center's infection prevention and control program;

(8) the center's emergency preparedness plan;

(9) the center's attendance policy;

(10) services the minor is receiving at the center, but not provided by the center;

(11) development of the minor's plan of care;

(12) the minor's emergency plan and needs; and

(13) the minor's transfer and discharge planning.

(b) A center must request and keep a copy of a minor's medical history and documentation of a physical examination performed by the [~~a~~] minor's prescribing physician within 30 days before or after the date of the minor's admission to the center.

(c) A center must have a signed order from a [~~the~~] minor's prescribing physician on the day of the minor's admission, as described in §550.701 [~~§15.701~~] of this subchapter (relating to Physician Orders).

§550.605. Initial and Updated Comprehensive Assessment.

(a) A center's RN must conduct and document a specific initial comprehensive assessment that identifies the minor's medical, nursing, psychosocial, therapeutic, nutritional, dietary, functional abilities, educational, and developmental needs and the adult minor's or minor's parent's training needs.

(b) The initial comprehensive assessment must include the minor's discharge planning, including transition support, self-advocacy guidance, and coordination of services required by the minor and the minor's parent.

(c) The initial comprehensive assessment must be conducted in consultation with an adult minor and the [~~a~~] minor's parent [~~and the minor, if the minor is an adult minor~~].

(d) An RN must complete an initial comprehensive assessment no earlier than three business days before the minor is admitted to the center and no later than the date the minor is admitted to the center.

(e) An RN must conduct, in consultation with a minor's parent or an [~~the~~] adult minor, a comprehensive assessment of the minor at least once every 180 days after admitting the minor into the center. An RN must conduct a new comprehensive assessment on the minor when the minor has a change of condition or the minor's needs change.

(f) The updated comprehensive assessment described in subsection (e) of this section must:

(1) identify a minor's ongoing medical, nursing, psychosocial, therapeutic, nutritional, dietary, functional, educational, and developmental needs and the training needs of the adult minor or parents of the minor [~~minor's and a minor's parent's training needs~~]; and

(2) include a minor's discharge planning, detailing transition support, if needed, self-advocacy guidance, and coordination with the minor's parent or the adult minor.

§550.606. Interdisciplinary Team.

(a) A center must designate an IDT.

(b) The IDT must monitor the services provided to a [~~the~~] minor at the center.

(c) A center must designate an RN to be a member of the IDT to:

(1) provide coordination of care for the minor;

(2) ensure continuous assessment of the minor's and the minor's parent's needs; and

(3) implement the minor's interdisciplinary plan of care.

(d) The IDT must prepare a written plan of care for the minor as described in §550.607 [~~§15.607~~] of this division (relating to Initial and Updated Plan of Care).

(e) The IDT must include:

(1) the minor's prescribing physician;

(2) the center's nursing director or an RN designated by the nursing director;

(3) the minor;

(4) the minor's parent;

(5) a social worker, if the minor is receiving social services at the center; and

(6) another individual providing basic services to a minor if the minor is receiving basic services other than nursing services at the center.

(f) The IDT must participate in the development of a plan of care with goals and objectives for a minor that includes discharge planning when goals and objectives are met.

§550.607. Initial and Updated Plan of Care.

(a) A center must develop an individualized written plan of care for a minor. The plan of care must include:

(1) the minor's and the minor's parent's goals and interventions based on the issues identified in the pre-admission conference and the initial and updated comprehensive assessments; and

(2) measurable goals with interventions based on the minor's care needs and means of achieving each goal and must address, as appropriate, rehabilitative and restorative measures, preventive intervention and training, and teaching of personal care by the minor's parent.

(b) An RN must address in the written interdisciplinary plan of care:

(1) the services needed to address the medical, nursing, psychosocial, therapeutic, dietary, functional, educational, and developmental needs of the minor and the training needs of the minor's parent;

(2) the minor's functional assessment;

(3) the specific goals of care;

(4) the time frame for achieving the goals and the schedule for evaluation of progress;

(5) the orders for treatment, services, medications, medical equipment, diet, and restraints, if applicable;

(6) specific criteria for transitioning from or discontinuing participation at the center; and

(7) the minor's scheduled days of attendance.

(c) In collaboration with the interdisciplinary team, an RN, a minor's parent, the minor, and an individual requested by the adult minor or the minor's parent must develop a plan of care based on the comprehensive assessment.

(d) The RN, an adult minor, and a minor's parent [~~and the minor, if the minor is an adult minor,~~] must sign the plan of care within five days after initiation of the plan.

(e) A minor's prescribing physician must review and sign the plan of care within 30 days after initiation of the plan.

(f) The center must incorporate the plan of care into a minor's medical record no later than 10 days after receiving the signed plan from a minor's prescribing physician.

(g) Copies of the plan of care must be given, in a language and format the recipient understands, to a minor's parent, an adult minor, the minor's prescribing physician, the center's staff, and other health care providers and providers of basic services as appropriate.

(h) The center's IDT and an RN must review and update a minor's plan of care at least every 180 days, or more often, if there is a change in the [~~a~~] minor's medical condition or changes in the [~~a~~] minor's needs.

(i) A minor's parent and an adult minor [~~and the minor, if the minor is an adult minor,~~] must review and sign the updated plan of care within five days before changes to the plan of care are implemented.

(j) A minor's prescribing physician must review and sign the updated plan of care within 30 days after initiation of the updated plan.

(k) The center must incorporate the updated plan of care into a minor's medical record no later than 10 days after receiving the signed plan from the [~~a~~] minor's prescribing physician.

(l) The center must adopt and enforce written policies and procedures regarding the communication and coordination of a minor's care with the [~~a~~] minor's prescribing physician in accordance with the plan of care.

(m) The policy described in subsection (l) of this section must ensure the communication between the center's staff and a [~~the~~] minor's prescribing physician is conveyed to the minor's parent and the minor in a language and format that the [~~an~~] adult minor and minor's parent understand.

(n) The center's nursing director or designee must:

(1) document communication with a [~~the~~] minor's prescribing physician;

(2) maintain the documentation in the minor's medical record; and

(3) ensure that the communication is conveyed to the minor's parent and the adult minor in a language and format the adult minor and minor's parent understand.

(o) The center staff must ensure the provision of services and treatments in accordance with the plan of care and as ordered by a [~~the~~] minor's prescribing physician.

§550.608. Discharge or Transfer Notification.

(a) A center intending to transfer or discharge a minor must provide both oral and written notification to the [~~a~~] minor's parent and adult minor no later than 15 days before the date the minor will be transferred or discharged, if the notification is provided in person.

(b) If the center does not provide the notice of transfer or discharge in person, the center must provide oral notification to a minor's parent and adult minor by telephone no later than 15 days before the date of transfer or discharge and mail the written notification no later than 15 days before the date of transfer or discharge.

(c) A center that intends to transfer or discharge a minor must also notify the minor's prescribing physician no later than 15 days before the date the minor will be transferred or discharged.

(d) A center may transfer or discharge a minor without providing the oral and written notification described in subsections (a) and (b) of this section:

(1) if the minor's parent or adult minor requests the transfer or discharge;

(2) if the minor's medical needs require transfer, including a medical emergency;

(3) if the minor's health and safety is at risk due to an emergency and a transfer is made in accordance with §550.209 [~~§15.209~~] of this subchapter (relating to Emergency Preparedness Planning and Implementation);

(4) for the protection of staff or a minor attending the center after the center makes a documented, reasonable effort to notify the minor's parent, the minor's prescribing physician, and appropriate state or local authorities of the center's concerns for the safety of staff or the minor, and in accordance with center policy;

(5) according to the minor's prescribing physician's orders; or

(6) if the minor's parent or an adult minor fails to pay for services, except as prohibited by state law.

(e) A center must keep in a minor's medical record:

(1) a copy of the written notification provided in accordance with subsection (a) or (b) of this section to the minor's parent or adult minor;

(2) documentation of the personal contact with the minor's parent or adult minor in accordance with subsection (b) of this section; and

(3) documentation that the minor's prescribing physician was notified of the date of transfer or discharge in accordance with subsection (c) of this section.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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DIVISION 6. PHYSICIAN, PHARMACY, MEDICATION, AND LABORATORY SERVICES

26 TAC §§550.701, 550.703, 550.705, 550.707

STATUTORY AUTHORITY

The amendments are authorized by Texas Government Code §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of services by the health and human services agencies, and Texas Human Resources Code §103.004 and §103.005, which respectively provide that the Executive Commissioner of HHSC shall adopt rules for implementing Chapter 103 and adopt rules for licensing and setting standards for facilities licensed under Chapter 103.

The amendments implement Texas Government Code §531.0055 and Texas Human Resources Code, Chapter 103.

§550.701. Physician Orders.

(a) A center must ensure that a minor admitted to the center is admitted under an order of the minor's prescribing physician and remains under the care of the prescribing physician for the duration of the minor's stay at the center. The minor's medical record must contain the written prescribing physician order used for admission as well as all subsequent prescribing physician orders.

(b) The prescribing physician orders must include:

(1) approval of a minor's admission to a center;

(2) nursing services;

(3) medication administration, if applicable;

(4) dietary needs, if applicable;

(5) permitted activities, if applicable;

(6) therapy [~~therapies~~] treatments, if applicable;

(7) transportation authorization, if applicable; and

(8) other services, if applicable.

§550.703. Pharmacist Services.

(a) If a center administers or stores medication, the center must have a pharmacist or a qualified RN with education and training in drug management [~~and~~] on a full-time, part-time, or on a consultant basis to provide consultation to the medical director, administrator, nursing director, and other center staff.

(b) A center must consult with a pharmacist or qualified RN as needed on the following:

(1) establishing written policies and procedures for the storage and administration of medications as described in §550.704 [~~§15.704~~] of this division (relating to Storage of Medication) and §550.705 [~~§15.705~~] of this division (relating to Administration of Medication);

(2) reviewing medical records to ensure that the medication records are accurate, updated, and reflect that medications are administered in accordance with the orders of a minor's prescribing physician;

(3) providing in-service training to staff on the storage and administration of medications; and

(4) ensuring pharmaceutical compliance.

§550.705. Administration of Medication.

(a) A center must adopt and enforce written policies and procedures for the administration of medication to a minor. The policies and procedures must address:

(1) removing an individual dose from a previously dispensed, properly labeled container;

(2) verifying the medication with the prescriber's orders;

(3) verifying the order with the correct minor;

(4) giving the correct medication dose to a minor;

(5) giving the medication by the correct route;

(6) observing that the medication is taken;

(7) recording the required information, including the method of administration; and

(8) documenting any medication not administered and the reason.

(b) A center's written policy must ensure compliance with:

(1) THSC Chapter 248A;

(2) this chapter;

(3) state law authorizing a person licensed under the Texas Occupations Code to administer medications;

(4) rules adopted by the Texas Board of Nursing 22 Texas Administrative Code [~~TAC~~] Chapter 224 (relating to Delegation of Nursing Tasks by Registered Professional Nurses to Unlicensed Personnel for Clients with Acute Conditions or in Acute Care Environments) governing when an RN may delegate the administration of medication to an unlicensed person; and

(5) any other applicable state and federal regulations relating to the administration of medication to a minor.

(c) If there is a direct conflict between this chapter and other applicable state and federal laws and regulations, a center must comply with the more stringent requirements.

(d) The administration of medication by center staff must be included in a minor's plan of care.

(e) A center must adopt and enforce written policies and procedures for maintaining a current medication list and a current medication administration record.

(f) A center's written policy must require center staff who supervise, assign, or delegate the administration of medication or administer medication to a minor to maintain a current medication list in the minor's medical record.

(g) A center may incorporate a current medication list and medication administration record into one document.

(h) An RN must review the medication list initially after a minor is admitted and update the list when necessary but at least every 90 days.

(i) An RN must report significant findings from a review of the medication list to the minor's prescribing physician.

(j) Review of the medication list includes evaluation of prescription and over-the-counter drugs, medication orders, and the medication list for:

(1) known allergies;

(2) rational drug therapy-contraindication;

(3) reasonable dose and route of administration;

(4) reasonable directions for use;

(5) duplication of drug therapy;

(6) drug-drug interaction;

(7) drug-food interaction;

(8) drug-disease interaction;

(9) adverse drug reaction; and

(10) proper use, including overuse or underuse.

(k) A center must adopt and enforce written policies and procedures on medication errors. The policy must ensure that the nursing director, a minor's prescribing physician and the minor's parent are notified immediately after the discovery of a medication error or an adverse reaction.

§550.707. Disposal of Special or Medical Waste.

(a) A center must adopt and enforce a written policy for the safe handling and disposal of special or medical waste and materials, including bio-hazardous waste and materials.

(b) A center that generates special or medical waste while providing services must dispose of the waste according to the requirements issued by the Texas Department of State Health Services in 25 Texas Administrative Code [~~TAC~~] Chapter 1, Subchapter K (relating to Definition, Treatment, and Disposition of Special Waste from Health Care-Related Facilities).

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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DIVISION 7. CARE POLICIES, COORDINATION OF SERVICES, AND CENSUS

26 TAC §550.802, §550.803

STATUTORY AUTHORITY

The amendments are authorized by Texas Government Code §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of services by the health and human services agencies, and Texas Human Resources Code §103.004 and §103.005, which respectively provide that the Executive Commissioner of HHSC shall adopt rules for implementing Chapter 103 and adopt rules for licensing and setting standards for facilities licensed under Chapter 103.

The amendments implement Texas Government Code §531.0055 and Texas Human Resources Code, Chapter 103.

§550.802. Coordination of Services.

(a) A center must adopt and enforce written policies and procedures regarding coordination of services to ensure the effective exchange of information, reporting, and coordination of a minor's services:

(1) among all staff providing services on behalf of a center; and

(2) between the center and a provider of services to the minor that is not providing services on behalf of the center, if known by the center.

(b) Documentation in a minor's medical records must demonstrate coordination of services as described in subsection (a) of this section.

(c) For a minor receiving services from a provider that is not providing services on behalf of a center, the center must:

(1) not duplicate or provide services that conflict with the minor's care plan or service plan with the provider;

(2) when requested by an adult minor or parent, make available the minor's records to support the coordination of services between the center and the provider;

(3) request copies of the [a] minor's records with the provider to support center care planning activities;

(4) if requested by an adult minor or parent, participate in planning activities for the adult minor or [a] minor conducted by the provider;

(5) request that the [a] minor's provider participate as part of the center's interdisciplinary team and QAPI committee, as applicable; and

(6) support the coordination of the [a] minor's services by allowing the minor's provider to serve a minor at the center, if:

(A) the center, the provider, the [a] minor's parent or the adult minor[, a ~~minor, if the minor is an adult minor and the provider~~] agree that the provision of services to the [a] minor by the provider at the center would be appropriate for the minor; and

(B) the center and the provider establish a written agreement that includes the provider's agreement to comply with center policies and this chapter for the provision of the provider's services at the center. [~~The written agreement must include the provider's compliance with center policies and this chapter.~~]

§550.803. Census.

(a) A center must adopt and enforce written policies and procedures for the development of the center's actual, daily, and total census lists.

(b) A center's written policies and procedures must address:

(1) developing and maintaining the census lists;

(2) the staff responsible for maintaining the census lists; and

(3) the retrieval of the census lists when requested by HHSC [~~DADS~~].

(c) A center must maintain the following lists of minors receiving services:

(1) actual census, which must be updated each time the number of minors at the center changes;

(2) daily census; and

(3) total census.

(d) The actual and daily census must include:

(1) the [a] minor's name;

(2) the services provided to the [a] minor and the provider responsible for the delivery of each service; and

(3) the time the [a] minor entered and left the center.

(e) The total census must include:

(1) the [a] minor's name;

(2) the [a] minor's diagnosis; and

(3) the name and contact information of the [a] minor's prescribing physician.

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DIVISION 8. RIGHTS AND RESPONSIBILITIES, ADVANCE DIRECTIVES, ABUSE, NEGLECT, AND EXPLOITATION, INVESTIGATIONS, DEATH REPORTING, AND INSPECTION RESULTS

26 TAC §§550.901 - 550.906

STATUTORY AUTHORITY

The amendments are authorized by Texas Government Code §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of services by the health and human services agencies, and Texas Human Resources Code §103.004 and §103.005, which respectively provide that the Executive Commissioner of HHSC shall adopt rules for implementing Chapter 103 and adopt rules for licensing and setting standards for facilities licensed under Chapter 103.

The amendments implement Texas Government Code §531.0055 and Texas Human Resources Code, Chapter 103.

§550.901. Rights and Responsibilities.

(a) A center must adopt and enforce written policies to ensure a minor's legal rights are observed and protected and to ensure compliance with this section. The policies must comply with relevant law and ensure that the center considers a minor's age and legal status, including whether a guardian has been appointed or the disabilities of minority have been removed, to determine the [a] minor's or other individual's authority to make decisions for the minor.

(b) Before providing services to a minor, a center must provide an adult minor and a minor's parent with oral and written notification of the requirements of this section in a language and format that the minor and parent understand. The center must obtain the signature of the adult minor and minor's parent to confirm that the individual received the notice.

(c) A center must:

(1) ensure that a minor is free from abuse, neglect, and exploitation at the center, as described in §550.903 [~~§15.903~~] of this division (relating to Abuse, Neglect, or Exploitation Reportable to HHSC [~~DADS~~]);

(2) inform the [a] minor and a minor's parent of the center's policy for reporting abuse, neglect, or exploitation of a minor;

(3) ensure that the [a] minor and the minor's property is treated with respect;

(4) at the time of admission, inform the [~~an~~] adult minor or the [~~and a~~] minor's parent, orally and in a written statement, that a complaint or question about the center may be directed to the HHSC Complaint and Incident Intake Section [~~Department of Aging and Disability Services, DADS Consumer Rights and Services Division~~], P.O.

Box 149030, Austin, Texas 78714-9030, toll free 1-800-458-9858, or through the online portal;

(5) at the time of admission, inform the [an] adult minor or the [and a] minor's parent, orally and in a written statement, that:

(A) states that complaints about services at the center may be directed to the administrator who will address them promptly;

(B) provides the time frame in which a center must review and resolve the complaint as described in §550.904 [§15.904] of this division (relating to Investigations of a Complaint and Grievance); and

(C) does not include a statement that a complaint must be made to the center administrator before directing a complaint to HHSC [DADS];

(6) ensure that the [a] minor is not subjected to unlawful discrimination or retaliation;

(7) ensure that the [a] minor is treated appropriate to the minor's [his or her] age and developmental status;

(8) ensure that the [a] minor is allowed to interact with other minors, including through planned and spontaneous active play, respective to a minor's condition and physician orders;

(9) ensure that the [an] adult minor or the [and a] minor's parent are informed in advance about the services to be provided, including:

(A) staff who will provide the services and the proposed frequency of each service; and

(B) any change in the plan of care before the change is made, except when a delay based on notification would compromise the health and safety of the [a] minor;

(10) ensure that the [an] adult minor or the [and a] minor's parent are informed of the expected outcomes of services and any specific limitations or barriers to services;

(11) ensure that the [an] adult minor or the [and a] minor's parent are allowed and encouraged to participate in planning services and in planning changes to services and that the adult minor or [and] the minor's parent consented to the changes before the changes are made, except when a delay based on participation in planning or obtaining consent would compromise the immediate health and safety of the [a] minor;

(12) ensure that the [an] adult minor or the [and a] minor's parent are informed of the center's policies on implementing an advance directive in accordance with §550.902 [§15.902] of this division (relating to Advance Directives) and to receive information about executing an advance directive;

(13) ensure that the [an] adult minor or the [and a] minor's parent are allowed to refuse services;

(14) ensure that the minor's medical record is kept confidential and the [an] adult minor or the [and a] minor's parent are informed of the center's policies and procedures regarding disclosure of medical records;

(15) ensure that the [an] adult minor or the [and a] minor's parent are informed, before care is provided, of the:

(A) extent to which payment for the center's services may be expected from Medicaid, or any other federally funded or aided program known to the center, or any other third-party payment source;

(B) charges for services not covered by a third-party payment source; and

(C) charges that the adult minor or minor's parent may have to pay;

(16) inform the [an] adult minor or the [and a] minor's parent of any changes in the information provided in accordance with paragraph (15) of this subsection as soon as possible after changes occur, but no later than 30 days after the date the center becomes aware of the change;

(17) inform the [an] adult minor or the [and a] minor's parent of the availability of other programs, including day care, early intervention programs, or school; and

(18) ensure that the [an] adult minor or the [and a] minor's parent are allowed to convene or participate in a council or support group for individuals receiving services at the center.

§550.902. Advance Directives.

(a) A center must adopt and enforce a written policy regarding implementation of advance directives. The policy must be in compliance with the Advance Directives Act, THSC, Chapter 166. The policy must include a clear and precise statement of any procedure the center is unwilling or unable to provide or withhold in accordance with an advance directive.

(b) A center must provide written notice to a minor's parent or an [the] adult minor of the written policy required by subsection (a) of this section. The notice must be provided at the earlier of:

(1) the time the [a] minor is admitted to receive services at the center; or

(2) the time service provision begins for the [a] minor.

(c) HHSC [DADS] assesses an administrative penalty of $500 against a center that violates this section.

§550.903. Abuse, Neglect, or Exploitation Reportable to HHSC [DADS].

(a) The following words and terms, when used in this section, have the following meanings, unless the context clearly indicates otherwise.

(1) Abuse, neglect, and exploitation of a minor have the meanings assigned in THSC Chapter 260A. [; and]

(2) Employee means an individual directly employed by a center, a contractor, or a volunteer.

(b) HHSC [DADS] investigates a complaint or an incident of abuse, neglect, or exploitation when the act occurs at a center, a center employee is responsible for the care of the [a] minor at the time the act occurs, or the alleged perpetrator is associated with the center. A complaint of abuse, neglect, or exploitation that does not meet these criteria must be referred to the Department of Family and Protective Services.

(c) A center must adopt and enforce a written policy relating to the center's procedures for preventing, detecting, and reporting alleged acts of abuse, neglect, and exploitation of a minor.

(d) A center's employee who has cause to believe that the physical or mental health or welfare of a minor has been or may be adversely affected by abuse, neglect, or exploitation must report the information immediately:

(1) to the HHSC Complaint and Incident Intake Section [DADS Consumer Rights and Services section] at 1-800-458-9858, ciicomplaints@hhs.texas.gov, or via the online portal [DADS website];

(2) to one of the following law enforcement agencies in accordance with THSC Chapter 260A:

(A) a municipal law enforcement agency, if the center is located in the territorial boundaries of a municipality; or

(B) the sheriff's department of the county in which the center is located if a center is not located in the territorial boundaries of a municipality; and

(3) in accordance with Texas Family Code, §261.101.

(e) The following information must be reported to HHSC [~~DADS~~]:

(1) name, age, and address of the alleged victim;

(2) name and address of the person responsible for the care of the alleged victim;

(3) nature of the alleged act;

(4) nature and extent of the alleged victim's condition;

(5) identity of the alleged perpetrator; and

(6) any other relevant information.

(f) A center must investigate allegations of abuse, neglect, or exploitation immediately and send a written report of the investigation using the HHSC [~~DADS~~] Provider Investigation Report form to the HHSC [~~DADS~~] Complaint Intake Unit no later than five days after the initial report.

(g) A center must complete the HHSC [~~DADS~~] Provider Investigation Report form and include the following information:

(1) incident date;

(2) the alleged victim;

(3) the alleged perpetrator;

(4) any witnesses;

(5) the allegation;

(6) any injury or adverse effect;

(7) any assessments made;

(8) any treatment required;

(9) the investigation summary; and

(10) any action taken.

(h) A center must require an employee, as a condition of employment with a center, to sign a statement indicating that the employee may be criminally liable for the failure to report abuse, neglect, or exploitation.

(i) A center must prominently and conspicuously post a readable sign for display in a public area accessible to minors, minors' parents, employees, and visitors that reads: "Cases of Suspected Abuse, Neglect, or Exploitation Shall be Reported to HHSC [~~the Department of Aging and Disability Services~~] by calling 1-800-458-9858."

§550.904. Investigations of a Complaint and Grievance.

(a) HHSC [~~DADS~~] investigates a complaint of non-compliance with THSC Chapter 248A or this chapter regarding:

(1) treatment or care that was furnished at a center;

(2) treatment or care that a center failed to furnish; or

(3) a lack of respect for a minor's property by anyone furnishing services at the center.

(b) A center must adopt and enforce a written policy relating to the center's procedures for prompt investigation of complaints, grievances, and reports of abuse, neglect, and exploitation.

(c) A center must:

(1) acknowledge receipt of a complaint or grievance;

(2) document receipt of a complaint or grievance;

(3) initiate an investigation no later than 10 days after a center receives a complaint or grievance; and

(4) document all components of an investigation.

(d) A center must retain all investigation documentation for a minimum of three years from the date a complaint or grievance was received.

(e) A center must not retaliate against a person for filing a complaint, presenting a grievance, or providing in good faith information relating to services provided by a center.

(1) A center may not retaliate against a minor or a minor's parent for filing a complaint, presenting a grievance, or providing, in good faith, information relating to services provided at the center.

(2) A center is not prohibited from terminating an employee for a reason other than retaliation.

(f) A center must not discharge or otherwise retaliate against a minor or a minor's parent for presenting a complaint or grievance against a center.

§550.905. Reporting of a Minor's Death.

(a) A center must report to HHSC [~~DADS~~] the death of a minor at the center and those minors transferred from the center to a hospital who expire within 24 hours after the transfer.

(b) A center must submit to the HHSC Complaint and Incident Intake Section an HHSC [~~DADS Consumer Rights and Services section a DADS~~] Provider Investigation Incident Report form no later than 10 days after the date a minor dies. A center must complete the HHSC [~~DADS~~] Provider Investigation Incident Report form and include the following information:

(1) name of a deceased minor;

(2) social security number of a deceased minor;

(3) date, time, place of death; and

(4) name and address of a center.

§550.906. Examination of Inspection Results.

(a) A center must make available to any person on request a copy of each HHSC [~~DADS~~] written notification of the inspection results pertaining to the center.

(b) Before making the inspection results available under this subsection, the center must redact from the report any information that is confidential under other state or federal law.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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Karen Ray
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DIVISION 9. MEDICAL RECORDS, QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT, DISSOLUTION AND RETENTION OF RECORDS

26 TAC §§550.1001 - 550.1003

STATUTORY AUTHORITY

The amendments are authorized by Texas Government Code §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of services by the health and human services agencies, and Texas Human Resources Code §103.004 and §103.005, which respectively provide that the Executive Commissioner of HHSC shall adopt rules for implementing Chapter 103 and adopt rules for licensing and setting standards for facilities licensed under Chapter 103.

The amendments implement Texas Government Code §531.0055 and Texas Human Resources Code, Chapter 103.

§550.1001. Medical Records.

(a) In accordance with accepted principles of practice, a center must establish and maintain a medical record system to ensure that the services provided to a minor are completely and accurately documented, readily accessible, and systematically organized to facilitate the compilation and retrieval of information.

(b) A center must establish a medical record for a minor and must maintain the record in accordance with and contain the information described in subsection (g) of this section.

(c) A center must keep a single file for services provided to a minor and a minor's parent.

(d) A center must adopt and enforce written procedures regarding the use and removal of records, the release of information, and when applicable, the incorporation of clinical, progress, or other notes into the medical record.

(e) A center may not release any portion of a minor's medical record to anyone other than the [~~an~~] adult minor or the [~~and a~~] minor's parent, except as allowed by law.

(f) A center must establish a secure area for original active medical record storage at the center's place of business.

(1) A center must ensure that a minor's medical record is treated as confidential, safeguarded against loss and unofficial use, and maintained according to professional standards of practice.

(2) A center must keep a minor's medical record in original form, as a microfilmed copy, on an electronic system, or as a certified copy.

(3) A medical record in its original form is a signed paper record or an electronically signed computer record.

(4) A center must ensure that electronic [~~computerized~~] medical records meet the requirements of paper records, including protection from unofficial use as specified in subsection (f)(1) [~~(g)~~] of this section [~~and retention for the period specified in §15.1004 of this division (relating to Retention of Records)~~].

(5) A center must ensure that an entry to a medical record regarding the delivery of services is not altered without evidence and explanation of the alteration.

(6) A center must ensure that an entry to a minor's medical record is current, accurate, legible, clear, complete, and appropriately authenticated and dated with the date of entry by the individual making the entry. The record must document all services provided on behalf of the center. The center must not use correction fluid or tape in the record. The center must make corrections by striking through the error with a single line and including the date the correction was made and the initials of the person making the correction.

(7) A center must store the record of an inactive minor's medical record on paper, microfilm, or electronically. The center must secure the medical record and ensure that it is readily retrievable by the center staff.

(g) Each medical record must include the following information as applicable to the services provided on behalf of a center:

(1) a minor's referral and application for services including, but not limited to:

(A) the [~~a~~] minor's full name;

(B) the minor's sex and date of birth;

(C) the name, address, and telephone number of the [~~a~~] minor's parent, or others as identified by the [~~a~~] minor's parent;

(D) the [~~a~~] minor's prescribing physician's name and telephone numbers, and an emergency contact number; and

(E) the [~~a~~] minor's prescribing physician's initial order for services;

(2) comprehensive assessments, pertinent medical history including allergies and special precautions, and subsequent assessments;

(3) plans of care, nursing care plans, and other plans as applicable;

(4) verbal orders of a physician reduced to writing and signed by the physician in accordance with the center's policy as required by §550.702 [~~§15.702~~] of this subchapter (relating to Receiving Physician Orders);

(5) documentation of nutritional counseling and special diets, as appropriate;

(6) clinical and progress notes from all professionals providing services to the [~~a~~] minor;

(7) documentation of all known services and significant events;

(8) current medication list;

(9) medication administration record, if medication is administered by center staff;

(10) current immunization record;

(11) written acknowledgment of the [~~an~~] adult minor's or the [~~and a~~] minor's parent's receipt of written notification of the requirements of §550.901 [~~§15.901~~] of this subchapter (relating to Rights and Responsibilities);

(12) written acknowledgment of the [~~an~~] adult minor's or the [~~and a~~] minor's parent's receipt of a center's policy relating to the reporting of abuse, neglect, or exploitation of a minor;

(13) written acknowledgement of the [~~an~~] adult minor's or the [~~and a~~] minor's parent's receipt of the notice of advance directives;

(14) written acknowledgement of the [~~an~~] adult minor's or the [~~and a~~] minor's parent's receipt of the center's policies relating to discipline and guidance;

(15) documentation demonstrating that the [~~an~~] adult minor or the [~~and a~~] minor's parent have been informed of how to register a complaint in accordance with §550.901 [~~§15.901~~] of this subchapter;

(16) discharge summary, including the reason for discharge or transfer and a center's documented notice to the [~~an~~] adult minor, the [~~a~~] minor's parent, the [~~a~~] minor's prescribing physician, and other individuals as required in §550.608 [~~§15.608~~] of this subchapter (relating to Discharge or Transfer Notification);

(17) services provided to the [~~a~~] minor's parent; and

(18) all consent and election forms, as applicable.

(h) A [~~The~~] center must ensure that clinical and progress notes are written the day service is rendered and incorporated into the medical record no later than two business days after the services are rendered.

(i) A center must ensure the retention of the medical record for a minor meets the requirements in §550.1004 of this division (relating to Retention of Records).

§550.1002. Quality Assessment and Performance Improvement.

(a) A center must develop, implement, and maintain a written quality assessment and performance improvement (QAPI) program.

(b) A center must designate in writing the group or individuals, by title, responsible for ensuring that a center's written QAPI program is developed, implemented, and maintained in accordance with this section.

(c) The center must implement the QAPI program using a QAPI Committee. The QAPI committee must be composed of the following persons based on the services provided at the center during the time period under review by the QAPI:

(1) the administrator;

(2) the medical director;

(3) the nursing director;

(4) a therapist from each therapy that provided services during the review period (e.g. [~~i.e.~~], if physical therapy was provided during the quarter being reviewed, a physical therapist [~~PT~~] must be on the QAPI committee);

(5) a social worker that provided services during the review period; and

(6) a supervisor of the direct care staff.

(d) The QAPI program must evaluate all services including:

(1) monitoring activities that have an impact on health and safety of minors;

(2) monitoring and evaluating the quality of services;

(3) improving measurable outcomes for minors, if applicable;

(4) resolving problems identified by a center and raised by parents and adult minors; and

(5) ensuring a center's compliance with THSC Chapter 248A and this chapter.

(e) The QAPI program must be ongoing. Ongoing means there is a continuous and periodic collection and assessment of measurable care provided to minors and administrative quality data.

(f) The written QAPI program must include the frequency and detail of data collection.

(g) A center must collect quality data at least quarterly for all services provided to a minor.

(h) The QAPI program must include a system that measures the quality, effectiveness, and safety of services provided to minors and identifies opportunities and priorities for performance improvement.

(i) The system of measures must allow the QAPI Committee to collect and analyze services provided to minors and administrative quality data. The measures must include a review and analysis of the following, as applicable to the services provided at the center and the problems a center identifies:

(1) a representative sample of active and closed medical records;

(2) negative care outcomes to minors or adverse events;

(3) complaints and grievances;

(4) self-reported incidents alleging abuse, neglect, or exploitation by the center employees, volunteers, or contractors;

(5) minor's parent satisfaction surveys;

(6) infection control activities;

(7) incident reports, including reports of medication errors and unprofessional conduct by licensed staff;

(8) the accuracy and completeness of center personnel records;

(9) the implementation and effectiveness of center policies;

(10) the effectiveness and safety of all services provided, including:

(A) competency and qualifications of staff;

(B) the promptness, safety, and quality of services provided to minors;

(C) the center's response to complaints and reports of abuse, neglect, or exploitation; and

(D) a determination that services are provided as outlined in each minor's plan of care; and

(11) an annual review and evaluation of a center's total operation.

(j) The QAPI Committee must meet quarterly or more often if needed to analyze the data collected and to use the data to improve services. A center must immediately correct identified problems that directly or potentially threaten health and safety of minors. The QAPI Committee must:

(1) plan and document actions taken to correct identified problems, and if necessary, to revise center policies;

(2) measure and document the outcome of the corrective action taken; and

(3) monitor and document the level of improvement over time to ensure sustained improvements.

(k) The QAPI Committee must review and update or revise the written QAPI program at least annually, or more often if needed.

(l) The center must document the ongoing implementation and annual review of the written QAPI program.

(m) The center must keep QAPI documents confidential and make the documents readily available to HHSC [~~DADS~~] upon request.

§550.1003. Dissolution.

(a) A center must adopt and enforce a written policy that describes the center's written contingency plan for dissolution.

(b) A center must implement the dissolution plan in the event of dissolution to ensure continuity of a minor's care.

(c) The plan must include procedures for a center to:

(1) notify each minor [~~minors~~] actively receiving services and the [~~a~~] minor's parent of a center's dissolution; and

(2) transfer or discharge minors actively receiving services consistent with §550.608 [~~§15.608~~] of this subchapter (relating to Discharge or Transfer Notification).

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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SUBCHAPTER D. TRANSPORTATION

26 TAC §550.1101, §550.1102

STATUTORY AUTHORITY

The amendments are authorized by Texas Government Code §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of services by the health and human services agencies, and Texas Human Resources Code §103.004 and §103.005, which respectively provide that the Executive Commissioner of HHSC shall adopt rules for implementing Chapter 103 and adopt rules for licensing and setting standards for facilities licensed under Chapter 103.

The amendments implement Texas Government Code §531.0055 and Texas Human Resources Code, Chapter 103.

§550.1101. Transportation Services.

(a) A center must ensure transportation services are provided for a minor, as authorized by an adult minor or [~~,~~] the minor's parent[~~,~~] and the minor's prescribing physician:

(1) from the minor's home to the center;

(2) from the center to the minor's home; and

(3) to and from the center for services coordinated by the center.

(b) A minor's parent is not required to accompany the minor when the center transports or provides for the transport of the minor.

(c) A center must ensure that vehicles are accessible for a minor with disabilities and equipped to meet the needs of a minor during transport.

(d) A minor's parent may decline a center's transportation services.

(e) A center must adopt and enforce written policies and procedures describing the staff and equipment that will accompany a minor during transportation. The staff must include a driver and a direct care staff member, or [~~and~~] a nurse, if necessary, depending on the acuity of the minors and as determined in coordination with the prescribing physician.

(f) A center must ensure that:

(1) a person transporting a minor on behalf of a center has a valid and appropriate Texas driver's license, a copy of which the center must keep on file;

(2) a vehicle used to transport a minor has a current Texas safety inspection sticker and vehicle registration decal properly affixed to a vehicle;

(3) the center maintains commercial insurance for the operation of a center's vehicles, including coverage for minors and staff in a center's vehicle in the event of accident or injury;

(4) documentation of the insurance is maintained and includes:

(A) the name of the insurance company;

(B) the insurance policy number;

(C) the period of coverage; and

(D) an explanation of the coverage;

(5) the center provides a driver and the center's staff riding in the vehicle [~~nurse~~] with an up-to-date master transportation list that includes a minor's name, pick up and drop off locations, and authorized persons to whom a minor may be released;

(6) the master transportation list is on file at the center;

(7) the driver and the center's staff [~~nurse~~] riding in the vehicle maintain a daily attendance record for each trip that includes the driver's name, the date, names of all passengers in the vehicle, the name of the person to whom a minor was released, and the time of release; and

(8) the number of people in a vehicle used to transport minors does not exceed the manufacturer's recommended capacity for the vehicle.

§550.1102. Transportation Safety Provisions.

(a) A center must adopt and enforce written policies and procedures to ensure the care and safety of minors during transport.

(b) A center must appropriately train staff on the needs of a minor being transported.

(c) A center must properly restrain or secure a minor when the minor is transported by the center in a motor vehicle, in accordance with applicable federal motor vehicle safety standards, state law, THSC [~~Texas Health and Safety Code (THSC)~~] Chapter 248A, and this chapter.

(d) A center must ensure that:

(1) a minor boards and leaves the vehicle from the curbside of the street and is safely accompanied to the minor's destination;

(2) there is a first aid kit with unexpired supplies, including oxygen, a pulse oximeter, and suction equipment in each center vehicle;

(3) the center prohibits the use of tobacco in any form, electronic cigarettes, alcohol, [~~and~~] possession of illegal substances or unauthorized potentially toxic substances, firearms, and pellet or BB guns, including loaded or unloaded BB guns, in any vehicle;

(4) the driver does not use a hand-held wireless communication device while operating a center vehicle;

(5) staff accompany a minor during transportation as described in §550.1101(e) of this subchapter (relating to Transportation Services) and paragraph (6) of this subsection;

[~~(5) a center's nurse accompanies minors, as necessary during transport, as determined by the minor's plan of care;~~]

(6) at least one direct care staff member, or more depending on the acuity of the minors, accompanies every seven minors;

(7) the driver or center's staff riding in the vehicle [~~nurse~~] does not leave a minor unattended in the vehicle at any time;

(8) the driver or the center's staff [~~nurse~~] riding in the vehicle inspects the vehicle at the completion of each trip to ensure that no minor is left in the vehicle; and

(9) the center maintains documentation that includes the signature of the individual conducting the inspection described in paragraph (8) of this subsection and the time of inspection.

(e) A center must post near the emergency exit of each vehicle that transports a minor the following information in an easily readable font:

(1) the name of the administrator;

(2) the center's name;

(3) the center's telephone number; and

(4) the center's address.

(f) The center must adopt and enforce a policy on emergencies while transporting a minor. The policy must include:

(1) procedures for mechanical break downs;

(2) procedures for vehicle accidents; and

(3) procedures for a minor's emergency.

(g) If a center conducts a field trip, the center must ensure that the driver or center's staff [~~nurse~~] riding in the vehicle [~~must~~] inspect the vehicle and account for each minor upon arrival and departure from each destination to ensure that no minor is left in the vehicle after reaching the vehicle's final destination.

(1) A center must ensure that the driver or center's staff [~~nurse~~] riding in the vehicle maintains a field trip record for each trip. The record must include the driver's name, the staff's [~~nurse's~~] name, the time and date, the vehicle's destinations, and names of all passengers in the vehicle.

(2) A center must maintain documentation that includes the signature of the person conducting the inspection and the time of each inspection during the field trip.

(3) Appropriate staff must be present when a minor is delivered to the center.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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SUBCHAPTER E. BUILDING REQUIREMENTS

26 TAC §§550.1202 - 550.1204, 550.1206, 550.1207, 550.1211, 550.1215, 550.1217 - 550.1220, 550.1222, 550.1224

STATUTORY AUTHORITY

The amendments are authorized by Texas Government Code §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of services by the health and human services agencies, and Texas Human Resources Code §103.004 and §103.005, which respectively provide that the Executive Commissioner of HHSC shall adopt rules for implementing Chapter 103 and adopt rules for licensing and setting standards for facilities licensed under Chapter 103.

The amendments implement Texas Government Code §531.0055 and Texas Human Resources Code, Chapter 103.

§550.1202. Plan Reviews.

(a) Plans for new buildings, additions, conversions of buildings not licensed by HHSC [~~DADS~~], and the remodeling of existing licensed facilities must be submitted to HHSC [~~DADS~~] for review. No later than 30 days after receipt of the plans, HHSC [~~DADS~~] informs an applicant in writing of the results of the review.

(b) If the submitted plans comply with HHSC [~~DADS~~] architectural requirements, HHSC [~~DADS~~] may not subsequently change the architectural requirement that applies to the project unless the change is required by federal law or an applicant fails to complete the project no later than two years after submitting the plans to HHSC [~~DADS~~].

(c) HHSC [~~DADS~~] may grant a waiver of the two-year period for delays due to unusual circumstances.

(d) HHSC [~~DADS~~] may impose a deadline for completing a project using requirements that are revised after the project was reviewed.

(e) Submittal of plans.

(1) One copy of contract documents must be submitted to HHSC [~~DADS~~] before construction begins. The documents must:

(A) include working drawing and specifications;

(B) have sufficient detail for HHSC [~~DADS~~] to interpret compliance with this chapter and for a general contractor or builder to ensure proper construction; and

(C) be prepared according to accepted architectural practice and include general construction, special conditions, and schedules.

(2) Final copies of plans must be submitted to HHSC [~~DADS~~] and include:

(A) a title block that shows the name of the center;

(B) the person or organization preparing the sheet;

(C) sheet numbers;

(D) the center's address; and

(E) the drawing date.

(3) Sheets and sections covering structural, electrical, mechanical, and sanitary engineering final plans, designs, and specifications must bear the seal of a professional engineer licensed by the Texas Board of Professional Engineers.

(4) The [~~An architect licensed by the Texas Board of Architectural Examiners must prepare~~] contract documents for additions, remodeling, and construction of a new center must be prepared by an architect licensed by the Texas Board of Architectural Examiners. Drawings must bear the seal of the architect.

(5) A final plan for a major addition to a center must be submitted to HHSC [~~DADS~~] and include a basic layout to scale of the entire building into which the addition will connect. North direction must be shown. The entire basic layout must be scaled to fit on a single 8 1/2-inch by 11-inch sheet.

(6) Final plans and specifications for conversions or remodeling must be submitted to HHSC [~~DADS~~] and include all parts and features involved.

(7) Qualified staff must be employed to prepare the contract documents for construction. If the contract documents have errors or omissions to the extent that compliance with this chapter cannot be reasonably ensured or determined, HHSC [~~DADS~~] may request a revised set of documents for review.

(8) HHSC [~~DADS~~] review of the plans and specifications is based on general utility and compliance with this chapter and the Life Safety Code. HHSC [~~DADS~~] review is not an all-inclusive review of the structural, electrical, or mechanical components of a center. HHSC [~~DADS~~] review does not include a review of building plans for compliance with the Texas Accessibility Standards as administered and enforced by the Texas Department of Licensing and Regulation.

(9) Plan review fees must be submitted in accordance with §550.113 [~~§15.113~~] of this chapter (relating to Plan Review Fees).

(f) Contract documents.

(1) Site plan documents must be submitted to HHSC [~~DADS~~] and include:

(A) grade contours;

(B) streets with names;

(C) north arrow;

(D) fire hydrants;

(E) fire lanes;

(F) public or private utilities;

(G) fences; and

(H) unusual site conditions, including:

(i) ditches;

(ii) low water levels;

(iii) other buildings on-site; and

(iv) indications of buildings five feet or less beyond site property lines.

(2) Foundation plan documents must be submitted to HHSC [~~DADS~~] and include general foundation design and details.

(3) Floor plan documents must be submitted to HHSC [~~DADS~~] and include:

(A) room names, numbers, and usages;

(B) numbered doors, including swing;

(C) windows;

(D) legend or clarification of wall types that include:

(i) dimensions;

(ii) fixed equipment;

(iii) plumbing fixtures;

(iv) basic layout of the food preparation area; and

(v) identification of all smoke barrier walls from outside wall to outside wall or fire walls.

(4) For both new construction and additions or remodeling to existing buildings, an overall plan of the entire building drawn or reduced to fit on a single 8 1/2-inch by 11-inch sheet must be submitted to HHSC [~~DADS~~].

(5) Schedules must be submitted to HHSC [~~DADS~~] and include:

(A) door materials, widths, and types;

(B) window materials, sizes, and types;

(C) room finishes; and

(D) special hardware.

(6) Elevations and roof plans must be submitted to HHSC [~~DADS~~]. Plans must include exterior elevations, including:

(A) material note indications;

(B) rooftop equipment;

(C) roof slopes;

(D) drains;

(E) gas piping; and

(F) interior elevations where needed for special conditions.

(7) Contract document details must be submitted to HHSC [~~DADS~~] and include:

(A) wall sections as needed, especially for special conditions;

(B) cabinet and built-in work, basic design only;

(C) cross sections through buildings as needed; and

(D) miscellaneous details and enlargements as needed.

(8) Building structure documents must be submitted to HHSC [~~DADS~~] and include:

(A) structural framing layout and details used primarily for column, beam, joist, and structural building;

(B) roof framing layout if it cannot be adequately shown on a cross section; and

(C) cross sections in quantity and detail to show sufficient structural design and structural details as necessary to ensure adequate structural design and calculated design loads.

(9) Electrical documents must be submitted to HHSC [~~DADS~~] and include:

(A) electrical layout, including lights, convenience outlets, equipment outlets, switches, and other electrical outlets and devices;

(B) service, circuiting, distribution, and panel diagrams;

(C) exit light systems with exit signs and emergency egress lighting;

(D) emergency electrical provisions, including generators and panels;

(E) staff communication systems;

(F) fire alarm and similar systems, including control panel, devices, and alarms; and

(G) sizes and details sufficient to ensure safe and properly operating systems.

(10) Plumbing documents must be submitted to HHSC [~~DADS~~] and include:

(A) plumbing layout with pipe sizes and details sufficient to ensure safe and properly operating systems;

(B) water systems;

(C) sanitary systems;

(D) gas systems; and

(E) other systems normally considered under the scope of plumbing, fixtures, and provisions for combustion air supply.

(11) Heating, ventilation [~~ventilating~~], and air-conditioning (HVAC) systems [~~(HVAC)~~] documents must be submitted to HHSC [~~DADS~~] and include:

(A) sufficient details of HVAC systems and components to ensure a safe and properly operating installation, including heating, ventilation [~~ventilating~~], and air-conditioning layout, ducts, protection of duct inlets and outlets, combustion air, piping, exhausts, and duct smoke and fire dampers; and

(B) equipment types, sizes, and locations.

(12) Sprinkler system documents must be submitted to HHSC [~~DADS~~] and include:

(A) plans and details of National Fire Protection Association (NFPA) designed systems to meet the requirements of NFPA 13, Standard for the Installation of Sprinklers;

(B) plans and details of partial systems provided only for hazardous areas; and

(C) electrical devices interconnected to the alarm system.

(13) Specifications must be submitted to HHSC [~~DADS~~] that include:

(A) installation techniques;

(B) quality standards and manufacturers;

(C) references to specific codes and standards;

(D) design criteria;

(E) special equipment;

(F) hardware;

(G) finishes; and

(H) other specifications as needed to amplify drawings and notes.

(14) Other layouts, plans or details must be submitted to HHSC [~~DADS~~] as necessary for HHSC [~~DADS~~] to obtain a clear understanding of the design and scope of the project. Plans covering private water or sewer systems that have been reviewed by the health or wastewater authority having appropriate jurisdiction must be submitted to HHSC [~~DADS~~].

(g) Construction phase.

(1) The HHSC [~~DADS~~] Architectural Unit must be notified in writing before beginning construction of a new center or the remodeling of an existing center.

(2) HHSC [~~DADS~~] requires additional drawings if construction of the center is not performed in accordance with the completed plans and specifications as submitted to HHSC [~~DADS~~] for review or as modified in accordance with HHSC [~~DADS~~] review requirements, if the change is significant.

(h) Initial inspection of completed construction.

(1) After completion of construction, including grounds and basic equipment and furnishings, HHSC [~~DADS~~] performs an initial architectural inspection of the center before the center admits a minor. HHSC [~~DADS~~] schedules an initial architectural inspection after HHSC [~~DADS~~] receives a licensure application, required fees, fire marshal approval, approval of local building authority, and a letter from an architect or engineer stating that, to the best of the architect or engineer's knowledge, the center meets the building requirements for licensure.

(2) If HHSC [~~DADS~~] Life Safety Code staff inspect the completed construction and find it in compliance with this chapter, the HHSC [~~DADS~~] Architectural Unit forwards the information to the HHSC [~~DADS~~] Licensing and Credentialing Unit as part of an applicant's license application. For additions to or remodeling of an existing center, HHSC [~~DADS~~] may require an applicant to submit a revision or modification to an existing license. The building, including basic furnishings and operational needs, grades, drives, and parking, must be 100 percent complete at the time of the HHSC [~~DADS~~] initial architectural inspection. A center may admit at least one but no more than three minors after it receives initial approval from HHSC [~~DADS~~] but before a license is issued.

(3) An applicant must make the following documents related to the completed building available to the HHSC [~~DADS~~] architectural inspection surveyor at the time of the inspection:

(A) written approval of the local authorities as required in paragraph (1) of this subsection;

(B) for fire detection and alarm systems:

(i) record drawings of the fire detection and alarm system as installed, signed by an alarm planning superintendent licensed by the State Fire Marshal's Office or sealed by a licensed professional engineer;

(ii) a sequence of operation, the owner's manuals and the manufacturer's published instructions covering all system equipment;

(iii) a signed copy of the State Fire Marshal's Office Fire Alarm Installation Certificate; and

(iv) for software-based systems, a record copy of the site-specific software, excluding the system executive software or external programmer software in non-volatile, non-erasable, non-rewritable memory;

(C) documentation of materials used in the building that are required to have a specific limited fire or flame spread rating, including special wall finishes or floor coverings, flame retardant rated ceilings and curtains, including cubicle curtains; [.]

(D) for carpeting that is required to have a specific limited fire or flame spread rating, a signed letter from the installer verifying that the carpeting installed is named in the laboratory test document; and

(E) for fire sprinkler systems:

(i) record drawings of the fire sprinkler system as installed, signed by a responsible managing employee, licensed by the State Fire Marshal's Office or sealed by a licensed professional engineer;

(ii) the hydraulic calculations;

(iii) the alarm configuration;

(iv) above ground and underground Contractor's Material and Test Certificate;

(v) the literature and instructions provided by the manufacturer describing the proper operation and maintenance of all equipment and devices in accordance with NFPA 25, Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems;

(vi) service contracts for maintenance and testing of alarm systems and sprinkler systems;

(vii) a copy of gas test results of the center's gas lines from the meter;

(viii) a written statement from an architect or engineer stating, to the best of the architect or engineer's knowledge, the building was constructed in substantial compliance with the construction documents, the Life Safety Code, this chapter, and local codes; and

(ix) any other such documentation as needed.

(i) Non-approval of new construction.

(1) If, during the initial on-site architectural inspection of completed construction, the HHSC [DADS] Life Safety Code surveyor finds certain basic requirements are not met, the surveyor may recommend that the center not be licensed or approved for occupancy. Items that may result in this recommendation include:

(A) substantial changes made during construction that were not submitted to HHSC [DADS] for review and that may require revised "as-built" drawings to include the changes, including[.] architectural, structural, mechanical, and electrical items as specified in this section;

(B) construction that does not meet minimum code or licensure standards, including corridors that are less than the required width, ceilings installed at less than the minimum seven-foot, six-inch height, and other features that would disrupt or otherwise adversely affect minors and staff if corrected after occupancy;

(C) lack of written approval by appropriate local authorities;

(D) fire protection systems, including fire alarm systems, emergency power and lighting, and sprinkler systems, that are not completely installed or functioning properly;

(E) required exits that not all usable according to NFPA 101 requirements;

(F) telephones that are not installed or not working properly;

(G) sufficient basic furnishings, essential appliances, and equipment that are not installed or functioning; and

(H) other basic operational or safety feature that would preclude safe and normal occupancy by a minor on that day.

(2) An applicant must submit copies of reduced-size floor plans on an 8 1/2-inch by 11-inch sheet, in duplicate, to HHSC [DADS] for records and for the center's use for an evacuation plan, or fire alarm zone identification. The plan must contain basic legible information including scale, room usage names, actual bedroom numbers, doors, windows, and any other pertinent information.

§550.1203. Design Criteria.

(a) A center must be designed in accordance with:

(1) the Health Care Occupancy chapter of the 2000 edition of the National Fire Protection Association (NFPA) 101 Life Safety Code for newly constructed centers or centers converting an existing unlicensed building to a center; and

(2) the requirements of Limited Care, as defined by NFPA 101.

(b) An applicant for a center license must submit to HHSC [DADS] site approval by the local building department and fire marshal having appropriate jurisdiction.

(c) An applicant for a center license must meet applicable local, state, or national codes and ordinances as determined by the authority having appropriate jurisdiction for those codes and ordinances and by HHSC [DADS].

(d) A center must meet the requirements of the International Plumbing Code or Uniform Plumbing Code, as adopted by the local municipality.

(e) If conflicting codes apply to the construction of the center, the more stringent codes apply.

(f) A center may not be built in an area designated as a floodplain of 100 years or less.

(g) A center must comply with the accessibility requirements for individuals with disabilities as referenced in the revised regulations for Title II and III (2010 ADA Standards for Accessible Design) of the Americans with Disabilities Act of 1990 at Title 42, United States Code, Chapter 126; federal regulations at 28 Code of Federal Regulations [Title 28,] Code of Federal Regulations, Part 35 and Part 36; Texas Accessibility Standards at Texas Government Code, Chapter 469; and Texas Department of Licensing and Regulation rules at 16 Texas Administrative Code [TAC] Chapter 68 (relating to Elimination of Architectural Barriers).

§550.1204. Fire Safety.

(a) A center's construction type is limited to the building construction shown in the minimum construction requirements in the Life Safety Code chapter for New Health Care Occupancies.

(b) A center must have a National Fire Protection Association (NFPA) 72 fire alarm system with initiation, notification, emergency

forces notification, annunciation, emergency control and detection in accordance with the Life Safety Code. The center must have a written contract with a fire alarm firm that has been issued an Alarm Certificate of Registration number from the Texas State Fire Marshal's Office to inspect, test and maintain a fire alarm system to meet NFPA 72 requirements, semiannually. Inspections required in the contract must be performed. The person performing the semiannual service must have an individual fire alarm license from the Texas State Fire Marshal's Office.

(c) A center must be protected throughout by an approved, supervised automatic sprinkler system installed in accordance with NFPA 13. The center must ensure that the sprinkler system is inspected, tested, and maintained in accordance with NFPA 25. The center must have a written contract with a fire protection sprinkler firm that has been issued a Sprinkler Certificate of Registration number from the Texas State Fire Marshal's Office to perform the required services, semiannually. The center must document and show to HHSC [~~DADS~~] that all the requirements of NFPA 25 are met including the annual inspection, test, and maintenance performed by the registered fire sprinkler firm. The center must retain one set of the fire sprinkler system plans and hydraulic calculations on the property.

(d) A center must distribute portable fire extinguishers throughout the center of size and type in accordance with NFPA 10.

(e) A center must provide emergency power for emergency lighting, exit signs, and the fire alarm by a generator.

(f) A center must ensure that the design, installation, and maintenance of emergency motor generators are in accordance with NFPA 37, NFPA 99, and NFPA 110.

(g) A center must ensure that the generator is of sufficient size to maintain Life Safety Code requirements, medical equipment, and heating, ventilation, and air-conditioning systems [~~HVAC~~] to operate in designated core areas of the center in the event of power failure.

(h) The center must ensure that emergency powered receptacles are used:

(1) for a patient care-related electrical appliance, including a biological refrigerator;

(2) at a nurse station; and

(3) in a medication room.

(i) The center must store and administer oxygen in accordance with NFPA 99.

§550.1206. Exterior Spaces.

(a) A center must have separate entrances for guests and minors.

(b) A center must have a covered entry with a covered drop-off for family, emergency medical services (EMS), and the center's vehicles.

(c) A center's roof overhang or canopy must extend as far as practicable to the face of the driveway or curb of the passenger access door of a passenger vehicle.

(d) A center's roof overhang or cover must be of sufficient height to allow entry or departure from EMS vehicles.

(e) A center must provide for an outdoor play space with a direct exit from the center into the outdoor play space. The outdoor play space should at least be 400 square feet in area with at least 20 percent of that area shaded.

(f) A center's play yard must meet the requirements of the Texas Accessibility Standards.

(g) A center must ensure that its structures and the grounds of the center that are used by minors are maintained in good repair and are free from hazards to health and safety.

(h) A center must fence or ensure natural barriers are present to protect a minor from areas determined to be unsafe by HHSC [~~DADS~~], including steep grades, cliffs, open pits, swimming pools, high voltage boosters, high voltage equipment, and high speed roads.

(i) A center must keep fences in good repair.

(j) A center must store garbage, rubbish, and trash securely in outdoor, covered containers.

(k) A center must keep trash collection receptacles and incinerators separated from outdoor recreational spaces and locate the receptacles and incinerators in a place to avoid being a nuisance.

§550.1207. Interior Spaces.

(a) A center must consist of a building suitable for the purpose intended, and have a minimum of 50 square feet of space per minor exclusive of kitchen, toilet facilities, storage areas, hallways, stairways, basements, and attics.

(b) If a center uses a room exclusively for dining or sleeping, the center must not count that space as part of the licensed capacity.

(c) A center must have sufficient rooms to accommodate and segregate the different age groups of minors being served at the center.

(d) A center must provide staff area and staff toilets.

(e) A center must provide a reception area.

(f) A center must provide an administrative office.

(g) A center must provide quiet rooms based on the needs of minors.

(h) A center's quiet room must contain a minimum of 100 square feet.

(i) A center must provide indoor recreational exercise play area.

(j) A center must provide a treatment room with a medication preparation area. The medication preparation area must contain a work counter, refrigerator, sink with hot and cold water, and locked storage for biologicals and drugs.

(k) A center must develop isolation procedures to prevent cross-infection and provide an isolation room with at least one large glass area for observation of a minor in accordance with §550.211 [~~§15.211~~] of this chapter (relating to Infection Prevention and Control Program and Vaccination Requirements). The isolation room must contain a minimum of 100 square feet.

(l) The center must make privacy accommodations available to attend to the personal care needs of a minor.

§550.1211. Linen Storage.

(a) A center must have a mechanical forced air exhaust system to the outside for soiled linen areas in accordance with §550.210 [~~§15.210~~] of this chapter (relating to Sanitation, Housekeeping, and Linens).

(b) A center must have separate storage areas for clean and soiled linen in accordance with §550.210 [~~§15.210~~] of this chapter.

§550.1215. Garbage.

(a) A center must store garbage, rubbish, and trash in an area separate from the areas used for the preparation and storage of food. A center must remove garbage, trash, and rubbish from the premises and sanitize the containers regularly.

(b) A center must meet the sanitation requirements in §550.210 [~~§15.210~~] of this chapter (relating to Sanitation, Housekeeping, and Linens).

§550.1217. Laundry.

(a) A center must have a supply of clean linen sufficient to meet the needs of a minor. Clean laundry must be provided by:

(1) an in-house laundry service;

(2) contract with another health care center; or

(3) an outside commercial laundry service.

(b) A center must handle, store, process, and transport laundry in a manner to prevent the spread of infection in accordance with §550.210 [~~§15.210~~] of this chapter (relating to Sanitation, Housekeeping, and Linens).

§550.1218. Housekeeping.

(a) A center must:

(1) maintain a clean and safe environment;[~~.~~]

(2) be free of unpleasant odors; and

(3) eliminate odors at the center at their source by prompt and thorough cleaning of commodes, urinals, bedpans, and other sources.

(b) A center must meet the housekeeping requirements in §550.210 [~~§15.210~~] of this chapter (relating to Sanitation, Housekeeping, and Linens).

§550.1219. Maintenance.

(a) A center must:

(1) ensure that the grounds and the exterior of the building, including the sidewalks, steps, porches, ramps, and fences are in good repair;

(2) keep equipment supplied by the center for a minor's needs in good repair, including wheelchairs, cribs, and mattresses;

(3) keep the interior of the building including walls, ceilings, floors, windows, window coverings, doors, plumbing, and electrical fixtures in good repair; and

(4) use pest control services provided by a licensed structural pest control applicator with a license category for pests.

(b) A center must meet the requirements in §550.210 [~~§15.210~~] of this chapter (relating to Sanitation, Housekeeping, and Linens).

§550.1220. Heating, Ventilation, and Air Conditioning Systems [~~(HVAC)~~].

(a) A center must use a safe heating, ventilation, and air conditioning (HVAC) [~~HVAC~~] system that meets the requirements of the National Fire Protection Association (NFPA) 90A and is sufficient to maintain a comfortable temperature, with a minimum of 65 degrees and a maximum of 80 degrees Fahrenheit, in all public and private areas year round.

(b) A center must ensure that during warm weather conditions, the temperature within the center does not exceed 80 degrees Fahrenheit. The center must ensure that the HVAC system operates in designated core areas of the center in the event of power failure.

(c) A center must maintain the HVAC system in good repair.

(d) A center must inspect gas-fired heating equipment before the cold weather season to ensure that the equipment operates properly and safely. The center must ensure that gas-fired heating equipment is inspected by a person licensed or approved by the State of Texas to inspect the equipment.

(e) The center must maintain a record of the inspection conducted in accordance with subsection (d) of this section.

(f) A center must correct any unsatisfactory condition or evacuate or relocate the minors.

(g) A center must ensure that a gas heating unit and water heater are vented in accordance with NFPA 54 to carry the products of combustion to the outside atmosphere. The center must ensure that a vent is constructed and maintained to provide a continuous draft to the outside atmosphere in accordance with NFPA 54. The center must ensure that a heating unit is provided with a sufficient supply of outside combustion air in accordance with NFPA 54. A center must not use a portable heater within the center.

§550.1222. Sewage.

A center must ensure that sewage is disposed of by a public system or an approved sewage disposal system constructed and operated to conform with the standards established for systems by the Texas Commission on Environmental Quality and in accordance with sanitation requirements in §550.210 [~~§15.210~~] of this chapter (relating to Sanitation, Housekeeping, and Linens).

§550.1224. Waivers.

(a) HHSC [~~DADS~~] may grant a waiver for certain provisions of the physical plant and environment requirements of HHSC [~~DADS~~] licensure standards, which, in HHSC [~~DADS~~] opinion, would be impractical for a center to meet. In granting the waiver, HHSC [~~DADS~~], on a case by case basis, determines if:

(1) there are adverse effects on the health and safety of a minor if the center does not meet the licensure requirement; and

(2) the center will experience an unreasonable hardship if the requirement is not waived.

(b) HHSC [~~DADS~~] may require a center to offset or comply with an equivalent provision if HHSC [~~DADS~~] grants a waiver. A center must demonstrate an equivalent safety feature by utilizing the National Fire Protection Association 101A, Guide on Alternative Approaches to Life Safety, for waivers of the Life Safety Code.

(c) An HHSC [~~A DADS~~] waiver is not transferable in a change of ownership and is subject to HHSC [~~DADS~~] review or revocation upon any change in circumstances at the center.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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Karen Ray
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Health and Human Services Commission
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For further information, please call: (512) 438-3161

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SUBCHAPTER F. INSPECTIONS AND VISITS

26 TAC §§550.1301 - 550.1305

STATUTORY AUTHORITY

The amendments are authorized by Texas Government Code §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of services by the health and human services agencies, and Texas Human Resources Code §103.004 and §103.005, which respectively provide that the Executive Commissioner of HHSC shall adopt rules for implementing Chapter 103 and adopt rules for licensing and setting standards for facilities licensed under Chapter 103.

The amendments implement Texas Government Code §531.0055 and Texas Human Resources Code, Chapter 103.

§550.1301. Inspections and Visits.

(a) HHSC [~~DADS~~] performs inspections, follow-up visits, compliance investigations, investigations of abuse, neglect and exploitation, and other contact visits at a center as deemed appropriate or as required to determine a center's compliance with this chapter.

(b) An inspection may be conducted by an inspector or by a team depending on the purpose of the inspection, size of a center, and other factors.

(c) HHSC [~~DADS~~] does not announce inspections or visits.

(d) HHSC [~~DADS~~] conducts at least one unannounced licensing inspection annually after issuance of a license.

(e) HHSC [~~DADS~~] may visit a center for purposes other than the reasons described in subsection (a) of this section.

(1) HHSC [~~DADS~~] may visit a center to consult with a center's staff to determine how a center's physical space may be expanded or upgraded or determine the progress of a center's construction or repairs, equipment installation or repairs, systems installation or repairs, or when conditions or emergencies arise, including fire, windstorm, or malfunctioning or nonfunctioning of electrical or mechanical systems.

(2) HHSC [~~DADS~~] may announce visits that are not for a purpose described in subsection (a) of this section.

§550.1302. Investigation of Complaints and Self-Reported Incidents.

(a) HHSC [~~DADS~~] investigates complaints of abuse, neglect, or exploitation if:

(1) the act occurs at the center;

(2) the center is responsible for the supervision of a minor at the time the act occurs;

(3) the alleged perpetrator is associated with the center; or

(4) the alleged perpetrator is present at the center.

(b) HHSC [~~DADS~~] refers complaints of abuse, neglect, or exploitation not meeting the criteria in subsection (a) of this section to the Department of Family and Protective Services.

(c) HHSC [~~DADS~~] conducts an investigation under this section in accordance with THSC §260A.007.

(d) A center's investigation of complaints and self-reported incidents does not preclude HHSC [~~DADS~~] from taking action in accordance with Subchapter G of this chapter (relating to Enforcement).

(e) HHSC [~~DADS~~] notifies the following individuals of the results of an HHSC [~~a DADS~~] investigation:

(1) the individual who reported the allegation or complaint;

(2) an adult minor;

(3) a minor's parent;

(4) any person designated by an adult minor or minor's parent to receive information concerning a minor; and

(5) a center.

§550.1303. Cooperation with an Inspection and Visit.

(a) By applying for and holding a license, a license holder consents to entry or inspection of the center's premises by an HHSC [~~a DADS~~] representative to verify compliance with THSC Chapter 248A and this chapter.

(b) A center must make all of its books, records, and other documents maintained by or on behalf of a center accessible to HHSC [~~DADS~~] upon request.

(1) HHSC [~~DADS~~] is authorized to photocopy documents, photograph minors, and use any other available recording devices to preserve all relevant evidence of conditions found during an inspection or investigation that HHSC [~~DADS~~] reasonably believes threaten the health and safety of a minor.

(2) HHSC [~~DADS~~] may request, photocopy, and otherwise reproduce records and documents including admission sheets, medication records, observation notes, medical records, clinical notes, and any other of a center's documents.

(3) HHSC [~~DADS~~] protects the copies for privacy and confidentially purposes in accordance with recognized standards of medical records practice, applicable state laws, and HHSC [~~DADS~~] policy.

(c) During an inspection or investigation, a center's representative and staff must not:

(1) make a false statement that a person knows or should know is false of a material fact about a matter under investigation by HHSC [~~DADS~~];

(2) willfully interfere with the work of an HHSC [~~a DADS~~] representative;

(3) willfully interfere with an HHSC [~~a DADS~~] representative in preserving evidence of a violation; or

(4) refuse to allow an HHSC [~~a DADS~~] representative to inspect a book, record, or file required to be maintained by or on behalf of a center.

(d) HHSC [~~DADS~~] may assess an administrative penalty for a violation of provisions in this section, or may take other enforcement action to deny, revoke, or suspend a license, if a center does not cooperate with an inspection.

(e) In order to preserve the integrity of the inspection and investigation process, a center must:

(1) not record, listen to, or eavesdrop on any HHSC interview with center staff or minors that the center staff knows HHSC intends to keep confidential, as evidenced by HHSC taking reasonable measures to prevent from being overheard; or

(2) not record, listen to, or eavesdrop on any HHSC internal discussions outside the presence of center staff when HHSC has requested a private room or office or distanced themselves from center staff, unless the center obtains HHSC written approval before beginning to record or listen to the discussion.

(f) A center must inform HHSC when security cameras or other existing recording devices in the center are in operation during any internal discussion by or among HHSC staff.

(g) When HHSC permits center staff by words or actions to be present, an interview or conversation for which center staff are present does not constitute a violation of this rule.

(h) This section does not prohibit a minor or a minor's parents from recording an HHSC interview with the minor.

§550.1304. Staff Requirements for an Inspection.

(a) The center's administrator, alternate administrator, nursing director, or alternate nursing director must be present in person at the entrance and exit conferences of every HHSC [~~DADS~~] inspection or visit and be available in person during the inspection.

(b) If a required individual is not at the center when the inspector arrives and is unavailable during the inspection, the inspector will make reasonable attempts to contact the individual.

(c) If an inspector arrives during regular business hours and the center is closed, an administrator, alternate administrator, nursing director, or alternate nursing director must provide the inspector entry to the center no later than two hours after the inspector's arrival at the center. The center must comply with the notice requirements described in §550.201 [~~§15.201~~] of this chapter (relating to Operating Hours).

§550.1305. General Provisions.

(a) HHSC [~~DADS~~] determines if a center meets the requirements of [~~the~~] THSC Chapter 248A and this chapter.

(b) After an inspection is completed, the inspector holds an exit conference to inform a center of the preliminary findings.

(c) A center may submit additional written documentation and facts after the exit conference only if the [~~a~~] center describes the additional documentation and facts to the inspector during the exit conference.

(1) A center must submit the additional written documentation and facts to the HHSC [~~DADS~~] inspector or inspection team no later than two business days after the end of the exit conference.

(2) If a center properly submits additional written documentation, the inspector may add the documentation to the record of the inspection.

(d) HHSC [~~DADS~~] provides a written notification of the inspection results to the center no later than 10 business days after the exit conference. The written notification includes a statement of violations and instructions for submitting an acceptable plan of correction and provides an opportunity for an informal dispute resolution (IDR).

(e) If a center receives HHSC [~~DADS~~] written notification of the inspection results indicating that the center is in violation of THSC Chapter 248A or this chapter, the center must follow HHSC [~~DADS~~] instructions included with the notification for submitting an acceptable plan of correction.

(f) If required, a center must submit an acceptable plan of correction that includes the corrective measures and time frame in which the center will comply to ensure correction of a violation. If a center fails to correct each violation by the date on the plan of correction, HHSC [~~DADS~~] may take enforcement action against the center.

(g) A center must submit an acceptable plan of correction for each violation no later than 10 calendar days after receipt of the [~~DADS~~] written notification of the inspection results. An acceptable plan of correction must address:

(1) how the center will accomplish corrective action for the minors affected by the violation;

(2) how the center will identify other minors with the potential to be affected by the same violation;

(3) the measures that the center will incorporate, or systemic changes the center made to ensure the violation will not recur;

(4) how the center will monitor its corrective actions to ensure that the violation is corrected and will not recur; and

(5) dates when the center's corrective action will be completed.

(h) A center's acceptable plan of correction does not preclude HHSC [~~DADS~~] from taking enforcement action against the center in accordance with Subchapter G of this chapter (relating to Enforcement).

(i) A center must submit a plan of correction in response to the [~~DADS~~] written notification of inspection results that specifies a violation even if the center disagrees with the inspection results.

(j) If a center disagrees with the inspection results, the center may request an IDR [~~informal dispute resolution (IDR)~~]. The center must submit a written request and all supporting documentation to HHSC [~~DADS~~] no later than the 10th calendar day after the date the center receives HHSC [~~DADS~~] statement of violations.

(k) A center waives its right to an IDR if the center fails to submit the required information to the HHSC [~~DADS~~] Regulatory Services, Survey and Certification Enforcement Unit, within the required time frames.

(l) A center must make available to any person on request a copy of each HHSC [~~DADS~~] inspection report. Before making an inspection report available under this subsection, the center must redact from the report any information that is confidential under other law.

(m) A center must post the most recent inspection results in a conspicuous location at the center.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on May 29, 2024.

TRD-202402407
Karen Ray
Chief Counsel
Health and Human Services Commission
Earliest possible date of adoption: July 14, 2024
For further information, please call: (512) 438-3161

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SUBCHAPTER G. ENFORCEMENT

26 TAC §§550.1401 - 550.1408

STATUTORY AUTHORITY

The amendments are authorized by Texas Government Code §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of services by the health and human services agencies, and Texas Human Resources Code §103.004 and §103.005, which respectively provide that the Executive Commissioner of HHSC shall adopt rules for implementing Chapter 103 and adopt rules for licensing and setting standards for facilities licensed under Chapter 103.

The amendments implement Texas Government Code §531.0055 and Texas Human Resources Code, Chapter 103.

§550.1401. Denial of License Application.

HHSC [~~DADS~~] may deny a license application for the reasons described in §550.115 [~~§15.115~~] of this chapter (relating to Criteria for Denial of a License).

§550.1402. License Suspension.

(a) HHSC [~~DADS~~] may suspend a center's license for:

(1) a violation of THSC Chapter 248A or a standard in this chapter committed by the license holder, applicant, or a person listed on the application;

(2) an intentional or negligent act by a center or an employee of a center that HHSC [~~DADS~~] determines significantly affects the health and safety of a minor served at a center;

(3) use of drugs or intoxicating liquors to an extent that it affects the license holder's or applicant's professional competence;

(4) a felony conviction, including a finding or verdict of guilty, an admission of guilt, or a plea of nolo contendere, in Texas or another state of any person required by this chapter to undergo a background and criminal history check;

(5) fraudulent acts, including acts relating to Medicaid fraud and obtaining or attempting to obtain a license by fraud or deception committed by any person listed on the application;

(6) license revocation, suspension, or other disciplinary action taken in Texas or another state against the license holder or any person listed in the application;

(7) criteria described in Chapter 560 [~~99~~] of this title (relating to Denial or Refusal of License) that applies to any person required by this chapter to undergo a background and criminal history check;

(8) aiding, abetting, or permitting a violation described in paragraph (1) of this subsection about which a person listed on the application had or should have had knowledge;

(9) a license holder or applicant's failure to provide the required information, facts, or references;

(10) a license holder or applicant who knowingly:

(A) submits false or intentionally misleading statements to HHSC [~~DADS~~] on an application;

(B) uses subterfuge or other evasive means of filing an application;

(C) engages in subterfuge or other evasive means of filing an application on behalf of another who is unqualified for licensure; or

(D) conceals a material fact on an application; or

(11) a person listed on the application failing to pay the following fees, taxes, and assessments when due:

(A) licensing fees as described in §550.112 [~~§15.112~~] of this chapter (relating to Licensing Fees);

(B) plan review fees as described in §550.113 [~~§15.113~~] of this chapter (relating to Plan Review Fees); or

(C) franchise taxes, if applicable.

(b) HHSC [~~DADS~~] may suspend a license simultaneously with any other enforcement action available to HHSC [~~DADS~~].

(c) HHSC [~~DADS~~] notifies the license holder by personal service, facsimile transmission, or registered or certified mail of its [~~DADS~~] intent to suspend the license, including the facts or conduct alleged to warrant the suspension.

(d) The license holder has an opportunity to show compliance with all requirements of law to retain the license, as provided in §550.1407 [~~§15.1407~~] of this subchapter (relating to Opportunity to Show Compliance). If the license holder requests an opportunity to show compliance, HHSC [~~DADS~~] gives the license holder a written affirmation or reversal of the proposed action.

(e) HHSC [~~DADS~~] notifies the license holder by personal services, facsimile transmission, or by registered or certified mail of its [~~DADS~~] suspension of the center license. The license holder has 20 days after receipt of the notice to request a hearing in accordance with Texas Government Code, Chapter 2001, and the formal hearing procedures in 1 Texas Administrative Code [~~TAC~~] Chapter 357, Subchapter I (relating to Hearings Under the Administrative Procedure Act) and Chapter 110 [~~91~~] of this title (relating to Hearings Under the Administrative Procedure Act). The license suspension takes effect when the deadline for an appeal of the suspension expires, unless the license holder appeals the suspension.

(f) If a license holder appeals, the license remains valid until all administrative appeals are final, unless the license expires without a timely application for renewal submitted to HHSC [~~DADS~~]. The license holder must continue to submit a renewal application in accordance with §550.106 [~~§15.106~~] of this chapter (relating to Renewal License Application Procedures and Issuance) until the action to suspend the license is completed. However, HHSC [~~DADS~~] does not renew the license until it determines the reason for the proposed action no longer exists.

(g) If a license holder appeals, the enforcement action takes effect when all administrative appeals are final and the proposed enforcement action is upheld. If the center wins the appeal, HHSC [~~DADS~~] does not take the proposed action.

(h) If HHSC [~~DADS~~] suspends a license, the suspension remains in effect until HHSC [~~DADS~~] determines that the reason for suspension no longer exists. A suspension may last no longer than the term of the license. HHSC [~~DADS~~] conducts an on-site investigation before making a determination. During the suspension, the license holder must return the license to HHSC [~~DADS~~].

§550.1403. Emergency License Suspension.

(a) HHSC [~~DADS~~] may issue an emergency order to suspend a license, as authorized by THSC Chapter 248A, if HHSC [~~DADS~~] has reasonable cause to believe that the conduct of a license holder creates an immediate danger to a minor served at the center or the public's health and safety.

(1) If HHSC [~~DADS~~] issues an order for emergency suspension of the center's license, HHSC [~~DADS~~] provides immediate notice to the controlling person, administrator, or alternate administrator of the center by personal service, facsimile transmission, or registered or certified mail. The notice includes:

(A) the action taken;

(B) legal grounds for the action;

(C) the procedure governing appeal of the action; and

(D) the effective date of the order.

(2) An order for emergency licensure suspension goes into effect immediately.

(3) On written request of a license holder, HHSC [~~DADS~~] conducts a hearing not earlier than the 10th day, or later than [~~then~~] the 30th day after, the date HHSC [~~DADS~~] receives the hearing request to determine if the emergency suspension should be continued, modified, or rescinded.

(4) The hearing and any appeal are governed by HHSC [~~DADS~~] rules for a contested case hearing and by Texas Government Code, Chapter 2001 [~~, Texas Government Code~~].

(b) If HHSC [~~DADS~~] suspends a license, the suspension remains in effect until HHSC [~~DADS~~] determines that the reason for an emergency licensure suspension no longer exists. An emergency licensure suspension may last no longer than the term of the license. HHSC [~~DADS~~] conducts an inspection of the center before making a determination to recommend cancellation of a suspension. During the suspension, the license holder must return the license to HHSC [~~DADS~~].

§550.1404. License Revocation.

(a) HHSC [~~DADS~~] may revoke a center's license for:

(1) a violation of THSC Chapter 248A or a standard in this chapter committed by the license holder, applicant, or a person listed on the application;

(2) an intentional or negligent act by a center or an employee of a center that HHSC [~~DADS~~] determines significantly affects the health and safety of a minor served at a center;

(3) use of drugs or intoxicating liquors to an extent that affects the license holder's or applicant's professional competence;

(4) a felony conviction, including a finding or verdict of guilty, an admission of guilt, or a plea of nolo contendere, in Texas or another state of any person required by this chapter to undergo a background and criminal history check;

(5) fraudulent acts, including acts relating to Medicaid fraud and obtaining or attempting to obtain a license by fraud or deception committed by any person listed on the application;

(6) license revocation, suspension, or other disciplinary action taken in Texas or another state against the license holder or any person listed in the application;

(7) criteria described in Chapter 560 [~~99~~] of this title (relating to Denial or Refusal of License) that applies to any person required by this chapter to undergo a background and criminal history check;

(8) aiding, abetting, or permitting a violation described in paragraph (1) of this subsection about which a person listed on the application had or should have had knowledge;

(9) a license holder or applicant's failure to provide the required information, facts, or references;

(10) a license holder or applicant who knowingly:

(A) submits false or intentionally misleading statements to HHSC [~~DADS~~] on an application;

(B) uses subterfuge or other evasive means of filing an application;

(C) engages in subterfuge or other evasive means of filing an application on behalf of another who is unqualified for licensure; or

(D) conceals a material fact on an application;

(11) a person listed on the application committing fraud; or

(12) a person listed on the application failing to pay the following fees, taxes, and assessments when due:

(A) licensing fees as described in §550.112 [~~§15.112~~] of this chapter (relating to Licensing Fees);

(B) plan review fees as described in §550.113 [~~§15.113~~] of this chapter (relating to Plan Review Fees); and

(C) franchise taxes, if applicable.

(b) HHSC [~~DADS~~] may revoke a license simultaneously with any other enforcement action available to HHSC [~~DADS~~].

(c) HHSC [~~DADS~~] notifies the license holder by personal service, facsimile transmission, registered or certified mail of its [~~DADS~~] intent to revoke the license, including the facts or conduct alleged to warrant the revocation, and sends a copy to the center. The license holder has an opportunity to show compliance with all requirements of the law to retain the license, as provided in §550.1407 [~~§15.1407~~] of this subchapter (relating to Opportunity to Show Compliance). If the license holder requests an opportunity to show compliance, HHSC [~~DADS~~] gives the license holder a written affirmation or reversal of the proposed action.

(d) HHSC [~~DADS~~] notifies a license holder by personal service, facsimile transmission, or by registered or certified mail of its [~~DADS~~] revocation of the center license and sends a copy to the center. The license holder has 20 days after receipt of the notice to request a hearing in accordance with the HHSC [~~Health and Human Services Commission's~~] formal hearing procedures in 1 Texas Administrative Code [~~TAC~~] Chapter 357, Subchapter I (relating to Hearings Under the Administrative Procedure Act), and HHSC [~~DADS~~] formal hearing procedures in Chapter 110 [~~91~~] of this title (relating to Hearings Under the Administrative Procedure Act). The revocation takes effect when the deadline for appeal of the revocation expires unless the license holder appeals the revocation.

(e) If a license holder appeals, the license remains valid until all appeals are final, unless the license expires without a timely application for renewal submitted to HHSC [~~DADS~~]. The license holder must continue to submit a renewal application in accordance with §550.106 [~~§15.106~~] of this chapter (relating to Renewal Application Procedures and Issuance) until the action to revoke the license is completed. However, HHSC [~~DADS~~] does not renew the license until it determines the reason for the proposed action no longer exists.

(f) If a license holder appeals, the enforcement action takes effect when all appeals are final and the proposed enforcement action is upheld. Upon revocation, the license must be returned to HHSC [~~DADS~~]. If the license holder wins the appeal, HHSC [~~DADS~~] does not take the proposed action.

§550.1405. Probation.

If HHSC [~~DADS~~] finds that a center is in repeated noncompliance with THSC Chapter 248A, this chapter or a plan of correction, but the noncompliance does not endanger a minor served at a center or the public health and safety, HHSC [~~DADS~~] may schedule the center for probation rather than suspending or revoking the center's license.

(1) HHSC [~~DADS~~] provides notice to the license holder of the probation and the items of noncompliance not later than the 10th day before the date the probation period begins.

(2) HHSC [~~DADS~~] designates a period of not less than 30 days during which the center remains on probation. During the probation period, the center must correct the items that were in noncompliance and report the corrections to HHSC [~~DADS~~] for approval.

(3) HHSC [~~DADS~~] may suspend or revoke the license of a center that does not correct items that were in noncompliance or does not comply with THSC Chapter 248A or this chapter within the applicable probation period.

§550.1406. Injunctive Relief or Civil Penalties.

(a) HHSC [~~DADS~~] may petition a district court for a temporary restraining order against a center to restrain a continuing violation

of THSC Chapter 248A or standard in this chapter if HHSC [~~DADS~~] finds that the violation creates an immediate threat to the health and safety of minors served at a center.

(b) A district court, on petition of HHSC [~~DADS~~], and on a finding of the court that a person is violating THSC Chapter 248A or a standard in this chapter, may by injunction:

(1) prohibit the person from continuing the violation;

(2) restrain or prevent the establishment or operation of a center without a license under THSC Chapter 248A; or

(3) grant any other injunctive relief warranted by the facts.

(c) HHSC [~~DADS~~] may request the attorney general to institute and conduct a suit authorized by this section.

(d) HHSC [~~DADS~~] may recover reasonable expenses incurred in obtaining relief under this section, including court costs, reasonable attorney's fees, investigation costs, witness fees, and deposition expenses.

(e) Venue for a suit brought under this section is in the county in which the center is located or in Travis County.

(f) If HHSC [~~DADS~~] determines that a violation of THSC Chapter 248A or a standard in this chapter threatens the health and safety of a minor served at the center, HHSC [~~DADS~~] may seek, against the person who violates THSC Chapter 248A, the requirements in this chapter, or fails to comply with a corrective action plan submitted in accordance with this chapter, a civil penalty of not more than $500 for each violation.

(1) Each day a violation continues constitutes a separate violation for the purpose of this section.

(2) HHSC [~~DADS~~] may request the attorney general to sue to collect the penalty. HHSC [~~DADS~~] may recover reasonable expenses incurred in obtaining relief under this section, including court costs, reasonable attorney fees, investigation costs, witness fees, and deposition expenses.

§550.1407. Opportunity to Show Compliance.

(a) Before revocation or suspension of a center's license or denial of an application for the renewal of a center's license, HHSC [~~DADS~~] gives the license holder:

(1) a notice by personal service, facsimile transmission, or by registered or certified mail of the facts or conduct alleged to warrant the proposed action, with a copy sent to the center; and

(2) an opportunity to show compliance with all requirements of law to retain the license by sending HHSC [~~DADS~~] a written request that [~~. The request~~] must:

(A) be postmarked no later than 10 days after the date of HHSC [~~DADS~~] notice and be received in HHSC [~~DADS~~] office no later than 10 days after the date of the postmark; and

(B) contain specific documentation refuting HHSC [~~DADS~~] allegations.

(b) HHSC [~~DADS~~] limits its review to the documentation submitted by the license holder and information HHSC [~~DADS~~] used as the basis for its proposed action. A license holder or center representative may not attend the [~~DADS~~] meeting to review the opportunity to show compliance documents. HHSC [~~DADS~~] gives a license holder a written affirmation or reversal of the proposed action.

(c) After an opportunity to show compliance, HHSC [~~DADS~~] sends a license holder a written notice that:

(1) informs the license holder of its [~~DADS~~] decision; and

(2) provides the license holder with an opportunity to appeal the [~~DADS~~] decision through a formal hearing process, if HHSC [~~DADS~~] affirms the proposed action.

§550.1408. Administrative Penalties.

(a) The following words and terms, when used in this section, have the following meanings unless the context clearly indicates otherwise.

(1) Actual harm--A negative outcome that compromises a minor's physical, mental, or emotional well-being.

(2) Immediate threat to the health or safety of a minor--A situation that causes, or is likely to cause, serious injury, harm, or impairment to or the death of a minor.

(3) Isolated--A very limited number of minors are affected and a very limited number of staff are involved, or the situation has occurred only occasionally.

(4) Pattern of violation--Repeated, but not widespread in scope, failures of a center to comply with THSC Chapter 248A or a rule, standard, or order adopted under THSC Chapter 248A that:

(A) result in a violation; and

(B) are found throughout the services provided by the center or that affect or involve the same minor or center employees.

(5) Potential for minimal harm--A violation that has the potential for causing no more than a minor negative impact on a minor.

(6) Widespread in scope--A violation that:

(A) is pervasive throughout the services provided by the center; or

(B) represents a systemic failure by the center that affects or has the potential to affect a large portion of or all of the minors of the center.

(b) Assessing penalties. HHSC may assess an administrative penalty against a person who violates:

(1) THSC, Chapter 248A; or

(2) a provision in this chapter for which a penalty may be assessed.

(c) Criteria for assessing penalties. HHSC assesses an administrative penalty based on the scope and severity of a violation in accordance with the table in this section. Within an established range, HHSC determines the amount of an administrative penalty based on the following criteria:

(1) the seriousness of the violation, including the nature, circumstances, extent, and gravity of the violation;

(2) the threat to the health or safety caused by the violation;

(3) any previous violations;

(4) the amount necessary to deter future violations;

(5) efforts made by the violator to correct the violation; and

(6) any other matters that justice may require.

(d) Penalty calculation and assessment. The table in this section sets forth the ranges for administrative penalties that HHSC assesses, based on the scope and severity of a violation. An administrative penalty may not exceed $500 for each violation. Each day a violation continues or occurs is a separate violation for purposes of imposing a penalty.

(e) Schedule of appropriate and graduated penalties.

(f) The penalty range for a Severity Level A violation is $400 - $500 per violation.

(g) A Severity Level A violation is a violation that results in immediate threat to a minor's health or safety.

(h) The penalty range for a Severity Level B violation is $300 - $400 per violation.

(i) A Severity Level B violation is a violation that results in actual harm that is not considered an immediate threat.

(j) The penalty range for a Severity Level C violation is $200 - $300 per violation.

(k) A Severity Level C violation is a violation with no actual harm with potential for more than minimal harm.

(l) The penalty range for a Severity Level D violation is $100 - $200 per violation.

(m) A Severity Level D violation is a violation with no actual harm with potential for minimal harm.
Figure: 26 TAC §550.1408(m)
[~~Figure: 40 TAC §15.1408(m)~~]

(n) Proposal of administrative penalties. If HHSC assesses an administrative penalty, HHSC provides a written notice of violation letter to a center. The notice includes:

(1) a brief summary of the violation;

(2) the amount of the proposed penalty; and

(3) a statement of the center's right to a formal administrative hearing on the occurrence of the violation, the amount of the penalty, or both the occurrence of the violation and the amount of the penalty.

(o) A center may accept the [~~HHSC's~~] determination and recommended penalty not later than 20 days after the date on which the center receives the notice of violation letter, including the proposed penalty, or make a written request for a formal administrative hearing on the occurrence of the violation, the amount of the penalty, or both.

(1) If a center that is notified of a violation accepts the [~~HHSC's~~] determination and recommended penalty or fails to respond to the notice, the executive commissioner or designee issues an order approving the determination and ordering that the center pay the proposed penalty.

(2) If a center that is notified of a violation does not accept the [~~HHSC's~~] determination, the center must submit to HHSC a written request for a formal administrative hearing on the determination and must not pay the proposed penalty. Remittance of the penalty to HHSC is deemed acceptance by the center that the [~~of HHSC's~~] determination is final, and the center waives the center's right to a formal administrative hearing.

(3) If a center requests a formal administrative hearing, the hearing is held in accordance with THSC §248A.255.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on May 29, 2024.

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Karen Ray
Chief Counsel
Health and Human Services Commission
Earliest possible date of adoption: July 14, 2024
For further information, please call: (512) 438-3161

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TITLE 28. INSURANCE

PART 1. TEXAS DEPARTMENT OF INSURANCE

CHAPTER 5. PROPERTY AND CASUALTY INSURANCE

SUBCHAPTER E. TEXAS WINDSTORM INSURANCE ASSOCIATION

DIVISION 4. CONSUMER ASSISTANCE; CLAIM PROCESSES

28 TAC §5.4215, §5.4233

The Texas Department of Insurance (TDI) proposes amendments to 28 TAC Chapter 5, Subchapter E, Division 4, §5.4215 and §5.4233, concerning updates to umpire and mediator roster application forms. The amendments implement Senate Bill 510, 88th Legislature, 2023.

EXPLANATION. SB 510 added Government Code §552.11765, which created new categories of confidential information for state agencies. Section 5.4215 provides requirements for the appraisal umpire roster that TDI maintains for Texas Windstorm Insurance Association (TWIA) claims. That section specifies the information that umpire applicants must provide to register with TDI. Section 5.4233 does the same for the mediator roster. The proposal amends §5.4215 and §5.4233 to add requirements related to applicants' consent to publish confidential information, and to state if umpires are insured by TWIA.

The following paragraphs describe the proposed amendments.

Section 5.4215. Section 5.4215(b) is amended to require the applicant to give consent to have information that might otherwise be confidential published on the umpire roster. In addition, to reflect TDI practice, §5.4215(b) is amended to require applicants to state whether they are insured by TWIA. The umpire application form already asks applicants to state whether they are TWIA policyholders. With this change, the umpire rule will parallel the mediator rule. Section 5.4215(e) is amended to specify that certain information collected from applicants will be published only to the extent the applicant consents.

Section 5.4233. Section 5.4233(b) is amended to require the applicant to give consent to have information that might otherwise be confidential published on the mediator roster. Section 5.4233(e) is amended to specify that certain information collected from applicants will be published only to the extent the applicant consents.

FISCAL NOTE AND LOCAL EMPLOYMENT IMPACT STATEMENT. Marianne Baker, director of Property and Casualty Lines, has determined that during each year of the first five years the proposed amendments are in effect, there will be no measurable fiscal impact on state and local governments as a result of enforcing or administering the amendments, other than that

imposed by the statute. Ms. Baker made this determination because the proposed amendments do not add to or decrease state revenues or expenditures, and because local governments are not involved in enforcing or complying with the proposed amendments.

Ms. Baker does not anticipate any measurable effect on local employment or the local economy as a result of this proposal.

PUBLIC BENEFIT AND COST NOTE. For each year of the first five years the proposed amendments are in effect, Ms. Baker expects that administering the proposed amendments will have the public benefit of ensuring that TDI's rules conform to the confidentiality requirements of Government Code §552.11765.

Ms. Baker does not expect the amendments will result in increased costs to any regulated entities. The amendments implement statutory provisions governing state agency use of information collected as part of a licensing application process and align TDI's rules with current practice.

ECONOMIC IMPACT STATEMENT AND REGULATORY FLEXIBILITY ANALYSIS. TDI has determined that the proposed amendments will not have an adverse economic effect on small or micro businesses, or on rural communities. The amendments do not add or subtract any costs to individuals or businesses; rather, the amendments implement a statute changing the categories of information considered confidential and reflect current TDI practice. As a result, and in accordance with Government Code §2006.002(c), TDI is not required to prepare a regulatory flexibility analysis.

EXAMINATION OF COSTS UNDER GOVERNMENT CODE §2001.0045. TDI has determined that this proposal does not impose a possible cost on regulated persons.

GOVERNMENT GROWTH IMPACT STATEMENT. TDI has determined that for each year of the first five years that the proposed amendments are in effect, the proposed rule:

- will not create or eliminate a government program;

- will not require the creation of new employee positions or the elimination of existing employee positions;

- will not require an increase or decrease in future legislative appropriations to the agency;

- will not require an increase or decrease in fees paid to the agency;

- will not create a new regulation;

- will not expand an existing regulation;

- will not increase or decrease the number of individuals subject to the rule's applicability; and

- will not positively or adversely affect the Texas economy.

TAKINGS IMPACT ASSESSMENT. TDI has determined that no private real property interests are affected by this proposal and that this proposal does not restrict or limit an owner's right to property that would otherwise exist in the absence of government action. As a result, this proposal does not constitute a taking or require a takings impact assessment under Government Code §2007.043.

REQUEST FOR PUBLIC COMMENT. TDI will consider any written comments on the proposal that are received by TDI no later than 5:00 p.m., central time, on July 15, 2024. Send your comments to ChiefClerk@tdi.texas.gov or to the Office of the Chief Clerk, MC: GC-CCO, Texas Department of Insurance, P.O. Box 12030, Austin, Texas 78711-2030.

To request a public hearing on the proposal, submit a request before the end of the comment period to ChiefClerk@tdi.texas.gov or to the Office of the Chief Clerk, MC: GC-CCO, Texas Department of Insurance, P.O. Box 12030, Austin, Texas 78711-2030. The request for public hearing must be separate from any comments and received by the TDI no later than 5:00 p.m., central time, on July 15, 2024. If TDI holds a public hearing, TDI will consider written and oral comments presented at the hearing.

STATUTORY AUTHORITY. TDI proposes amendments to §5.4215 and §5.4233 under Insurance Code §§2210.008, 2210.575, 2210.580 and 36.001.

Insurance Code §2210.008 provides that the commissioner may adopt rules as reasonable and necessary to implement Chapter 2210.

Insurance Code §2210.575 requires the commissioner to establish rules for alternative dispute resolution for disputes concerning denied coverage.

Insurance Code §2210.580 provides that the commissioner must adopt rules regarding the qualifications and selection of appraisers for the appraisal process, and the qualifications and selection of mediators.

Insurance Code §36.001 provides that the commissioner may adopt any rules necessary and appropriate to implement the powers and duties of TDI under the Insurance Code and other laws of this state.

CROSS-REFERENCE TO STATUTE. The revisions to §5.4215 and §5.4233 implement Government Code §552.11765.

§5.4215. Appraisal Process - Umpire Roster.

(a) Eligibility. To be placed on the umpire roster, a person must register with the department and must meet the qualifications in §5.4214 of this title (relating to Appraisal Process - Umpire Qualifications and Conflicts of Interest).

(b) Registration. The registration must include contact information and details about:

(1) the person's training and experience related to building construction, repair, estimating, or investigating property damage;

(2) any training and experience related to estimating property damage claims;

(3) whether the person's experience is with residential or commercial property damage;

(4) any relevant licenses or certifications;

(5) a general description of the approximate number, type of policies, and value and complexity of property damage claims on which the applicant worked over the previous three years;

(6) the counties in which the person is willing to work;

(7) the type of policies, and value and complexity of claims on which the person is willing to work;

(8) potential conflicts of interest, under §5.4214 of this title;

(9) any professional disciplinary actions or criminal convictions; [~~and~~]

(10) whether the umpire is insured by the association;

(11) [~~(10)~~] an up-to-date biography, resume, or curriculum vitae; and[~~.~~]

(12) whether the applicant consents to have information that might otherwise be confidential published on the roster.

(c) Notice. A person is not on the umpire roster until the department sends written notice of placement on the roster.

(d) Limited number. The department may limit the number of umpires on the roster.

(e) Publication. The department will publish the umpire roster on the department's website. Published roster information will include an umpire's name, and, to the extent that the applicant consents, contact information, required qualifications, preferred types of claims, and preferred geographic areas.

(f) Disqualifying conflicts. The umpire must notify the department of a disqualifying conflict of interest under §5.4214 of this title within 10 days of learning about the conflict.

(g) Term. An umpire will be on the umpire roster for a term of three years, except as provided under §5.4216 of this title (relating to Appraisal Process - Removal of Umpire from Roster). To remain on the roster for additional terms, an umpire must submit a new registration to the department.

(h) Submissions. Notices and registrations sent to the department under this section must comply with §5.4251 of this title (relating to Requests and Submissions to the Department).

§5.4233. Mediation Process - Mediator Roster.

(a) Eligibility. To be placed on the mediator roster, a mediator must register with the department and must meet the qualifications in §5.4232 of this title (relating to Mediation Process - Mediator Qualifications and Conflicts of Interest).

(b) Registration. The registration must include contact information and details about:

(1) the mediator's mediation training;

(2) any mediation certification;

(3) any other relevant licenses or certifications;

(4) any training or experience relating to property damage claims;

(5) a general description of the approximate number, value, complexity, and nature of disputes mediated over the previous three years;

(6) the counties in which the mediator is willing to mediate;

(7) the types of policies, and value and complexity of claims the mediator is willing to mediate;

(8) potential conflicts of interest, under §5.4232 of this title;

(9) any professional disciplinary actions or criminal convictions;

(10) whether the mediator is insured by the association; [~~and~~]

(11) an up-to-date biography, resume, or curriculum vitae; and

(12) whether the applicant consents to have information that might otherwise be confidential published on the roster.

(c) Notice. A person is not on the mediator roster until the department sends written notice of placement on the roster.

(d) Limited number. The department may limit the number of mediators on the roster.

(e) Publication. The department will publish the mediator roster on the department's website. Published roster information will include a mediator's name, and, to the extent that the applicant consents, contact information, required qualifications, preferred types of claims, and preferred geographic areas.

(f) Disqualifying conflicts. The mediator must notify the department of a disqualifying conflict of interest, under §5.4232 of this title.

(g) Term. A mediator will be on the mediator roster for a term of three years, except as provided under §5.4234 of this title (relating to Mediation Process - Removal of Mediator from Roster). To remain on the roster for additional terms, a mediator must submit a new registration to the department.

(h) Submissions. Notices and registrations under this section must comply with §5.4251 of this title (relating to Requests and Submissions to the Department).

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on May 24, 2024.

TRD-202402352
Jessica Barta
General Counsel
Texas Department of Insurance
Earliest possible date of adoption: July 14, 2024
For further information, please call: (512) 676-6555

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TITLE 31. NATURAL RESOURCES AND CONSERVATION

PART 4. SCHOOL LAND BOARD

CHAPTER 155. LAND RESOURCES

SUBCHAPTER A. COASTAL PUBLIC LANDS

31 TAC §155.15

The School Land Board (Board) proposes amendments to 31 Texas Administrative Code (TAC) §155.15 relating to rent and fees for residential, commercial, and industrial activities on coastal public lands. The proposed amendments include changes to the text of §155.15 and to the related graphics in §§155.15(b)(1)(C)(i), 155.15(b)(1)(C)(ii), 155.15(b)(1)(C)(iii), and 155.15(b)(1)(C)(iv).

BACKGROUND AND ANALYSIS OF PROPOSED AMENDMENTS

In accordance with the Texas Natural Resources Code (TNRC) Chapter 33, the Board may execute grants of easements for rights-of-way across, through, and under unsold Permanent School Fund (PSF) land, the portion of the Gulf of Mexico within the jurisdiction of the state, the state-owned riverbeds and beds of navigable streams in the public domain, and all islands, saltwater lakes, bays, inlets, marshes, and reefs owned by

the state within tidewater limits. TNRC §33.103 authorizes the Board to grant interests in coastal public land, including leases, easements, permits, and other interests for public purposes and easements connected with littoral ownership and cabin permits. The leases and easements are for structures such as breakwaters, jetties, and piers, as well as for open encumbrances, dredging, and fill placement.

Currently, the rent and fees for many coastal easements and leases issued by the Board are tied to the appraised market value of the adjacent littoral property. Recently, market values have increased at an unprecedented rate, resulting in rate increases that are unreasonable and often inconsistent with market conditions. The Board is proposing this rulemaking due to the rapid increase in real estate appraised values during the past five years. The amended rule will ensure that rent and fees on the coast are reasonable and more accurately reflect market value. In addition, some residential rent and fee rates are being revised in consideration of the environmental benefits of certain structures.

Rent and fees for residential coastal easements and leases are set based on the specifications in the graphics attached to 31 TAC §155.15 in §§155.15(b)(1)(C)(i), 155.15(b)(1)(C)(ii), and 155.15(b)(1)(C)(iii). The Board is proposing to decrease the annual rent for breakwaters, jetties, and groins from 20 cents per square foot to 3 cents per square foot. The rent decrease is proposed in consideration of the benefit these structures provide in the coastal environment, including the creation of habitat for small fish, crabs, and other animals. They also provide a hard substrate for oysters, barnacles, mussels, and other sessile animals. In addition, when breakwaters are a component of a living shoreline, which is an alternative to traditional shoreline armoring that incorporates nature-based features, no rent is assessed. Reducing the rents for all breakwaters is appropriate since they serve similar environmentally beneficial functions even if they are not part of a living shoreline. In addition, reducing rent may encourage more of these structures, adding environmental protection and coastal resiliency, eventually increasing revenue to the PSF.

The Board is also proposing an adjustment to the fees for fill for residential use to address the recent unreasonably high rates caused by the rising assessed value of adjacent littoral property. The proposed amendment would result in residential fill fees of either $0.10 per square foot, or an amount based on the fill formula, whichever is greater, as the baseline for annual rent, not to exceed $1.00 per square foot. Annual rent below $1.00 per square foot will escalate in accordance with the terms currently in the rule, not to exceed $1.00 per square foot. This rate also aligns with the proposed new rate for commercial fill, which will start at a $1.00 per square foot and increase based on the Consumer Price Index for All Urban Consumers (CPI-U). In addition, the phrase "no minimum rent" is being changed to "no rent" for clarity in all of the graphics.

The Board is also proposing changes to the Commercial and Industrial Activity rent and fees graphic that include the elimination of the basin formula, which ties rental fees to the assessed value of the adjacent littoral property. In its place, the Board is proposing a component formula, which charges a separate rental fee to each component of the leased premises, standardizing the fees for most commercial leases and mitigating the impact of rising property values.

In addition, the Board is proposing an amendment that would require an update to the published fee schedule every five years. The fee schedule update would be based on the Consumer Price Index for All Urban Consumers (CPI-U). Rent and fees for Commercial and Industrial Activity will be based on the updated fee schedule in effect at the time of the execution of a new agreement or a renewal. The proposed changes will result in reduced revenue for the Permanent School Fund (PSF) initially; however, updating the fee schedule based on the CPI-U every five years ensures fees will adjust to inflation over time, stabilizing and potentially increasing long-term revenue. Standardizing fee calculations and aligning them with market conditions also attracts consistent lessees, enhancing occupancy rates and lease income. The lower initial rent benefits the public by making coastal commercial leases more affordable, promoting economic activity and job creation, and supporting local economies. Eliminating the basin formula and standardizing fee structures makes the rent and fees for commercial industries more predictable and transparent.

Other proposed adjustments aim to ensure consistent rates across all coastal commercial leases. These include the removal of the Submerged Land Discount, which is linked to the Basin Formula, setting a uniform fill rate at $1.00 per square foot, and decreasing the fee for Clear Lake Marina from $4.00 to $3.00 per linear foot of boatslip to align with the rates charged in other coastal counties. The proposal standardizes fee structures across different uses of submerged lands and aligns them with market conditions and regulatory standards, thereby ensuring consistent, predictable, and transparent pricing for coastal commercial leases.

The graphic attached to 31 TAC §155.15(b)(1)(C)(iv) lists the fees for commercial and industrial activity. The proposed amended graphic has been edited with the above changes and also to reflect a previously implemented rate increase from $0.20 per square foot to $0.32 per square foot of proposed fill. This increase was approved in 2022 but was inadvertently omitted from the graphic due to a scrivener's error. Footnote 3 is also being updated to remove language about whether existing fill was placed under the authority of a permit since it is no longer applicable. The phrase "no minimum rent" is being changed to "no rent" for clarity in all of the attached graphics. The rule is also being revised to make the text consistent with the amendments to the rent and fees graphics and to make minor administrative, non-substantive edits to the text of the rule.

FISCAL AND EMPLOYMENT IMPACTS

The Board has determined that during the first five-year period the proposed amended rule is in effect, there will be no negative fiscal implications for state or local government as a result of enforcing or administering the amended section. The Board has also determined that during the first five-year period the proposed amended rule is in effect, there will be decreased economic costs to businesses that execute a new coastal lease or easement renew an existing lease or easement since the adjacent land value will no longer be used as a factor in the rent calculation. The Board has determined that the proposed rulemaking will have no adverse local employment impact that requires an impact statement pursuant to Texas Government Code §2001.022.

PUBLIC BENEFIT

The Board has determined that the public will benefit from the proposed amendments because the new rental rates will no longer be tied to surging market values for coastal land,

which increased rent considerably. With continued development on the coast, the number of coastal projects continues to increase, thus increasing overall revenue for the PSF even with the lower rent and fees. The proposed changes will result in reduced revenue for the PSF initially; however, updating the fee schedule based on the CPI-U every five years ensures fees will adjust to inflation over time, stabilizing and potentially increasing long-term revenue. The lower initial rent benefits the public by making coastal commercial leases more affordable, promoting economic activity, job creation, and supporting local economies. Although rent and fees are also being lowered for some residential structures, the Board anticipates that the number of these environmentally beneficial structures will increase. The revenue from coastal rent and fees is deposited into the Permanent School Fund, which ultimately benefits kindergarten through 12th grade school children in Texas.

ENVIRONMENTAL REGULATORY ANALYSIS

The Board has evaluated the proposed rulemaking action in light of the regulatory analysis requirements of Texas Government Code §2001.0225 and determined that the action is not subject to §2001.0225 because it does not meet the definition of a "major environmental rule" as defined in the statute. "Major environmental rule" means a rule, the specific intent of which is to protect the environment or reduce risks to human health from environmental exposure and that may adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, or the public health and safety of the state or a sector of the state. The proposed amendments are not anticipated to adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, or the public health and safety of the state or a sector of the state.

GOVERNMENT GROWTH IMPACT STATEMENT

The Board prepared a Government Growth Impact Statement assessment for this proposed rulemaking. The proposed rulemaking does not create or eliminate a government program; implementation of the proposed rule will not require the creation of new employee positions or the elimination of existing employee positions; implementation of the proposed rule does not require an increase or decrease in future legislative appropriations to the agency and will not create a new regulation; the proposed rule will not expand, limit, or repeal an existing regulation; the proposed rule will not increase or decrease the number of individuals subject to the rule's applicability; and the proposed rule will not positively or adversely affect this state's economy. The proposed rule will result in a decrease in fees paid per lease or easement to the agency during the first five years the rule is in effect. During the first five years that the proposed rules would be in effect it is not anticipated that there will be an adverse impact on the state's economy. The Board anticipates that any potential decreased revenue will be offset by regular, structured increases in the base component rates.

TAKINGS IMPACT ASSESSMENT

The Board has evaluated the proposed rulemaking in accordance with Texas Government Code §2007.043(b) and §2.18 of the Attorney General's Private Real Property Rights Preservation Act Guidelines to determine whether a detailed takings impact assessment is required. GLO has determined that the proposed rulemaking does not affect private real property in a manner that requires real property owners to be compensated as provided by the Fifth and Fourteenth Amendments to the United States Constitution or Article I, §17 and §19 of the Texas Constitution. Furthermore, the Board has determined that the proposed rulemaking would not affect any private real property in a manner that restricts or limits the owner's right to the property that would otherwise exist in the absence of the rule amendment.

CONSISTENCY WITH COASTAL MANAGEMENT PROGRAM (CMP)

The proposed rulemaking is subject to the CMP, 31 TAC §29.11(a)(1) and §29.11(c), relating to the Actions and Rules subject to the CMP. The Board has reviewed these proposed actions for consistency with the CMP goals and policies. Because all requests for the use of coastal public land must continue to meet the same criteria for Board approval, the Board has determined that the proposed actions are consistent with applicable CMP goals and policies.

PUBLIC COMMENT REQUEST

Comments may be submitted to Walter Talley, Office of General Counsel, Texas General Land Office, 1700 N. Congress Avenue, Austin, Texas 78701, or by email to walter.talley@glo.texas.gov, by no later than 30 days after publication.

STATUTORY AUTHORITY

The amendments to 31 TAC, Part 4, Chapter 155, Subchapter A, §155.15 are proposed under the TNRC §33.063 relating to the Board's authority to charge fees for leases, easements, permits, and other interests in or rights to use coastal public land, and §33.064 providing that the Board may adopt rules necessary to carry out the provisions of Chapter 33, Texas Natural Resources Code. TNRC §§33.101-33.136 are affected by the proposed amendments.

The proposed amendments affect no other code, article, or statute.

§155.15. Fees.

(a) General.

(1) Form of payment. Fees may be paid by cash, check or other legal means acceptable to the commissioner.

(2) Time for payment. Payment is generally required in advance of issuance of easements, permits, leases and other documents and/or delivery of services and/or materials by the General Land Office (GLO).

(3) Dishonor or nonpayment by other means. In the event a fee is not paid due to dishonor, nonpayment, or otherwise, the GLO shall have no further obligation to issue easements, permits, leases and other documents and/or provide services and/or materials to the grantee, permittee, lessee, or applicant.

(b) Board fees and charges. The board is authorized and required under the Texas Natural Resources Code, Chapter 33, to collect the fees and charges set forth in this subsection where applicable. The board will charge the following coastal lease and coastal easement fees for use of coastal public land, and will charge the following structure registration and permit fees. The board charge will be based on either the fixed fee schedule or the alternate commercial, industrial, residential, and published [~~public~~] formulas as delineated in paragraph (1)(C) of this subsection. The greater of the fixed fee or formula rate will be charged [~~except in the calculation of fees for residential use, Category II and residential use, Category III, where only the fixed rate method will be used~~]. The board may adopt an escalation schedule that will allow for escalation of annual fees based on the term of a coastal lease or coastal easement.

(1) Rental and Fees

(A) Structure registration. Structure registration fee is required for private piers or docks that are 115 feet long or less and 25 feet wide or less and require no dredging or filling, as authorized by the Texas Natural Resources Code, §33.115. Though board approval is not required for construction, the applicant must register the location of the structure. The registration is valid for the life of the structure.

(i) application fee: $25 (per occurrence for new, amendment and assignment applications).

(ii) annual rent: none.

(B) Coastal lease. The board may grant coastal leases for public purposes as prescribed by the Texas Natural Resources Code, §§33.103(1), 33.105 and 33.109. The application fee and annual rent shall be negotiable.

(C) The following tables list the rental fees for easements and permits on coastal public land.

(i) Residential Use, Category I.
Figure: 31 TAC §155.15(b)(1)(C)(i)
[~~Figure: 31 TAC §155.15(b)(1)(C)(i)~~]

(ii) Residential Use, Category II.
Figure: 31 TAC §155.15(b)(1)(C)(ii)
[~~Figure: 31 TAC §155.15(b)(1)(C)(ii)~~]

(iii) Residential Use, Category III.
Figure: 31 TAC §155.15(b)(1)(C)(iii)
[~~Figure: 31 TAC §155.15(b)(1)(C)(iii)~~]

(iv) Commercial and Industrial Activity.
Figure: 31 TAC §155.15(b)(1)(C)(iv)
[~~Figure: 31 TAC §155.15(b)(1)(C)(iv)~~]

(v) Structure (Cabin) Permits.
Figure: 31 TAC §155.15(b)(1)(C)(v) (No change.)

(2) Senior Rent Freeze. Upon application to the GLO and submission of proof of age by a grantee, fees for coastal easements associated with a single family residence will not be increased after the point in time when the littoral property owner (one person in the case of joint ownership) reaches the age of 65, unless the area of encumbered state land increases or there is a change in use of the coastal public land.

(3) Resource Impact Fee.

(A) Public use projects and Residential Use, Category I projects constructed within guidelines: exempt.

(B) All others: $100 plus $1.00 per square foot of impacted area.

(4) New Dredge Rent. A one time rental fee due upon completion of the initial dredging for a new project. The board may consider reduced new dredge rent on a case by case basis when the material is used for habitat creation, restoration, and enhancement projects, or when it is in the public interest to do so.

(5) Term. The term for all coastal leases and coastal easements is negotiable. Board approval is required prior to construction.

(6) Rental adjustments--all commercial and industrial easements. At every five-year interval in the term of commercial and industrial easements, the rental fee for the easement will be subject to adjustment. The adjustment, if any, will be in accordance with the then current Fee Schedule as adopted by the board.

(7) Implementation.

(A) New residential developments. Upon the application for an easement associated with the development of a multi-unit or single-family residential project, the easement application will be processed and fee determined according to the appropriate commercial activity rate. Upon the sale of an individual residential unit associated with the easement, with sufficient infrastructure in place to convert use of the unit to individual use (and use of associated easement to private activity), the original easement applicant, upon agreement with the commissioner of the GLO, may pay a $50 conversion fee. The easement fee may then be reduced by the percentage that the sold unit represented to the total number of units associated with the easement. At the time the conversion fee is paid under the provisions herein, the unit will then be considered to be subject to the residential activity rates upon renewal of the easement. For units already sold prior to the effective date of this section, conversion to a residential activity rate will be granted without the payment of the conversion fee.

(B) Additional terms. The commissioner of the GLO may require, as a condition for the granting of an easement set forth in this section, such additional terms that he feels are necessary to secure performance under any such easement.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on June 3, 2024.

TRD-202402450
Mark Havens
Chief Clerk
School Land Board
Earliest possible date of adoption: July 14, 2024
For further information, please call: (512) 475-1859

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TITLE 34. PUBLIC FINANCE

PART 3. TEACHER RETIREMENT SYSTEM OF TEXAS

CHAPTER 51. GENERAL ADMINISTRATION

34 TAC §51.2

The Teacher Retirement System of Texas (TRS) proposes to repeal §51.2 (relating to Vendor Protests, Dispute Resolutions, and Hearings) under Chapter 51 in Part 3 of Title 34 of the Texas Administrative Code. This repeal is proposed in conjunction with the proposed new §51.2 (relating to Vendor Protests and Appeals) under Chapter 51 published elsewhere in this issue of the *Texas Register.*

BACKGROUND AND PURPOSE

TRS proposes to repeal §51.2 in order to replace it with updates to TRS' vendor protest and appeal procedures to align with TRS' procurement and contracting processes and to make the process more efficient and streamlined. For the same purpose, TRS is proposing a new §51.2 elsewhere in this issue of the *Texas Register.* The proposed new §51.2 removes obsolete requirements or makes other substantive changes for purposes of efficiency and timeliness. The proposed new §51.2 effectively incorporates many of the substantive requirements of the proposed repealed rule but makes formatting and stylistic changes to those provisions for readability purposes. A complete descrip-

tion of these changes can be found in the preamble to the proposed new §51.2.

TRS has determined that the proposed repealed rule, if adopted, shall become effective on the same date that the proposed new §51.2 becomes effective.

FISCAL NOTE

Don Green, TRS Chief Financial Officer, has determined that for each year of the first five years the proposed repealed rule will be in effect, there will be no foreseeable fiscal implications for state or local governments as a result of the proposed repealed rule.

PUBLIC COST/BENEFIT

For each year of the first five years the proposed repealed §51.2 will be in effect, Mr. Green also has determined that the public benefit anticipated as a result of adopting the proposed repeal of §51.2 will be to streamline and clarify provisions relating to the general administration of the TRS' procurement and contracting processes.

Mr. Green has also determined that the public will incur no new costs as a result of the proposed repealed rule.

ECONOMIC IMPACT STATEMENT AND REGULATORY FLEXIBILITY ANALYSIS

TRS has determined that there will be no adverse economic effect on small businesses, micro-businesses, or rural communities as a result of the proposed repealed rule. Therefore, neither an economic impact statement nor a regulatory flexibility analysis is required under Government Code §2006.002.

LOCAL EMPLOYMENT IMPACT STATEMENT

TRS has determined that there will be no effect on local employment because of the proposed repealed rule. Therefore, no local employment impact statement is required under Government Code §2001.022.

GOVERNMENT GROWTH IMPACT STATEMENT

TRS has determined that for the first five years the proposed repealed rule is in effect, the proposed repealed rule will not create or eliminate any TRS programs; will not require the creation or elimination of employee positions; will not require an increase or decrease in future legislative appropriations to TRS; will not eliminate any fees currently paid to TRS; will not create a new regulation; will not expand or limit an existing regulation; will not increase or decrease the number of individuals subject to the rule's applicability; and will not affect the state's economy.

The proposed repealed rule will repeal one existing rule for the reasons stated above in this preamble.

TAKINGS IMPACT ASSESSMENT

TRS has determined that there are no private real property interests affected by the proposed repealed rule, therefore, a takings impact assessment is not required under Government Code §2007.043.

COSTS TO REGULATED PERSONS

TRS has determined that Government Code §2001.0045 does not apply to the proposed repealed rule because the proposed repealed rule does not impose a cost on regulated persons.

COMMENTS

Comments may be submitted in writing to Brian Guthrie, TRS Executive Director, 1000 Red River Street, Austin, Texas 78701-2698. Written comments must be received by TRS no later than 30 days after publication of this notice in the *Texas Register.*

STATUTORY AUTHORITY

The proposed repealed rule is proposed under the authority of Government Code §825.102, which authorizes the board of trustees to adopt rules for the transaction of the business of the board.

CROSS-REFERENCE TO STATUTE

The proposed repealed rule affects the following section: Government Code §825.103(d) relating to TRS' purchase of goods and services.

§51.2. Vendor Protests, Dispute Resolution, and Hearing.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on May 31, 2024.

TRD-202402435
Don Green
Chief Financial Officer
Teacher Retirement System of Texas
Earliest possible date of adoption: July 14, 2024
For further information, please call: (512) 542-6238

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34 TAC §51.2

The Teacher Retirement System of Texas (TRS) proposes new §51.2 (relating to Vendor Protests and Appeals) of Chapter 51 in Part 3 of Title 34 of the Texas Administrative Code. This new rule is proposed in conjunction with the proposed repeal of current §51.2 (relating to Vendor Protests, Dispute Resolution, and Appeal) in Part 3 of Title 34 of the Texas Administrative Code as published elsewhere in this issue of the *Texas Register.*

BACKGROUND AND PURPOSE

TRS proposes one new rule relating to vendor protests and appeals of TRS' procurements. The proposed new rule is consistent with TRS' efforts to update, streamline, and clarify its vendor protest process. For the same purpose, TRS is also proposing to repeal current §51.2 elsewhere in this issue of the *Texas Register.* The proposed new rule removes obsolete requirements or makes other changes for the purpose of efficiency and clarity. The proposed new rule effectively incorporates many of the substantive requirements of the proposed repealed rule but makes formatting and stylistic changes to those provisions for readability purposes.

SECTION-BY-SECTION SUMMARY

Proposed New §51.2 revises the title of current rule §51.2 from Vendor Protests, Dispute Resolution, and Hearing to Vendor Protests and Appeals.

Proposed New §51.2 adds headings to each subsection to improve readability.

Proposed New §51.2(a) adds a definition section that is not included in current §51.2.

Proposed New §51.2(b) incorporates the existing provisions of current §51.2(a), regarding the purpose of the proposed new rule.

Proposed New §51.2(c) incorporates the existing provisions of current §51.2 regarding exceptions, separates its content into subparagraphs to improve readability, and under §51.2(c)(1)(D), confirms that transactions in which TRS buys or sells securities are excluded from the vendor protest process as well as any other transactions not subject to state purchasing rules.

Proposed New §51.2(d) largely incorporates the existing provisions of current §51.2(j) and adds guidance regarding the process of submitting a stay request to TRS.

Proposed New §51.2(e) largely incorporates the existing provisions of current §51.2(b) regarding the filing of a protest. In addition, Proposed New §51.2(e)(1) substitutes TRS Legal & Compliance for the chief officer of the TRS business unit for whom the procurement is being made, as the recipient of a vendor protest and clarifies the deadline for filing a protest. Under current §51.2(b), to be considered timely, a protesting party must file its protest "within 10 working days after the protestor knows or should have known, of the occurrence of the action which is protested." New §51.2(e)(2) provides that a protest contesting (1) the solicitation be filed by the end of posted solicitation period or (2) the evaluation or award be filed within 10 calendar days after the notice of contract award is posted either to the ESBD, or the TRS website, which may be accessed at https://www.trs.texas.gov as applicable. In addition, proposed new §51.2(e)(3) revises the required content of a protest to also include the specific identification of the TRS regulatory policy or the TRS Procurement and Contract Guide section, or both, that TRS is alleged to have violated. Finally, under new §51.2(e)(3)(F) the protesting party must also provide a precise statement of the remedy requested.

Proposed New §51.2(f) largely restates current §51.2(d) and (e) regarding the chief officer's disposition of a protest. Proposed New §51.2(f)(1) adds that TRS L&C will be responsible for the management of the protest, in coordination with the appropriate TRS chief officer, with support provided by the TRS Director of Procurement and Contracting.

Proposed New §51.2(g) largely incorporates the existing provisions of current §51.2(f) regarding the filing of an appeal. Proposed New Rule §51.2(g)(1) revises current §51.2(b) by requiring that an appeal be filed in accordance with the instructions stated in the solicitation document or on the TRS website, which may be accessed at https://www.trs.texas.gov/, as applicable, rather than by submitting the appeal to the executive director or his designee.

FISCAL NOTE

Don Green, TRS Chief Financial Officer, has determined that for each year of the first five years the proposed new rule will be in effect, there will be no foreseeable fiscal implications for state or local governments as a result of administering the proposed new rule.

PUBLIC COST/BENEFIT

For each year of the first five years proposed new §51.2 will be in effect, Mr. Green also has determined that the public benefit anticipated as a result of adopting the proposed new rule and repealing current §51.2 will be to streamline and clarify provisions relating to the general administration of the TRS' procurement and contracting processes.

Mr. Green has also determined that the public will incur no new costs as a result of complying with the proposed new rule.

ECONOMIC IMPACT STATEMENT AND REGULATORY FLEXIBILITY ANALYSIS

TRS has determined that there will be no adverse economic effect on small businesses, micro-businesses, or rural communities as a result of the proposed new rules. Therefore, neither an economic impact statement nor a regulatory flexibility analysis is required under Government Code §2006.002.

LOCAL EMPLOYMENT IMPACT STATEMENT

TRS has determined that there will be no effect on local employment because of the proposed new rule. Therefore, no local employment impact statement is required under Government Code §2001.022.

GOVERNMENT GROWTH IMPACT STATEMENT

TRS has determined that for the first five years the proposed new rule is in effect, the proposed new rule will not create or eliminate any TRS programs; will not require the creation or elimination of employee positions; will not require an increase or decrease in future legislative appropriations to TRS; will not eliminate any fees currently paid to TRS; will not expand, limit or repeal an existing regulation; will not increase or decrease the number of individuals subject to the rule's applicability; and will not affect the state's economy.

The proposed new rule will add one new rule for the reasons stated above in this preamble.

TAKINGS IMPACT ASSESSMENT

TRS has determined that there are no private real property interests affected by the proposed new rule, therefore, a takings impact assessment is not required under Government Code §2007.043.

COSTS TO REGULATED PERSONS

TRS has determined that Government Code §2001.0045 does not apply to the proposed new rule because the proposed new rule does not impose a cost on regulated persons.

COMMENTS

Comments may be submitted in writing to Brian Guthrie, TRS Executive Director, 1000 Red River Street, Austin, Texas 78701-2698. Written comments must be received by TRS no later than 30 days after publication of this notice in the *Texas Register.*

STATUTORY AUTHORITY

The new rule is proposed under the authority of Government Code §825.102, which authorizes the board of trustees to adopt rules for the transaction of the business of the board.

CROSS-REFERENCE TO STATUTE

The proposed new rule affects the following Government Code §825.103(d) relating to TRS' purchase of goods and services.

§51.2. Vendor Protests and Appeals.

(a) Definitions. The following words and terms, when used in this rule, shall have the following meanings unless the context clearly indicates otherwise.

(1) Appeal: A written appeal of the Determination of the Chief Officer.

(2) Appealing Party: A party who files an Appeal to the Determination.

(3) Chief Officer: the head of any business unit of TRS.

(4) Determination: A determination issued by the Chief Officer in response to a Protest.

(5) Director of Procurement & Contracts (P&C Director): The head of the TRS division responsible for overseeing the procurement of goods and services.

(6) Executive Director: Appointed by the TRS Board of Trustees pursuant to Government Code §825.202.

(7) Final Decision: A decision issued by the Executive Director in response to an Appeal.

(8) Interested Parties: Vendors who submitted a bid, offer, or proposal, as applicable, in response to the subject procurement.

(9) Protest: A process initiated in accordance with this rule by a Vendor who believes they have been aggrieved in connection with a solicitation, evaluation, or award of a contract.

(10) Protesting Party: A party who files a Protest.

(11) Solicitation Documents: All documents (including Invitation for Bids, Request for Offers, Request for Proposals, and Request for Qualifications) requesting responses from Vendors to provide specified goods or services, or both. Solicitation Documents also include any addenda posted by TRS to the Electronic State Business Daily (ESBD) or the TRS website, which may be accessed at https://www.trs.texas.gov/, as applicable, for the subject procurement.

(12) TRS Legal & Compliance (TRS L&C): The TRS legal and compliance division.

(13) TRS Legal Counsel: The TRS General Counsel or any attorney designated by TRS General Counsel.

(14) Vendor: An individual, company, partnership, corporation, or other entity that has filed a response to a TRS solicitation.

(b) Purpose. The purpose of this rule is to provide a procedure for a Vendor to Protest or Appeal, if applicable, the process by which TRS purchases goods, services, or both.

(c) Exceptions.

(1) This section does not apply to protests of purchases made by:

(A) the Texas Facilities Commission (Facilities Commission) on behalf of TRS, which are addressed in 1 Texas Administrative Code Chapter 111, Subchapter C (relating to Complaints and Dispute Resolution);

(B) the Department of Information Resources (DIR) on behalf of TRS, which are addressed in 1 Texas Administrative Code Chapter 201, §201.1 (relating to Procedures for Vendor Protests and the Negotiation and Mediation of Certain Contract Disputes and Bid Submission, Opening and Tabulation Procedures);

(C) the Comptroller of Public Accounts (Comptroller's Office) on behalf of TRS, which are addressed in 34 Texas Administrative Code Chapter 20, Subchapter F, Division 3 (relating to Protests and Appeals); or

(D) TRS, for transactions in which TRS buys or sells securities (whether publicly traded or privately issued) under the authority of Government Code §825.302, as well as any other transactions not subject to state purchasing rules.

(2) The rules of the Facilities Commission, DIR, and the Comptroller's Office may be accessed through the website of the Office of the Secretary of State, Texas Register Division located at: www.sos.state.tx.us/tac/index.shtml.

(d) Stay of Protest or Appeal. If a timely Protest or Appeal is filed, the Protesting Party or the Appealing Party may request in writing that TRS not proceed further with the solicitation or with the award of the contract. In support of the request, the Protesting Party or Appealing Party is required to show why a stay is necessary and that harm to TRS will not result from the stay. If the Executive Director determines that it is in the interest of TRS not to proceed with the solicitation or contract award, the Executive Director may make such a decision in writing and partially or fully suspend procurement or contract activity. Any request for a stay must be submitted in accordance with the requirements stated in the Solicitation Document (relating to Vendor Protests and Appeals) or on the TRS website, may be accessed at https://www.trs.texas.gov/., as applicable.

(e) Protest Procedures.

(1) A Vendor who believes they have been aggrieved in connection with a solicitation, evaluation, or award of a contract may formally Protest to TRS. Such Protest must be in writing and timely received by TRS L&C in accordance with the instructions provided in the Solicitation Document or on the TRS website, which may be accessed at https://www.trs.texas.gov/., as applicable. Copies of the Protest must be concurrently mailed or delivered by the Protesting Party to all other Interested Parties.

(2) To be considered timely, the Protest must be filed:

(A) by the end of the posted solicitation period, if the Protest concerns the Solicitation Documents or actions associated with the publication of the Solicitation Documents; or

(B) no later than 10 calendar days after the notice of contract award is posted to either the ESBD or the TRS website, which may be accessed at https://www.trs.texas.gov/, as applicable, if the Protest concerns the evaluation or award. Notice of Awards posted to the TRS website may be accessed at https://www.trs.texas.gov/.

(3) A formal Protest must be sworn and contain:

(A) a specific identification of the State of Texas statutory provision(s), TRS policy, or TRS Procurement and Contract Management Guide (Guide) requirement that the action complained of is alleged to have violated;

(B) a specific description of each act alleged to have violated a State of Texas statutory provision(s), TRS regulatory policy, or Guide requirement;

(C) a precise statement of the relevant facts;

(D) an identification of the issue or issues to be resolved;

(E) argument and authorities in support of the Protest;

(F) a precise statement of the remedy requested by the Protesting Party; and

(G) a statement that copies of the Protest have been mailed or delivered to all other Interested Parties. Upon request, TRS will provide the Protesting Party with a list of Interested Parties as reflected in TRS records.

(f) Review and Disposition of Protests.

(1) TRS L&C will be responsible for management of the Protest and will coordinate TRS' disposition of the Protest with the Chief Officer, with support provided by the P&C Director.

(2) The Chief Officer may:

(A) dismiss the Protest if the Chief Officer determines the Protest was not timely filed or does not meet the requirements of subsection (d) of this section; or

(B) settle and resolve a timely Protest by mutual agreement of TRS and the Protesting Party.

(3) If the Chief Officer does not dismiss or resolve the Protest, the Chief Officer may, in his or her sole discretion, solicit written responses to the Protest from other Interested Parties.

(4) If the Protest is not dismissed or resolved under paragraph (2) of this subsection, the Chief Officer will issue to the Protesting Party and other Interested Parties a written Determination as to whether a violation of State of Texas statutes, TRS regulatory policies, or Guide requirements has occurred.

(5) The Determination will set forth the reasons for the Determination, and any appropriate remedial action, if applicable. Such remedial action, if applicable, may include, but is not limited to, declaring the procurement void; reversing the award and awarding the contract to a different Interested Party; or re-advertising the procurement.

(g) Appeal of Protest.

(1) The Protesting Party or an Interested Party may Appeal the Determination to the Executive Director. The written Appeal must be received in accordance with the requirements stated in the Solicitation Document or on the TRS website, which may be accessed at https://www.trs.texas.gov, as applicable, no later than ten working days after the date of the Determination. The Appeal is limited to a review of the Determination.

(2) The Appealing Party must concurrently mail or deliver copies of the Appeal to all other Interested Parties and must include an affidavit that such copies have been provided.

(3) TRS L&C shall review the Protest, the Determination, and the Appeal and prepare a written opinion with a recommendation to the Executive Director. The Executive Director may, in his or her discretion, refer the matter to the Board of Trustees at a regularly scheduled open meeting or issue in writing a Final Decision.

(4) When a Protest has been appealed to the Executive Director under paragraph (1) of this subsection and has been referred to the Board of Trustees by the Executive Director under paragraph (3) of this subsection, the following requirements shall apply:

(A) Copies of the Appeal, responses of Interested Parties, if any, and the TRS L&C recommendation shall be mailed to the Board members and Interested Parties. Copies of the TRS L&C recommendation and responses of Interested Parties shall be mailed to the Appealing Party.

(B) All Interested Parties who wish to make an oral presentation at the open meeting are requested to notify the TRS L&C in accordance with the requirements stated in the Solicitation Document or on the TRS website, which may be accessed at https://www.trs.texas.gov/, as applicable, at least 48 hours in advance of the open meeting.

(C) The Board of Trustees may consider oral presentations and written documents presented by staff, the Appealing Party, and Interested Parties. The chairman shall set the order and amount of time allowed for presentations.

(D) The Board of Trustees' determination of an Appeal shall be by duly adopted resolution reflected in the minutes of the open meeting and shall be final.

(5) A Final Decision issued either by the Board of Trustees in open meeting or in writing by the Executive Director shall be the final administrative action of TRS.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on May 31, 2024.

TRD-202402436
Don Green
Chief Financial Officer
Teacher Retirement System of Texas
Earliest possible date of adoption: July 14, 2024
For further information, please call: (512) 542-6238

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