Adopted rules include new rules, amendments to existing rules, and repeals of existing rules. A rule adopted by a state agency takes effect 20 days after the date on which it is filed with the Secretary of State unless a later date is required by statute or specified in the rule (Government Code, §2001.036). If a rule is adopted without change to the text of the proposed rule, then the *Texas Register* does not republish the rule text here. If a rule is adopted with change to the text of the proposed rule, then the final rule text is included here. The final rule text will appear in the Texas Administrative Code on the effective date.

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 Texas Health and Human Services Commission (HHSC) adopts an amendment to §354.1149, concerning Exclusions and Limitations.

Section 354.1149 is adopted without changes to the proposed text as published in the June 14, 2024, issue of the *Texas Register* (49 TexReg 4117). This rule will not be republished.

BACKGROUND AND JUSTIFICATION

The purpose of the adoption 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 were 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 adopted rule removes the exclusion of all FDA-approved and ACIP-recommended vaccines used solely for travel to or from foreign countries as a Medicaid benefit for the adult population.

COMMENTS

The 31-day comment period ended July 15, 2024.

During this period, HHSC received comments regarding the proposed rule from two individuals with The University of Texas Southwestern Medical Center. A summary of comments relating to the rule and HHSC's responses follows.

Comment: One individual commented that the proposed rule is an opportunity to provide equitable access to necessary vaccines for adults and that expanding coverage to include all ACIP-recommended vaccines not only aligns with state and federal requirements but also addresses gaps in immunization. The commenter expressed concern about the implementation of the proposed rule and suggested that efforts should be made to increase awareness.

Response: HHSC agrees with the commenter that the proposed rule will increase access to adult vaccines. Regarding implementation of the proposed rule, HHSC publishes provider notifications to the Texas Medicaid & Healthcare Partnership website when new benefits are added. The process is and will continue to be applied to new ACIP-recommended vaccine benefits.

Comment: The second individual commented and provided support of the proposal to amend §354.1149 to align Texas Medicaid coverage of vaccines for adults with federal requirements to remove travel-based exclusions. The commenter expressed that the change is critical to ensure that all adults have access to FDA-approved and ACIP-recommended vaccines regardless of their occupation or travel plans and that vaccines prevent the spread of disease through travel to new areas and provides all Texans with the opportunity to get vaccinated and stay healthy. The commenter urges HHSC to adopt the proposed rule as the proposed rule is a common-sense change that will improve the health of Texans, save lives, and meet IRA of 2022 requirements.

Response: HHSC agrees with the commenter and thanks the commenter for their support.

STATUTORY AUTHORITY

The amendment is adopted under 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 agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on September 17, 2024.

TRD-202404465
Karen Ray
Chief Counsel
Texas Health and Human Services Commission
Effective date: October 7, 2024
Proposal publication date: June 14, 2024
For further information, please call: (512) 438-4651

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TITLE 19. EDUCATION

PART 2. TEXAS EDUCATION AGENCY

CHAPTER 151. COMMISSIONER'S RULES CONCERNING PASSING STANDARDS FOR EDUCATOR CERTIFICATION EXAMINATIONS

19 TAC §151.1001

The Texas Education Agency (TEA) adopts an amendment to §151.1001, concerning passing standards for educator certification examinations. The amendment is adopted without changes to the proposed text as published in the June 28, 2024 issue of the *Texas Register* (49 TexReg 4680) and will not be republished. The adopted amendment specifies the satisfactory scores for the examinations for English Language Arts and Reading 7-12; Health Early Childhood (EC)-12; Physical Education EC-12; edTPA: Elementary Literacy; edTPA: Elementary Mathematics; edTPA: Early Childhood Education; edTPA: Elementary Education-Mathematics with Literacy Task 4; and edTPA: Career and Technical Education and remove Pedagogy and Professional Responsibilities for Trade and Industrial Education 6-12.

REASONED JUSTIFICATION: Texas Education Code (TEC), §21.048(a), requires the commissioner to establish the satisfactory levels of performance required on educator certification examinations and requires a satisfactory level of performance on each core subject covered by an examination. The adopted passing standards were established by subject-matter expert stakeholder committee groups.

Section 151.1001 specifies the passing standards for all pedagogical and content certification examinations as approved by the commissioner. The adopted amendment to Figure: 19 TAC §151.1001(b)(4) introduces passing standards for the English Language Arts and Reading 7-12 examination.

The adopted amendment to Figure: 19 TAC §151.1001(b)(7) introduces passing standards for the Health EC-12 and Physical Education EC-12 examinations.

The adopted amendment to Figure: 19 TAC §151.1001(b)(14) removes Pedagogy and Professional Responsibilities for Trade and Industrial Education 6-12 TExES as a valid exam and introduces passing standards for the edTPA: Elementary Literacy; edTPA: Elementary Mathematics; edTPA: Early Childhood Education; edTPA: Elementary Education-Mathematics with Literacy Task 4; and edTPA: Career and Technical Education.

The average passing standard is expressed as an average raw cut score of all active forms of a test or the minimum proficiency level. It is critical to note that the actual raw cut scores may vary slightly from form to form to balance the overall difficulty of the test yet maintain consistency in scoring.

SUMMARY OF COMMENTS AND AGENCY RESPONSES: The public comment period on the proposal began June 28, 2024, and ended July 29, 2024. Following is a summary of the public comments received and agency responses.

Comment: The Texas-American Federation of Teachers and Texas State Teachers Association commented that Figure: 19 TAC §151.1001(b)(14) should reflect a numerical passing standard for all edTPA exams.

Response: The agency agrees that standard-setting activities should be completed to assign a numerical minimum passing score to each edTPA examination recently adopted by the State Board for Educator Certification. After recommended standards are established, TEA will propose changes to Figure: 19 TAC §151.1001(b)(14) to incorporate the standards.

STATUTORY AUTHORITY. The amendment is adopted under Texas Education Code, §21.048(a), which requires the commissioner of education to determine the level of performance considered to be satisfactory on educator certification examinations and further authorizes the commissioner to require a satisfactory level of performance on each core subject covered by an examination.

CROSS REFERENCE TO STATUTE. The amendment implements Texas Education Code, §21.048(a).

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on September 18, 2024.

TRD-202404487
Cristina De La Fuente-Valadez
Director, Rulemaking
Texas Education Agency
Effective date: October 8, 2024
Proposal publication date: June 28, 2024
For further information, please call: (512) 475-1497

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TITLE 22. EXAMINING BOARDS

PART 22. TEXAS STATE BOARD OF PUBLIC ACCOUNTANCY

CHAPTER 511. ELIGIBILITY

SUBCHAPTER H. CERTIFICATION

22 TAC §511.161

The Texas State Board of Public Accountancy (Board) adopts an amendment to §511.161 concerning Qualifications for Issuance of a Certificate, without changes to the proposed text as published in the July 26, 2024, issue of the *Texas Register* (49 TexReg 5485) and will not be republished.

An existing Board rule, §511.163, requires an applicant to complete a four-hour CPE ethics course before taking the Uniform Certified Public Accountancy Exam. That rule provision is being transferred to the section of the Board's rules that address Continuing Professional Education.

No comments were received regarding adoption of the amendment.

The amendment is adopted under the Public Accountancy Act (Act), Texas Occupations Code, §901.151 and §901.655 which provides the agency with the authority to amend, adopt and repeal rules deemed necessary or advisable to effectuate the Act.

No other article, statute or code is affected by the adoption.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on September 19, 2024.

TRD-202404535
J. Randel (Jerry) Hill
General Counsel
Texas State Board of Public Accountancy
Effective date: October 9, 2024
Proposal publication date: July 26, 2024
For further information, please call: (512) 305-7842

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CHAPTER 520. PROVISIONS FOR THE ACCOUNTING STUDENTS SCHOLARSHIP PROGRAM

22 TAC §520.1

The Texas State Board of Public Accountancy (Board) adopts an amendment to §520.1 concerning Authority and Purpose, without changes to the proposed text as published in the July 26, 2024, issue of the *Texas Register* (49 TexReg 5486) and will not be republished.

The amendment establishes the Examination Fee Financial Aid program to assist applicants who can demonstrate the need for assistance in paying the cost of taking the Uniform Certified Public Accountancy Exam.

No comments were received regarding adoption of the amendment.

The amendment is adopted under the Public Accountancy Act (Act), Texas Occupations Code, §901.151 and §901.655 which provides the agency with the authority to amend, adopt and repeal rules deemed necessary or advisable to effectuate the Act.

No other article, statute or code is affected by the adoption.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on September 19, 2024.

TRD-202404536
J. Randel (Jerry) Hill
General Counsel
Texas State Board of Public Accountancy
Effective date: October 9, 2024
Proposal publication date: July 26, 2024
For further information, please call: (512) 305-7842

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22 TAC §520.2

The Texas State Board of Public Accountancy (Board) adopts an amendment to §520.2 concerning Definitions, without changes to the proposed text as published in the July 26, 2024, issue of the *Texas Register* (49 TexReg 5487) and will not be republished.

The amendment defines the terms used in the creation of the Examination Fee Financial Aid program to assist applicants in need of financial assistance in the costs to take the Uniform Certified Public Accountancy Exam.

No comments were received regarding adoption of the amendment.

The amendment is adopted under the Public Accountancy Act (Act), Texas Occupations Code, §901.151 and §901.655 which provides the agency with the authority to amend, adopt and repeal rules deemed necessary or advisable to effectuate the Act.

No other article, statute or code is affected by the adoption.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on September 19, 2024.

TRD-202404537
J. Randel (Jerry) Hill
General Counsel
Texas State Board of Public Accountancy
Effective date: October 9, 2024
Proposal publication date: July 26, 2024
For further information, please call: (512) 305-7842

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22 TAC §520.3

The Texas State Board of Public Accountancy (Board) adopts an amendment to §520.3 concerning Institutions for the Accounting Students Scholarship Program, without changes to the proposed text as published in the July 26, 2024, issue of the *Texas Register* (49 TexReg 5488) and will not be republished.

The amendment adds descriptive language to the title of the rule for the reader to understand that the rule applies only to the accounting students scholarship program.

No comments were received regarding adoption of the amendment.

The amendment is adopted under the Public Accountancy Act (Act), Texas Occupations Code, §901.151 and §901.655 which provides the agency with the authority to amend, adopt and repeal rules deemed necessary or advisable to effectuate the Act.

No other article, statute or code is affected by the adoption.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on September 19, 2024.

TRD-202404538
J. Randel (Jerry) Hill
General Counsel
Texas State Board of Public Accountancy
Effective date: October 9, 2024
Proposal publication date: July 26, 2024
For further information, please call: (512) 305-7842

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22 TAC §520.4

The Texas State Board of Public Accountancy (Board) adopts an amendment to §520.4 concerning Eligible Students for the Accounting Students Scholarship Program, without changes to the proposed text as published in the July 26, 2024, issue of the *Texas Register* (49 TexReg 5490) and will not be republished.

The amendment adds descriptive language to the title of the rule for the reader to understand that the rule applies only to the accounting students scholarship program.

No comments were received regarding adoption of the amendment.

The amendment is adopted under the Public Accountancy Act (Act), Texas Occupations Code, §901.151 and §901.655 which provides the agency with the authority to amend, adopt and repeal rules deemed necessary or advisable to effectuate the Act.

No other article, statute or code is affected by the adoption.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on September 19, 2024.

TRD-202404539
J. Randel (Jerry) Hill
General Counsel
Texas State Board of Public Accountancy
Effective date: October 9, 2024
Proposal publication date: July 26, 2024
For further information, please call: (512) 305-7842

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22 TAC §520.5

The Texas State Board of Public Accountancy (Board) adopts an amendment to §520.5 concerning Award Amount and Uses for the Accounting Students Scholarship Program, without changes to the proposed text as published in the July 26, 2024, issue of the *Texas Register* (49 TexReg 5491) and will not be republished.

The amendment adds descriptive language to the title of the rule for the reader to understand that the rule applies only to the accounting students scholarship program.

No comments were received regarding adoption of the amendment.

The amendment is adopted under the Public Accountancy Act (Act), Texas Occupations Code, §901.151 and §901.655 which provides the agency with the authority to amend, adopt and repeal rules deemed necessary or advisable to effectuate the Act.

No other article, statute or code is affected by the adoption.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on September 19, 2024.

TRD-202404540
J. Randel (Jerry) Hill
General Counsel
Texas State Board of Public Accountancy
Effective date: October 9, 2024
Proposal publication date: July 26, 2024
For further information, please call: (512) 305-7842

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22 TAC §520.6

The Texas State Board of Public Accountancy (Board) adopts an amendment to §520.6 concerning Allocations for the Accounting Students Scholarship Program, without changes to the proposed text as published in the July 26, 2024, issue of the *Texas Register* (49 TexReg 5492) and will not be republished.

The amendment adds descriptive language to the title of the rule for the reader to understand that the rule applies only to the accounting students scholarship program.

No comments were received regarding adoption of the amendment.

The amendment is adopted under the Public Accountancy Act (Act), Texas Occupations Code, §901.151 and §901.655 which provides the agency with the authority to amend, adopt and repeal rules deemed necessary or advisable to effectuate the Act.

No other article, statute or code is affected by the adoption.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on September 19, 2024.

TRD-202404541
J. Randel (Jerry) Hill
General Counsel
Texas State Board of Public Accountancy
Effective date: October 9, 2024
Proposal publication date: July 26, 2024
For further information, please call: (512) 305-7842

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22 TAC §520.7

The Texas State Board of Public Accountancy (Board) adopts an amendment to §520.7 concerning Disbursements to Institutions for the Accounting Students Scholarship Program, without changes to the proposed text as published in the July 26, 2024, issue of the *Texas Register* (49 TexReg 5493) and will not be republished.

The amendment adds descriptive language to the title of the rule for the reader to understand that the rule applies only to the accounting students scholarship program.

No comments were received regarding adoption of the amendment.

The amendment is adopted under the Public Accountancy Act (Act), Texas Occupations Code, §901.151 and §901.655 which provides the agency with the authority to amend, adopt and repeal rules deemed necessary or advisable to effectuate the Act.

No other article, statute or code is affected by the adoption. gency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on September 19, 2024.

TRD-202404542
J. Randel (Jerry) Hill
General Counsel
Texas State Board of Public Accountancy
Effective date: October 9, 2024
Proposal publication date: July 26, 2024
For further information, please call: (512) 305-7842

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22 TAC §520.8

The Texas State Board of Public Accountancy (Board) adopts an amendment to §520.8 concerning Retroactive Disbursements for the Accounting Students Scholarship Program, without changes to the proposed text as published in the July 26, 2024, issue of the *Texas Register* (49 TexReg 5494) and will not be republished.

The amendment adds descriptive language to the title of the rule for the reader to understand that the rule applies only to the accounting students scholarship program.

No comments were received regarding adoption of the amendment.

The amendment is adopted under the Public Accountancy Act (Act), Texas Occupations Code, §901.151 and §901.655 which provides the agency with the authority to amend, adopt and repeal rules deemed necessary or advisable to effectuate the Act.

No other article, statute or code is affected by the adoption.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on September 19, 2024.

TRD-202404543
J. Randel (Jerry) Hill
General Counsel
Texas State Board of Public Accountancy
Effective date: October 9, 2024
Proposal publication date: July 26, 2024
For further information, please call: (512) 305-7842

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22 TAC §520.11

The Texas State Board of Public Accountancy (Board) adopts new rule §520.11 concerning Eligible Applicants for Examination Fee Financial Aid (EFFA) Program, without changes to the proposed text as published in the July 26, 2024, issue of the *Texas Register* (49 TexReg 5495) and will not be republished.

The rule will establish criteria for eligibility for the financial aid.

No comments were received regarding adoption of the new rule.

The new rule is adopted under the Public Accountancy Act (Act), Texas Occupations Code, §901.151 and §901.655 which provides the agency with the authority to amend, adopt and repeal rules deemed necessary or advisable to effectuate the Act.

No other article, statute or code is affected by the adoption.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on September 19, 2024.

TRD-202404544
J. Randel (Jerry) Hill
General Counsel
Texas State Board of Public Accountancy
Effective date: October 9, 2024
Proposal publication date: July 26, 2024
For further information, please call: (512) 305-7842

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22 TAC §520.12

The Texas State Board of Public Accountancy (Board) adopts new rule §520.12 concerning Award Amounts and Uses Through the Examination Fee Financial Aid (EFFA) Program, without changes to the proposed text as published in the July 26, 2024, issue of the *Texas Register* (49 TexReg 5496) and will not be republished.

The rule makes it clear that the amount reimbursed is based upon the CPA examination fee and once the applicant has paid for the exam fee and passed the exam the reimbursed amount may be used for other legal purposes.

No comments were received regarding adoption of the new rule.

The new rule is adopted under the Public Accountancy Act (Act), Texas Occupations Code, §901.151 and §901.655 which provides the agency with the authority to amend, adopt and repeal rules deemed necessary or advisable to effectuate the Act.

No other article, statute or code is affected by the adoption.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on September 19, 2024.

TRD-202404545
J. Randel (Jerry) Hill
General Counsel
Texas State Board of Public Accountancy
Effective date: October 9, 2024
Proposal publication date: July 26, 2024
For further information, please call: (512) 305-7842

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22 TAC §520.13

The Texas State Board of Public Accountancy (Board) adopts new rule §520.13 concerning Documentation for the Examination Fee Financial Aid (EFFA) Program, without changes to the

proposed text as published in the July 26, 2024, issue of the *Texas Register* (49 TexReg 5497) and will not be republished.

The applicant is required to apply to the board for the award and provide evidence of financial need.

No comments were received regarding adoption of the new rule.

The new rule is adopted under the Public Accountancy Act (Act), Texas Occupations Code, §901.151 and §901.655 which provides the agency with the authority to amend, adopt and repeal rules deemed necessary or advisable to effectuate the Act.

No other article, statute or code is affected by the adoption.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on September 19, 2024.

TRD-202404546
J. Randel (Jerry) Hill
General Counsel
Texas State Board of Public Accountancy
Effective date: October 9, 2024
Proposal publication date: July 26, 2024
For further information, please call: (512) 305-7842

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TITLE 25. HEALTH SERVICES

PART 1. DEPARTMENT OF STATE HEALTH SERVICES

CHAPTER 229. FOOD AND DRUG SUBCHAPTER HH. LABELING OF ANALOGUE PRODUCTS

25 TAC §§229.901 - 229.903

The Executive Commissioner of the Texas Health and Human Services Commission (HHSC), on behalf of the Department of State Health Services (DSHS), adopts new Subchapter HH, §§229.901 - 229.903, concerning Labeling of Analogue Products. New §§229.901 - 229.903 are adopted without changes to the proposed text as published in the July 19, 2024, issue of the *Texas Register* (49 TexReg 5260). These rules will not be republished.

BACKGROUND AND JUSTIFICATION

The new sections are necessary to comply with Senate Bill (S.B.) 664, 88th Legislature, Regular Session, 2023, which adds Texas Health and Safety Code §431.0805. S.B. 664 defines "analogue product," "cell-cultured product," "close proximity," "egg," "egg product," "fish," "meat," "meat food product," "poultry," and "poultry product."

S.B. 664 also includes labeling requirements for an analogue meat product, a meat food product, poultry, a poultry product, an egg product, or fish.

COMMENTS

The 31-day comment period ended August 19, 2024.

During this period, DSHS received a comment regarding the proposed rules from one individual. A summary of the comment and DSHS' response follows.

Comment: One commenter wrote the definition of "fish" is very general and suggested the label include the specific type of seafood or fish so it is clear to the consumer in case of allergies.

Response: DSHS disagrees and declines to revise the rule in response to this comment. The federal definition of fish is used to capture all the products that could be an analogue product of fish. The analogue product mimics a fish product and will not contain fish. Any allergens contained within the analogue product are required to be included on the label.

STATUTORY AUTHORITY

The new sections are adopted under Texas Health and Safety Code Chapter 431, which directs the Executive Commissioner of HHSC to adopt rules to implement legislation; and Texas Government Code §531.0055 and Texas Health and Safety Code §1001.075, which authorize the Executive Commissioner of HHSC to adopt rules 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.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on September 19, 2024.

TRD-202404522
Cynthia Hernandez
General Counsel
Department of State Health Services
Effective date: October 9, 2024
Proposal publication date: July 19, 2024
For further information, please call: (512) 834-6670

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CHAPTER 289. RADIATION CONTROL

The Executive Commissioner of the Texas Health and Human Services Commission (HHSC), on behalf of the Department of State Health Services (DSHS), adopts 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. The amendments to §§289.202, 289.257, and 289.258 are adopted without changes to the proposed text as published in the June 14, 2024, issue of the *Texas Register* (49 TexReg 4200), and therefore will not be republished. The amendments to §§289.201, 289.253, 289.255, and 289.256 are adopted with changes to the proposed text as published in the June 14, 2024, issue of the *Texas Register* (49 TexReg 4200). These rules will be republished.

BACKGROUND AND JUSTIFICATION

The 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. The amendments also clarify or correct references and include a requirement to report transactions involving nationally tracked sources.

The 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 amendments update, correct, improve, and clarify the rule language and incorporate plain language where appropriate.

COMMENTS

The 31-day comment period ended July 15, 2024.

During this period, DSHS received three public comments regarding the proposed rules. A summary of the comments and responses from DSHS follows.

Comment: One commenter specified, "On page 98 (289.201(g)(2)(C)), the document states that 100 Ci is 3.7 MBq. 100 Ci is actually 3,700,000 MBq."

Response: The commenter's conversion is correct; however, the incorrect conversion was due to a known publishing error in the June 14, 2024, issue of the *Texas Register* that included an incorrect symbol for "microcuries." The June 21, 2024, issue of the *Texas Register* (49 TexReg 4624) identified and corrected this publishing error that addressed the discrepancy.

Comment: The Texas Society of Radiologic Technologists expressed their support for changes to §289.201 related to the "inclusion of 'digital output personnel dosimeter' to the definition of individual monitoring device."

Response: No additional action is necessary.

Comment: The Texas Society of Radiologic Technologists expressed their support for changes to §289.256 concerning Medical and Veterinary Use of Radioactive Material.

Response: No additional action is necessary.

DSHS made minor editorial changes to §289.201(b)(26) and §289.201(b)(42) to correct a publishing error by the *Texas Register*, which added unnecessary parentheses to the definitions.

Additional editorial or minor changes were made by DSHS to include the following:

- An editorial change was made to §289.253(s)(2)(B) to correct the reference for radiation safety officer training requirements to subsection (p).

- An editorial change was made to §289.255(u)(11)(B)(i) to correct the transposed conversions of "740 gigabecquerels" and "3.7 terabecquerels."

- An editorial change was made to §289.255(v)(2) to replace the references to "additional authorized use/storage sites" with "field stations" or "field station" as is consistent with the amendments to §289.255(c), Definitions.

- A change was made to §289.256(i)(1) to remove "as approved by the department:" DSHS believes removal will reduce licensee burden when changing RSC membership and is compatible with NRC regulation.

- Editorial changes were made to §289.256(n)(4) and §289.256(p)(11) to update the reference for establishing an RSC to subsection (i).

- A change was made to §289.256(r)(5)(C) to replace "byproduct" with "radioactive" to ensure consistency with referenced subsections (ff) and (hh), which relate to "radioactive material."

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.

§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 person is subject to regulation by the United States Nuclear Regulatory Commission (NRC). This section does not apply to radioactive material in the possession of federal agencies. State regulation 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). A person who receives, possesses, uses, owns, transfers, or acquires radioactive material before receiving a license is subject to the requirements of this chapter.

(b) Definitions. The following words and terms when used in this chapter 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) 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) Agreement state--Any state with which NRC has entered into an effective agreement under Section 274 of the Atomic Energy Act of 1954, as amended.

(9) Airborne radioactive material--Any radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

(10) Airborne radioactivity area--A room, enclosure, or area in which airborne radioactive materials exist in concentrations:

(A) over the derived air concentrations (DACs) specified in Table I, Column 3 of §289.202(ggg)(2)(F) of this subchapter (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 of the annual limit on intake (ALI) or 12 derived air concentration-hours (DAC-hours).

(11) 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) of this chapter (relating to Licensing of Radioactive Material) and who has completed the training required by §289.252(ii)(10)(C) of this chapter.

(12) 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) Background investigation--The investigation conducted by a licensee or applicant to support the determination of trustworthiness and reliability.

(14) 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 global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents, such as Chernobyl, contributing to background radiation and not under the control of the licensee. "Background radiation" does not include radiation from sources of radiation regulated by the department.

(15) Becquerel (Bq)--The International System of Units (SI) unit of activity. One becquerel is equal to one disintegration or transformation per second (dps or tps). Commonly used multiples of the becquerel are the kBq (kilobecquerel, 10^3 Bq), MBq (megabecquerel, 10^6 Bq), GBq (gigabecquerel, 10^9 Bq), and TBq (terabecquerel, 10^{12} Bq). 1 Ci = 37 GBq.

(16) 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) 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) 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;

(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

(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 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) 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. 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, 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) 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. 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, 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) Certificate of registration--A form of permission to engage in regulated activities given by the department to an applicant who has met the requirements for registration or mammography system certification set out in the Act and this chapter.

(22) Certification of mammography systems (state certification)--A form of permission to engage in regulated activities given by the department to an applicant who has met the requirements for mammography system certification set out in the Act and this chapter.

(23) 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) Commercial--Having financial profit as the primary aim.

(25) Committed dose equivalent ($H_{T,50}$) --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) Committed effective dose equivalent ($H_{E,50}$)--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 ($H_{E,50} = \Sigma W_T H_{T,50}$).

(27) 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 radionuclides for production and noncommercial distribution of radioactive drugs among consortium members for medical use and is located at an educational institution or a medical facility.

(28) Constraint (dose constraint)--A value above which specified licensee actions are required.

(29) Critical group--The group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

(30) Curie (Ci)--A unit of measurement of radioactivity. One curie (Ci) is the 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 (μCi). One mCi = 1×10^{-3} Ci = 3.7×10^{7} dps. One μCi = 1×10^{-6} Ci = 3.7×10^{4} dps. One nanocurie (nCi) = 1×10^{-9} Ci = 3.7×10^{1} dps. One picocurie (pCi) = 1×10^{-12} Ci = 3.7×10^{-2} dps.

(31) 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 termination of license; or

(B) release of the property under alternate requirements for license termination.

(32) Deep dose equivalent (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)).

(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 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)--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 this chapter. For purposes of this chapter, "limits" is an equivalent term.

(42) Effective dose equivalent (H_E)--The sum of the products of the dose equivalent to each organ or tissue (H_T) and the weighting factor (W_T) applicable to each of the body organs or tissues that are irradiated ($H_E = \Sigma W_T H_T$).

(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 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.

(51) Generally applicable environmental radiation standards--Standards issued by the 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 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 development specifically authorized by the department.

(55) Individual--Any human being.

(56) Individual monitoring--The assessment of:

(A) dose equivalent to an individual using 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); or

(C) dose equivalent to an individual using survey data.

(57) Individual monitoring device--Device 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.

(58) Inspection--An official examination or observation, including records, tests, surveys, and monitoring to determine compliance with the Act and rules, orders, requirements, and conditions of the department.

(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, 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).

(63) License--A form of permission to engage in regulated activities given by the department 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.

(65) Licensee--Any person who is licensed by the department as specified in the Act and this chapter.

(66) 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) 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) Low-level radioactive waste (LLRW)--Radioactive material that meets the following criteria:

(A) LLRW includes:

(i) discarded or unwanted radioactive material 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; and

(iii) radioactive material subject to:

(I) concentration limits established in 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 Title 10 of the CFR or established by the department or TCEQ, as applicable.

(B) LLRW does not include:

(i) high-level radioactive waste as defined by 10 CFR §60.2;

(ii) spent nuclear fuel as defined by 10 CFR §72.3;

(iii) byproduct material defined in 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) Manufacture--To fabricate or mechanically produce.

(70) Member of the public--Any individual, except when that individual is receiving an occupational dose.

(71) Minor--An individual less than 18 years of age.

(72) Mobile device--A piece of equipment containing licensed radioactive material that either is mounted on a permanent base with wheels 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) 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) Movement control center--An operations center remote from the transport activity 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) Naturally occurring or accelerator-produced radioactive material (NARM)--Any naturally occurring or accelerator-produced radioactive material except source material or special nuclear material.

(76) Natural radioactivity--Radioactivity of naturally occurring nuclides whose location and chemical and physical form have not been altered by man.

(77) 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 hours after the estimated arrival time for shipments of category 2 quantities of radioactive material.

(78) NRC--The United States Nuclear Regulatory Commission or its duly authorized representatives.

(79) 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 this chapter, from voluntary participation in medical research programs, or as a member of the public.

(80) 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 1 million electron volts (MeV).

(81) 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) Personnel monitoring equipment (See definition for individual monitoring devices.)

(83) Pharmacist--An individual licensed by the Texas State Board of Pharmacy to compound and dispense drugs, prescriptions, and poisons.

(84) 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 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 this chapter, or from voluntary participation in medical research programs.

(90) Quality factor (Q)--The modifying factor listed in subsection (m)(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 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 knowledge, authority, and responsibility to apply appropriate radiation protection rules, standards, and practices, who is specifically authorized on a radioactive material license, and who is the primary contact with the department. Specific training and responsibilities for

an RSO are listed in §289.252 of this chapter, §289.253 of this chapter (relating to Radiation Safety Requirements for Well Logging Service Operations and Tracer Studies), §289.255 of this chapter (relating to Radiation Safety Requirements and Licensing and Registration Procedures for Industrial Radiography), and §289.256 of this chapter (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.

(101) Registrant--Any person issued a certificate of registration by the department as specified in the Act and this chapter.

(102) Regulation--See definition for rule.

(103) Regulations of the United States Department of Transportation (DOT)--The federal requirements in 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 live, and the grounds on which these structures are located, including 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.

(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 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 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 2001)--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 does not include a statement regarding only the internal management or organization of a state 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 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.

(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) (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).

(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 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 the following conditions:

(A) either a single solid piece or contained in a sealed capsule only opened by destroying the capsule;

(B) the piece or capsule has at least one dimension not less than 5 millimeters (mm) (0.2 inch); and

(C) satisfies the requirements specified by NRC. A special form encapsulation designed as specified in NRC requirements in effect on June 30, 1983, and constructed before July 1, 1985, may continue to be used. A special form encapsulation designed as specified

in NRC requirements in effect on March 31, 1996, and constructed before 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 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 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 kinds of special nuclear material in combination must 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 presence of sources of radiation. When appropriate, such survey includes 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 engineered controls.

(128) Telemetric position monitoring system--A data transfer system that captures information by instrumentation 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) Termination--A release by the department 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) Test--A method of determining the characteristics or condition of sources of radiation or components thereof.

(132) Texas Regulations for Control of Radiation (TRCR)--All sections of 25 Texas Administrative Code (TAC) Chapter 289.

(133) 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) 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.

(135) 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).

(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, whichever is larger.

(136) 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) 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 and A_2 are given in §289.257(ee) of this chapter (relating to Packaging and Transportation of Radioactive Material) or may be determined by procedures described in §289.257(ee) of this chapter.

(138) Type B quantity--A quantity of radioactive material greater than a type A quantity.

(139) Unescorted access--Solitary access to an aggregated category 1 or category 2 quantity of radioactive material or the devices that contain the material.

(140) Unrefined and unprocessed ore--Ore in its natural form before 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) 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) 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 500 rads (5 Gy in one hour at 1 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) Veterinarian--An individual licensed by the Texas State Board of Veterinary Medical Examiners to practice veterinary medicine under Texas Occupations Code Chapter 801.

(144) 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) of this subsection.

(145) Week--Seven consecutive days starting on Sunday.

(146) Whole body--For purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.

(147) Worker--An individual engaged in work under a license or certificate of registration issued by the department and controlled by a licensee or registrant but does not include the licensee or registrant.

(148) 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) 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) 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 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 may, upon application or its own initiative, exempt a source of radiation or a kind of use or user from the requirements of this chapter if the department 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:

(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 §289.204 of this subchapter (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;

(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 and NRC jointly determine that:

(i) the exemption of the prime contractor or subcontractor is authorized by law; and

(ii) as specified in the terms of the contract or subcontract, there is adequate assurance that the work can be accomplished without undue risk to the public health and safety and the environment.

(d) Records.

(1) Each licensee must 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 include, as a minimum:

(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 of radioactive material must be retained by the licensee until disposal of the records is authorized by the department. 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 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 throughout the retention period specified by the department. The licensee must maintain adequate safeguards against tampering with and loss of records.

(e) Inspections.

(1) The department may enter public or private property at reasonable times to determine whether, in a matter under the depart-

ment's jurisdiction, there is compliance with the Act, the department's rules, license conditions, and orders issued by the department.

(2) Each licensee must afford the department, at all reasonable times, opportunity to inspect sources of radiation and the premises and facilities where sources of radiation are used or stored.

(3) Each licensee must make available to the department for inspection, upon reasonable notice, records maintained as specified in this chapter.

(f) Tests.

(1) Each licensee must perform, upon instructions from the department, or must permit the department to perform, reasonable tests the department deems appropriate or necessary, including tests of:

(A) sources of radiation;

(B) facilities where 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, samples collected from its facility or from areas that are radioactive resulting from its licensed activities.

(g) Tests for leakage or contamination of sealed sources.

(1) The licensee possessing any sealed source must assure that:

(A) each sealed source, except as specified in paragraph (2) of this subsection and §289.253(j) of this chapter, 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 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 months or at alternative intervals approved by the department, the NRC, or any agreement state after evaluation of information specified in §289.252(v) of this chapter 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 months or at alternative intervals approved by the department, the NRC, or any agreement state after evaluation of information specified in §289.252(v) of this chapter, 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 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 capable of detecting the presence of 0.005 μCi (185 Bq) of radioactive material on a test sample. Test samples must 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 capable of detecting an absolute leakage rate of 0.001 μCi (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 taken on the interior surface of brachytherapy source storage containers and are capable of detecting the presence of 0.005 μCi (185 Bq) of a radium daughter that has a half-life greater than four days; and

(H) tests for leakage or contamination are performed using a leak test kit or method approved by the department, the NRC, or any agreement state.

(2) A licensee need not perform tests for leakage or contamination on the following:

(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 μCi (3.7 MBq) or less of beta or gamma-emitting material or 10 μCi (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 are stored, not being used, and identified as in storage. However, the licensee must test each 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 six months before the date of use or transfer.

(3) Analysis of tests for leakage or contamination from sealed sources must be performed by persons specifically authorized by the department, the NRC, or any agreement state to perform such services.

(4) Test results must be kept in units of microcurie or becquerel and maintained for inspection by the department.

(5) The following is considered evidence that a sealed source is leaking:

(A) the presence of 0.005 μCi (185 Bq) or more of removable contamination on any test sample;

(B) leakage of 0.001 μCi (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 μCi (185 Bq) or more of radium.

(6) The licensee must immediately withdraw a leaking sealed source from use and must 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 be repaired or transferred for disposal as specified in §289.202 of this subchapter. The licensee must check the equipment associated with the leaking source for radioactive contamination and, if contaminated, have it decontaminated or disposed of as specified in §289.202 of this subchapter.

(7) Reports of test results for leaking or contaminated sealed sources must be made as specified in §289.202(bbb) of this subchapter.

(h) Additional requirements. The department 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 subject to impounding as specified in §401.068 of the Act and §289.205 of this subchapter (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 office located at 1100 West 49th Street, Austin, Texas.

(2) Documents transmitted to the department will be deemed submitted on the date of the postmark or other electronic media transmission.

(l) Interpretations. Except as specifically authorized by the department in writing, no interpretation of the meaning of this chapter by any officer or employee of the department other than a written interpretation by the Office of General Counsel, Department of State Health Services, will be considered binding upon the department.

(m) 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)

(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)

(n) 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 = 3.7×10^{10} dps or tps = 3.7×10^{10} Bq = 2.22×10^{12} disintegrations or transformations per minute (dpm or tpm).

(2) 1 Bq = 1 dps or tps.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

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Cynthia Hernandez
General Counsel
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 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.

§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).

(c) Definitions. The following words and terms when used in this section 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 (μCi) (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 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 (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 live, and the grounds on which these structures are located, including 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 company whose equipment is connected to licensee's equipment and 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.

(16) Temporary job site--A location where well logging or tracer studies are performed other than the specific locations 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 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 satisfy the general requirements specified in this subsection and in §289.252(e) of this subchapter.

(2) The applicant must develop a program for training logging supervisors and logging assistants and submit to the department a description of this program which specifies:

(A) initial training;

(B) on-the-job training;

(C) annual safety reviews provided by the licensee;

(D) how the applicant will demonstrate the logging supervisor's knowledge and understanding of and ability to comply with the department's regulations and licensing requirements and the applicant's operating and emergency procedures; and

(E) how the applicant will 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 submit to the department written operating and emergency procedures as described in subsection (ee)(4) of this section.

(4) The applicant must establish and submit to the department its program for annual inspections of the job performance of each logging supervisor to ensure the department's regulations, license requirements, and the applicant's operating and emergency procedures are followed. Inspection records must be retained for three years after each annual internal inspection.

(5) The applicant must 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 identify the manufacturers and the model numbers of the leak test kits used. If the applicant wants to analyze its own wipe samples, the applicant must establish procedures to follow and submit a description of these procedures to the department. The description must include the:

(A) instruments 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 perform well logging service operations with a sealed source in any well or wellbore unless, before 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:

(A) a reasonable effort at recovery will be made in the event a sealed source is lost or lodged downhole;

(B) a person does not attempt to recover a sealed source in a manner that, in the licensee's opinion, could result in a source rupture;

(C) if 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 performed; and

(D) the requirements of subsection (dd)(4) of this section are met if a decision is made to abandon the sealed source downhole.

(2) Licensees must not perform tracer study operations with a substance tagged with radioactive material in any well or wellbore unless, before 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 who is responsible for ensuring:

(A) in the event the service company's personnel or equipment are contaminated with radioactive material, they will be decontaminated as specified in §289.202(n) or (ddd) of this chapter 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 be decontaminated as specified in §289.202(ddd) of this chapter; and

(C) in the event radioactive material is reversed from the well or the well screens out, the licensee will have established procedures and equipment or facilities to:

(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 in the event of a screen out.

(3) The licensee must maintain, as specified in 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 be used, stored, and transported in such a manner that the requirements of §289.202 of this chapter, §289.231 of this chapter, and §289.257 of this subchapter, as applicable, are met.

(g) Storage precautions.

(1) Each source of radiation, except accelerators, must be provided with a storage or transport container. Each container must 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 be posted as specified in §289.202(aa)(5) or §289.231(x) of this chapter, as applicable.

(3) Sources of radiation, except accelerators, must be stored downhole or in a bunker to minimize the danger from explosion or fire.

(4) Sources of radiation may not be stored in residential locations unless specifically authorized by the department.

(5) Sources of radiation in storage must be secured to prevent tampering or removal by unauthorized individuals.

(h) Transport precautions. Transport containers must 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 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, as applicable. Instrumentation must be capable of measuring 0.1 milliroentgen per hour (mR/hr) (1 microsievert per hour (μSv/hr)) through at least 50 mR/hr (500 μSv/hr). (Instrumentation capable of measuring 0.1 mR/hr (1 μSv/hr) through 50 mR/hr (500 μSv/hr) may not be sufficient to determine compliance with DOT requirements.)

(2) A licensee using tracer material must 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.

(3) Each radiation survey instrument required under paragraph (1) of this subsection must be calibrated:

(A) by a person specifically licensed or registered by the department, 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 of the true radiation level at each calibration point.

(4) The licensee or registrant must maintain calibration records as specified in subsection (ee)(5) of this section.

(j) Leak testing of sealed sources.

(1) Testing and record keeping. Sealed sources must be tested for leakage and contamination as specified in this section and §289.201(g) of this chapter. The licensee must maintain records of leak tests as specified in subsection (ee)(5) of this section.

(2) Each energy compensation source that is not exempt from testing as specified in §289.201(g)(2) of this chapter must 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 not be used until tested as specified in §289.201(g) of this chapter.

(3) If a sealed source is found to be leaking as specified in §289.201(g) of this chapter, the licensee must 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, the NRC, or an agreement state, to perform such services.

(k) Quarterly inventory. Each licensee or registrant must 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 make and maintain records of inventories as specified in subsection (ee)(5) of this section and must include:

(1) the quantities and kinds of sources of radiation;

(2) the location where sources of radiation are assigned;

(3) the 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 records must be maintained by each licensee or registrant as specified in subsection (ee)(5) of this section and must include:

(1) identification of each source of radiation, including:

(A) the make and model number 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 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 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 be held at negative 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 be dropped from a height of 1 meter (m) onto the test source.

(III) Vibration. The test source must 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) hammer and pin, 0.3 cm pin diameter, must be dropped from a height of 1 m onto the test source.

(V) Pressure. The test source must be subjected to an external pressure of 24,600 pounds per square inch absolute (1.695×10^7 pascals) without leakage.

(2) The requirements in paragraph (1) of this subsection do not apply to sealed sources containing 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 bear a durable, legible, and clearly visible marking or label, including, 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 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 have permanently attached a durable, legible, and clearly visible label having, 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 have attached a durable, legible, and clearly visible label having, at 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 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 be made and maintained by the licensee or registrant as specified in subsection (ee)(5) of this section.

(2) If any inspection conducted as specified in paragraph (1) of this subsection reveals damage to labeling or components critical to radiation safety, the device must 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 be performed on the source holder only by persons specifically licensed to do so by the department, another agreement state, or the NRC. The provisions of this paragraph do not apply to logging tool recovery (fishing) operations conducted as specified in the provisions of subsection (dd)(4) of this section.

(4) The repair, opening, or modification of any sealed source must be performed only by persons specifically licensed to do so by the department, another agreement state, or the NRC.

(p) Training requirements.

(1) Licensees or registrants must not permit any individual to act as a logging supervisor until such individual has:

(A) completed a course 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:

(i) the requirements contained in this section and the applicable subsections of §§289.201, 289.202, 289.203, and 289.231 of this chapter 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 permit any individual to act as a logging assistant until such individual has:

(A) received copies of and instruction in the applicable subsections of §§289.201, 289.202, 289.203, and 289.231 of this chapter 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 used in the job assignment.

(3) The licensee or registrant must provide an annual radiation safety review for logging supervisors and logging assistants.

(4) Each licensee or registrant must maintain records documenting the requirements of paragraphs (1) - (3) of this subsection are met. Such records must be maintained as specified in subsection (ee)(5) of this section.

(q) Operating, safety, and emergency procedures. The licensee or registrant must 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 or §289.231(n) and (s)(3) of this chapter, as applicable, no licensee or registrant may permit any individual to act as a logging supervisor or logging assistant unless that individual wears an individual monitoring device at all times during well logging service operations or tracer studies utilizing sources of radiation. Each individual monitoring device must be assigned to and worn by only one individual. Film badges must be replaced at least monthly. Other individual monitoring devices requiring replacement must be replaced at least quarterly. After replacement, each individual monitoring device requiring processing must 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.

(2) When necessary to aid in determining the extent of an individual's intake of radioactive material, the department 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.

(3) Personnel monitoring records must be maintained by the licensee or registrant as specified in subsection (ee)(5) of this section.

(s) Radiation safety officer.

(1) A radiation safety officer (RSO) must be designated for every license and certificate of registration issued by the department.

(2) The RSO's documented qualifications must 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 (p)(1) of this section; and

(C) two years of experience as a logging supervisor, including knowledge of well logging service operations and tracer studies.

(3) The duties of the RSO include:

(A) establishing and overseeing operating, safety, emergency, and as low as reasonably achievable (ALARA) procedures, and reviewing them regularly to ensure 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 tracer studies personnel so that appropriate and effective radiation protection practices are taught;

(C) ensuring required radiation surveys and leak tests are performed and documented as specified in this chapter, including any corrective measures when levels of radiation exceed established limits;

(D) ensuring personnel monitoring is used properly by occupationally exposed personnel, records are kept of the monitoring results, and timely notifications are made, as required by §289.203 of this chapter;

(E) investigating and reporting to the department each known or suspected case of radiation exposure to an individual or radiation level detected over the limits established by this chapter and each theft or loss of each source of radiation, determining the cause, and taking 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 transport containers;

(J) ensuring inventories are performed as specified in subsection (k) of this section;

(K) ensuring 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.

(t) Security.

(1) A logging supervisor must be physically present at a temporary job site 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 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 maintain direct surveillance of the operation to prevent unauthorized entry into a restricted area, as defined in §289.201(b) of this chapter, or §289.231(c) of this chapter, as applicable.

(u) Handling tools. The licensee must provide and require the use of tools that assure remote handling of sealed sources, other than low activity calibration sources.

(v) Tracer studies.

(1) Appropriate protective clothing and equipment must be used by all personnel handling radioactive tracer material. Precautions must 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 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.

(3) The well operator must contact the licensee when a decision is made to reverse the radioactive tracer material out of a well. The licensee must be onsite and present at the well when radioactive tracer material is reversed out of a well.

(w) Particle accelerators. Licensees or registrants must not 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, or §289.231(m) or (o) of this chapter, 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). 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 that is contained within a logging tool or other tool components.

(2) For well logging applications with a surface casing for protecting freshwater 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 aquifers, use of the ECS is only subject to the requirements of subsections (e), (j), (k), (l), (dd), and (ee)(4)(A) 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 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 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 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 be made and recorded. Such surveys (and calculations for neutron sources) must 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 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 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 be made and recorded at the job site and well head for each tracer operation except for those utilizing hydrogen-3, carbon-14, sulfur-35, or krypton-85. These surveys must include measurements of radiation levels before and after the operation.

(6) Records required as specified in paragraphs (1) - (5) of this subsection must include the dates, the identification of personnel making the survey, the unique identification of survey instruments used, radiation measurements in milliroentgen per hour (mR/hr), calculations in millirem per hour (mrem/hr) or microsievert per hour (μSv/hr), and an exact description of the location of the survey. Each licensee or registrant must make and maintain records of these surveys as specified in subsection (ee)(5) of this section.

(cc) Records/documents for inspection by the department.

(1) Each licensee or registrant must maintain the records/documents specified in subsection (ee)(5) of this section.

(2) Each licensee or registrant maintaining additional authorized use/storage locations from which well logging service operations are conducted must 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.

(3) Records/documents required as specified in paragraph (2) of this subsection must be maintained as specified in subsection (ee)(5) of this section.

(4) Each licensee or registrant conducting well logging service operations at a temporary job site must 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.

(5) Records/documents required by paragraph (4) of this subsection must be maintained at the temporary job site for the period of operation at that site.

(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 be made as specified in appropriate provisions of §289.202 of this chapter, or §289.231 of this chapter, 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 notify the department immediately by telephone and submit written notification within 30 days. The written notification must designate:

(A) the well or other location;

(B) the magnitude and extent of the escape of radioactive material;

(C) the consequences of the rupture; and

(D) 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 notify the department immediately by telephone before beginning source recovery operations.

(4) Whenever a sealed source or device containing radioactive material is lost downhole, the licensee must:

(A) consult with the well operator, well owner, drilling contractor, or landowner 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; and

(C) notify the department 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:

(A) notify the department by telephone of the circumstances that resulted in the inability to retrieve the source and obtain approval from the department to implement abandonment procedures, or that the licensee implemented abandonment before receiving 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:

(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 by telephone, giving the circumstances of the loss; and

(D) file a written report with the department within 30 days of the abandonment, providing:

(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 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:

(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 or other designation;

(vi) radionuclides and activities of the sources;

(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:

(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 immediately notify the department 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 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 notify the department 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 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 include descriptions of and instructions in:

(A) the handling and use of sources of radiation in wells without surface casing for protecting freshwater 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 the limits established in §289.202 of this chapter, or §289.231 of this chapter, as applicable. Every reasonable effort must 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 radioactive material from storage, transporting 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 to storage;

(G) minimizing exposure of individuals during routine use and in the event of an accident;

(H) notifying proper personnel in the event of an accident or well excursion;

(I) maintaining records;

(J) using, inspecting, and maintaining source holders, logging tools, source handling tools, storage containers, transport containers, and injection tools;

(K) actions to be taken if a sealed source is lost or lodged downhole;

(L) picking up, receiving, handling, and opening packages containing radioactive material;

(M) surveying temporary job sites and equipment, and decontamination of vehicles, associated equipment, and clothing following tracer studies;

(N) storing and disposing of radioactive waste;

(O) 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 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 the spread of contamination and minimizing 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 be maintained by the licensee or registrant for inspection by the department.
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.

(4) Each licensee and registrant is responsible for ensuring radiographic personnel performing activities under a license or registration comply with this chapter, license and registration conditions, and orders of the department.

(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 (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) §289.251 of this subchapter (relating to Exemptions, General Licenses, and General License Acknowledgements);

(G) §289.252 of this subchapter (relating to Licensing of Radioactive Material); and

(H) §289.257 of this subchapter (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;

(B) §289.204 of this chapter;

(C) §289.205 of this chapter;

(D) §289.226 of this chapter (relating to Registration of Radiation Machine Use and Services); and

(E) §289.231 of this chapter (relating to General Provisions and Standards for Protection Against Machine-Produced Radiation).

(4) The requirements of §289.228 of this chapter (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 (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 have the following meaning unless the context clearly indicates otherwise.

(1) ANSI--American National Standards Institute.

(2) Annual refresher safety training--A review conducted or provided by the licensee or registrant for its employees on radia-

tion 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) Associated equipment--Equipment, 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) 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) Certifiable cabinet x-ray system--An existing uncertified x-ray system modified to meet the certification requirements specified in 21 Code of Federal Regulations (CFR) §1020.40.

(6) Certification identification (ID) card--The document issued by the department to individuals who have completed the requirements stated in subsection (e)(2)(A) of this section.

(7) Certified cabinet x-ray system--An x-ray system that has been certified as specified in 21 CFR §1010.2 as being manufactured and assembled on or after April 10, 1975, as specified in the provisions of 21 CFR §1020.40.

(8) 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 Part 34, Appendix A, Parts II and III for radioactive material; or

(C) a radiation control agency whose x-ray or combination certification requirements are found to be equivalent to criteria established by the Conference of Radiation Control Program Directors, Inc..

(9) Collimator--A radiation shield 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) 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) Control cable (drive cable)--The cable connected to the source assembly and used to drive the source from and return it to the shielded position.

(12) Control mechanism (drive mechanism)--A device enabling the source assembly to be moved from and returned to the shielded position. A drive mechanism is also known as a crank assembly.

(13) Control tube--A protective sheath for guiding the control cable. The control tube connects the control drive mechanism to the radiographic exposure device.

(14) 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) 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) 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) Independent certifying organization--An independent organization meeting the criteria of 10 CFR Part 34, Appendix A, for radioactive material, or comparable standards for x-ray machines.

(19) Industrial radiography (radiography)--A non-destructive testing method using ionizing radiation, such as gamma rays or x-rays, to make radiographic images for the purpose of detecting flaws in objects without destroying them.

(20) Lay-barge radiography--Industrial radiography performed on any water vessel used for laying pipe.

(21) Lock-out survey--A radiation survey performed to determine 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) 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) On-the-job training (hands-on experience)--Experience in all 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) Permanent radiographic installation--An enclosed shielded room, cell, or vault, not located at a temporary job site, in which radiography is performed and meets the criteria of subsection (n) of this section.

(25) Personal supervision--Guidance and instruction provided to a radiographer trainee by a radiographer trainer 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) Pipeliners--A directional beam radiographic exposure device.

(27) Platform radiography--Industrial radiography performed on an offshore platform or other structure over a body of water.

(28) 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) Radiation safety officer (RSO)--An individual named by the licensee or registrant and listed on the license or certificate of registration having 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) Radiographer--Any individual who has successfully completed the 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 is responsible to the licensee or registrant for assuring compliance with the requirements of the department's regulations and conditions of the license or certificate of registration. These individuals may be referred to as certified industrial radiographers or certified radiographers.

(31) Radiographer certification--Written approval received from a certifying entity stating an individual has satisfactorily met certain established radiation safety, testing, and experience criteria.

(32) Radiographer trainee--Any individual who has successfully completed the training and documentation requirements of subsection (e)(1)(A) of this section and uses sources of radiation and associated equipment or radiation survey instruments under the personal supervision of a radiographer trainer.

(33) Radiographer trainer--A radiographer who instructs and supervises radiographer trainees during on-the-job training and meets the requirements of subsection (e)(3) of this section.

(34) Radiographic exposure device--Any instrument containing a sealed source fastened or contained therein, where the sealed source or shielding may be moved, or otherwise changed, from a shielded to unshielded position for purposes of making a radiographic exposure (e.g., camera).

(35) 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) Radiographic personnel--Any radiographer, radiographer trainer, or radiographer trainee.

(37) Residential location--Any area where a structure or structures are located, in which people live, and the grounds on which these structures are located, including houses, apartments, condominiums, and garages.

(38) S-tube--A tube through which the radioactive source travels when inside a radiographic exposure device.

(39) Shielded position--The location within the radiographic exposure device or source changer where the sealed source is secured and restricted from movement.

(40) 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 or §289.231(o) of this chapter, as applicable. A shielded room is also known as a bay or bunker.

(41) Source assembly (pigtail)--An assembly consisting 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) 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) Storage area--Any location, facility, or vehicle used to store and secure a radiation machine, radiographic exposure device, a storage container, or a sealed source when it is not in use. 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) Storage container--A device in which the sealed source is secured and stored.

(45) Temporary job site--A location where radiographic operations are conducted and where licensed or registered sources of radiation may be stored other than the specific use location or locations listed on a license or certificate of registration.

(46) Trainee status card--The document issued by the department following completion of the requirements of subsection (e)(1)(A) of this section.

(47) 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) Underwater radiography--Industrial radiography performed when the radiographic exposure device 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 meet the applicable requirements of this section and §289.252 of this subchapter or §289.226 of this chapter, 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 to constitute a minimal threat to human health and safety as specified in §289.231(ll)(3) of this chapter 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), (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 permit any individual to act as a radiographer trainee until the individual possesses the original or a copy of a department-issued trainee status card or certification ID card.

(A) To obtain a department-issued trainee status card, the licensee, registrant, or the individual must document to the department 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.

(B) The trainee must carry a copy of the completed RC Form 255-E in the interim period after submitting documentation to the department and before receiving a trainee status card. The copy of the completed RC Form 255-E submitted to the department 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 notify the department, in writing, of the need for a replacement trainee status card. The individual must carry a copy of documentation of the request while performing industrial radiographic operations until a replacement trainee status card is received from the department.

(D) Records required by subparagraph (A) of this paragraph must be made and maintained as specified in subsection (v)(1) of this section.

(E) Each licensee and registrant must maintain, for inspection by the department, clear and legible records demonstrating all 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 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 submit the fee as prescribed in subsection (h)(1) of this section and:

(i) complete the requirements of paragraph (1)(A) of this subsection;

(ii) document to the department 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;

(I) The radiographer trainee must carry a legible trainee status card as specified in 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 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 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) may be substituted for the requirements of subclauses (II) or (III) of this clause. The documentation must be submitted to the department on RC Form 255-OS or equivalent.

(VI) The trainee must 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 the radiation machine has stopped producing radiation; or

(-2-) subsection (u)(9) of this section to determine the sealed source has returned to the shielded position after an exposure.

(VII) The personal supervision must include:

(-a-) the radiographer trainer's physical presence at the site where the sources of radiation are being used;

(-b-) the availability of the radiographer trainer to give immediate assistance if required; and

(-c-) 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 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 subsection (h)(2) of this section or by another certifying entity affording 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 of an individual radiographer certification may be granted as specified in 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 be made and maintained as specified in subsection (v)(1) of this section.

(E) Each licensee and registrant must maintain for inspection by the department, clear and legible records demonstrating 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 permit any individual to act as a radiographer trainer until:

(i) it has been documented to the department on RC Form 255-T or equivalent the individual has:

(I) met the radiographer certification requirements of paragraph (2)(A) of this subsection; and

(II) documented 2000 hours of direct experience as a certified radiographer.

(ii) the individual is in receipt of a valid trainer certification ID card issued by the department and under which the individual is acting as a radiographer trainer; and

(iii) determination is made by the department the individual is not currently under order from the department prohibiting the individual from acting as a radiographer trainer.

(B) The specific duties of the radiographer trainer include:

(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. An RSO must be designated on every industrial radiography license and certificate of registration issued by the department. 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.

(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.

(C) The specific duties of the RSO include:

(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 required radiation surveys and leak tests are performed and documented as specified in this chapter, including any corrective measures when levels of radiation exceed established limits;

(iv) ensuring personnel monitoring devices are calibrated and used properly by occupationally exposed personnel;

(v) ensuring timely notifications to employees are made as specified in §289.203 of this chapter;

(vi) ensuring timely notifications to the department are made as specified in this section and §289.202 of this chapter or §289.231 of this chapter, as applicable;

(vii) ensuring any required interlock switches and warning signals are functioning and 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 each:

(I) known or suspected case of radiation exposure to an individual or radiation level detected over the limits established by this chapter; and

(II) theft or loss of sources 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 subsection (v)(1) of this section;

(xii) ensuring the proper storing, labeling, transport, and use of exposure devices and sources of radiation;

(xiii) ensuring inventory and inspection and maintenance programs are performed as specified in subsections (k) and (m) of this section;

(xiv) ensuring personnel are complying with the requirements of this chapter and the conditions of the license or the certificate of registration; and

(xv) ensuring the operating, safety, and emergency procedures of the licensee or registrant are met as specified in 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 permit any individual to act as a radiographer trainee, radiographer, radiographer trainer, or RSO until the individual has met the certification requirements as specified in 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, §289.202 of this chapter, §289.203 of this chapter, §289.231 of this chapter, and §289.257 of this subchapter;

(ii) the appropriate license and certificate of registration conditions;

(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 ensure radiographic operations to which the individual is assigned are conducted as specified in the requirements of this section.

(3) Records of the administration of and the examinations required by paragraph (1) of this subsection must be made and maintained as specified in subsection (v)(1) of this section. Records must include:

(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 be on forms prescribed and furnished by the department.

(B) The non-refundable and non-transferable application fee for examination is $120.

(C) The appropriate fee must be submitted with the application for examination.

(D) The application and the non-refundable and non-transferable fee must be submitted to the department on or before the dates specified by the department.

(E) Applicants who fail to appear at a scheduled exam and do not reschedule 48 hours before their assigned exam session must apply for a future exam session and submit the appropriate fee, as specified in subparagraphs (A) - (D) of this paragraph.

(2) Examination. The examination must 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 prescribed by the department. The examination assesses 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, §289.202 of this chapter, and §289.231 of this chapter.

(B) The examination is administered by the department or persons authorized by the department.

(C) A candidate failing an examination may apply for re-examination as specified in paragraph (1) of this subsection. A candidate may not retake the same version of the department-administered examination.

(D) The examination is normally offered once each month. Times, dates, and locations of the examination are furnished by the department.

(E) The examination is in the English language.

(F) To take the examination, an individual must 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 or computers with preprogrammed data or formulas, including exposure calculators, are not permitted during the examination.

(H) The examination is a "closed-book" examination.

(I) Any individual observed by a department proctor compromising the integrity of the examination will be required to surrender the examination, the answer sheet, and all scratch paper. The individual is not allowed to complete the examination, forfeits the examination fee, and leaves the examination site to avoid disturbing other examinees. The individual must wait 90 days before taking a new examination and must resubmit a new application and a $120 non-refundable and non-transferable examination fee.

(J) Examination material must be returned to the department at the end of the examination. No photographic or other copying of examination questions or materials is permitted. Disclosure by any individual of the contents of any examination before its administration is prohibited.

(K) The names and scores of individuals taking the examination are a public record.

(h) Radiographer certification.

(1) An application for radiographer certification must be on RC Form 255-R, RC Form 255-OS, or equivalent.

(A) The non-refundable fee for radiographer certification is $110.

(B) The appropriate fee must be submitted with the application for radiographer certification when filing with the department.

(2) A certification ID card will be issued to each individual successfully completing the requirements of subsection (e)(2)(A)(i) - (iii) of this section.

(A) Each individual's certification ID card contains the individual's photograph. The department takes the photograph at the time the examination is administered.

(B) The certification ID card remains the property of the department 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 submit to the department 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 be paid to the department for each replacement of a certification ID card. The prescribed fee must be submitted with the written request for a replacement certification ID card. The individual must carry a copy of the request while performing industrial radiographic operations until a replacement certification ID card is received from the department.

(D) Each certification ID card is valid for a period of five years, unless revoked or suspended as specified in 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 be filed as specified in subsection (g)(1) of this section.

(B) The examination for renewal of a radiographer certification must be administered as specified in subsection (g)(2) of this section.

(C) A renewal certification ID card will be issued as specified in paragraph (2) of this subsection.

(4) Suspension or revocation of a radiographer certification.

(A) Any radiographer violating the requirements of this chapter, or providing any material false statement in the application or any statement of fact required by 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 §289.205 of this chapter.

(B) When a department order has been issued for an industrial radiographer to cease and desist from the use of sources of radiation or the department suspends or revokes the individual's radiographer certification, the radiographer must surrender the certification ID card to the department until the order is changed or the suspension expires.

(C) An individual whose radiographer certification has been suspended or revoked by the department or another certifying entity must comply with the process and conditions of the suspension or

revocation orders before certification is reinstated or the individual is permitted to apply for a new certification.

(5) Reciprocity of a radiographer certification.

(A) Reciprocal recognition by the department of an individual radiographer certification is granted if:

(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 Texas.

(B) Enforcement actions with the department, another agreement state, or the NRC or sanctions by an independent certifying entity are considered when reviewing a request for reciprocal recognition from a licensee, registrant, or certified radiographer.

(C) Certified radiographers granted reciprocity by the department must maintain the certification upon which the reciprocal recognition was granted, or before the expiration of such certification, must meet the requirements of paragraph (3) of this subsection.

(i) Receipt, transfer, and disposal of industrial radiography sealed sources and radiography exposure devices using depleted uranium (DU) for shielding.

(1) Each licensee and registrant must make and maintain records as specified in subsection (v)(1) of this section, showing the receipt, transfer, and disposal of industrial radiography sealed sources and radiography exposure devices using DU for shielding.

(2) These records must include, 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 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 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 and §289.231(s)(1) and (2) of this chapter, as applicable. These radiation survey instruments must 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 be calibrated:

(A) by a person licensed or registered by the department, 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 of the true radiation level at each point checked.

(3) Each radiation survey instrument must 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 be maintained as specified in subsection (v)(1) of this section.

(k) Inventory.

(1) Each licensee and registrant must 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 be made and maintained as specified in subsection (v)(1) of this section.

(3) The record must include, 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 make and maintain current logs of the use, removal, and return to storage of each source of radiation. The information must be recorded in the log when the source is removed from and returned to storage. The logs must include:

(A) a unique identification, for example, make, model, and serial number, of:

(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 and dates where each source of radiation is used; and

(D) the dates each source of radiation is removed from storage and returned to storage.

(2) Utilization logs must be kept on clear legible records containing all the information required by paragraph (1) of this subsection.

(3) Records of utilization logs must be made and maintained as specified in 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:

(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:

(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 perform and must 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 be maintained as specified in manufacturers' specifications. Radiation machines, radiographic exposure devices, transport containers, and source changers being stored are exempted from this requirement provided each radiation machine, radiographic exposure device, transport container, or source changer is inspected and repaired before being returned to service. This inspection and maintenance program must cover, at 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 include procedures to assure Type B packages are shipped and maintained as specified in 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 paragraph (1) of this subsection must be made and maintained as specified in subsection (v)(1) of this section.

(4) The record must include:

(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 have high radiation area entrance controls (for example, a control device that energizes a conspicuous visible and audible alarm signal or continuous direct or electronic surveillance) as described in §289.202(s)(1) - (4) of this chapter or §289.231(t)(1) - (4) of this chapter, or, if applicable, §289.229 of this chapter.

(2) The entrance controls must be tested for proper operation at the beginning of each day of equipment use.

(3) The alarm system must be tested for proper operation with a source of radiation each day before the installation is used for radiographic operations. The test must include a check for the visible and audible signals.

(4) Entrance control devices reducing the radiation level upon entry (designated in paragraph (1) of this subsection) must be tested monthly.

(5) If an entrance control device or alarm is operating improperly, it must 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 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 be made and maintained as specified in subsection (v)(1) of this section.

(o) Notifications.

(1) The department must be notified of the loss or theft of sources of radiation, overexposures, and excessive levels as specified in §289.202(ww) - (yy) and (bbb) of this chapter or §289.231(gg) - (jj) of this chapter, as applicable.

(2) In addition, whenever one of the following events occurs, each licensee or registrant must make the initial notification report by telephone to the department within 24 hours and submit a written report to the department within 30 days:

(A) a source assembly cannot be returned to the 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 licensee or registrant must include in each report submitted:

(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 taken to establish normal operations;

(F) the corrective action 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 meet the applicable requirements of §289.202 of this chapter or §289.231 of this chapter.

(2) During industrial radiographic operations, the following applies:

(A) Licensees or registrants must not 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 the applicable requirements of §289.202(p)(4) and (5), (q), and (r) of this chapter or §289.231(s)(3) of this chapter;

(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 meet the criteria in ANSI 13.5-1972 at the time of manufacture and must 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 be recharged at the start of each work shift.

(E) As a minimum, direct-reading pocket dosimeters must 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 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 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 cease and the individual's monitoring device requiring processing must be sent for processing immediately. The individual's monitoring device not requiring processing must be evaluated immediately. The individual must not return to work with sources of radiation until a determination of the radiation exposure has been made. This determination must be made by the RSO or the RSO's designee. The results of this determination must be included in the records maintained as specified in paragraphs (5) and (6) of this subsection and subsection (v)(1) of this section.

(H) Each individual monitoring device must be assigned to and worn by only one individual.

(I) Film badges must be replaced at periods not to exceed one month and all other individual monitoring devices requiring replacement must be replaced at least quarterly. After replacement, each individual monitoring device requiring processing must be returned to the supplier for processing within 14 calendar days of the exchange date specified by the 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.

(J) If an individual monitoring device is lost or damaged, the worker must 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 be included in the records maintained as specified in paragraph (6) of this subsection and subsection (v)(1) of this section.

(3) Pocket dosimeters or electronic personal dosimeters must be checked for correct response to radiation at periods not to exceed one year. Acceptable dosimeters must read within plus or minus 20 percent of the true radiation exposure.

(4) Each alarming ratemeter must:

(A) be checked without being exposed to radiation before use at the start of each work shift, to ensure 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 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 be made and maintained by the licensee or registrant for inspection

by the department as specified in 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 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 be maintained for department inspection until disposal is authorized by the department.

(B) Records of pocket dosimeter and electronic personal dosimeter readings of personnel exposures must be maintained for three years.

(C) Records of estimates of exposures resulting from off-scale personal direct-reading dosimeters or lost or damaged individual monitoring devices must be maintained until disposal is authorized by the department.

(6) The following records required by this subsection must be maintained as specified in the following time requirements and subsection (v)(1) of this section.

(A) Records of alarming ratemeter calibrations must be maintained for three years.

(B) Records of individual monitoring device results must be maintained until disposal is authorized by the department.

(q) Access control.

(1) During each industrial radiographic operation, radiographic personnel must 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 not be left unattended except when in storage or physically secured against unauthorized removal or tampering.

(r) Posting. All areas where industrial radiography is being performed must be posted conspicuously as specified in §289.202 of this chapter or §289.231 of this chapter, as applicable, including the following.

(1) Radiation areas. Each radiation area must be posted conspicuously with a sign or signs displaying the radiation caution symbol and the words "CAUTION, RADIATION AREA" or "DANGER, RADIATION AREA."

(2) High radiation area. Each high radiation area must be posted conspicuously with a sign or signs displaying the radiation caution symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA."

(3) Whenever practicable, ropes or barriers must be used in addition to appropriate signs to designate areas as specified in §289.202(n)(1) of this chapter or §289.231(o)(1) of this chapter, as applicable, and to help prevent unauthorized entry.

(4) During pipeline industrial radiographic operations, sufficient radiation signs and other barriers must be posted to prevent unmonitored individuals from entering the area as specified in §289.202(n)(1) of this chapter or §289.231(o)(1) of this chapter, 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 §289.202(n)(1) of this chapter or §289.231(o)(1) of this chapter, as applicable, and be posted as specified in 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 or §289.231(y) of this chapter, 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 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), (q), and (r) of this chapter or §289.231(s)(3) of this chapter, 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 carry a valid certification ID card issued by the department or another certifying entity whose certification offers the same or comparable certification standards.

(3) Each radiographer trainee at a job site must carry a trainee status card issued by the department or equivalent documentation as specified in subsection (e)(1) of this section.

(4) Radiographic personnel must 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 ensure the items listed in paragraph (1) of this subsection, radiographic exposure devices, and radiation machines are used as specified in the requirements of this section.

(5) During an inspection by the department, a department 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 not resume 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 be registered as specified in §289.226 of this chapter.

(B) In addition to the registration requirements in §289.226(e) and (i) of this chapter, an application for a certificate of registration must include:

(i) 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 employed in industrial radiographic assignments.

(ii) written operating, safety, and emergency procedures 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 document that each individual operating a radiation machine has read the operating and safety procedures and must maintain this documentation for inspection by the department. The documentation must include:

(-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 include the items listed in subsection (x)(3) of this section;

(iii) a description of the internal audit program to ensure 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 list and description of all field stations and permanent radiographic installations

(v) 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 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 issued if the requirements of this paragraph of this subsection and §289.226(e) and (i) of this chapter are met.

(2) Locking of radiation machines. The control panel of each radiation machine must be equipped with a locking device preventing the unauthorized use of an x-ray system or the accidental production of radiation. The radiation machine must be kept locked and the key removed except when under the direct visual surveillance of a radiographer.

(3) Permanent storage precautions for the use of radiation machines. Radiation machines must 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 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 be prominently displayed with a durable, legible, clearly visible label 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 conduct an internal audit program to ensure 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 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 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 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 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, other than a radiographer or a radiographer trainee, under the personal supervision of a radiographer trainer, must not 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 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 be made and maintained as specified in subsection (v)(1) of this section.

(J) Records of annual refresher safety training and audits of job performance made as specified in this subsection must include:

(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, records must 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 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 be made after each radiographic exposure using radiation machines to determine the machine is "off."

(C) All potential radiation areas where industrial radiographic operations are performed must be posted as specified in subsection (r) of this section, based on estimated dose rates, before industrial radiographic operations begin. An area survey must be performed during the first radiographic exposure to confirm the requirements of subsection (r) of this section have been met and unrestricted areas do not have radiation levels over the limits specified in §289.231(o)(1)(B) of this chapter.

(D) Records of the surveys required by subparagraph (C) of this paragraph must be made and maintained as specified in 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 be maintained for inspection by the department until disposal is authorized by the department.

(7) Requirements for radiation machines in shielded rooms.

(A) Radiation machines in shielded rooms must comply with all applicable requirements of this section.

(B) Radiation machines in shielded rooms must 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.

(C) Records of the annual evaluation of radiation machines in shielded rooms required by subparagraph (B) of this paragraph must be made and maintained as specified in 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:

(i) Registrants must not 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 be conducted and recorded at intervals not to exceed 12 months.

(iii) The registrant must perform an evaluation to determine compliance with §289.231(o)(1) - (3) of this chapter and 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 be made and maintained as specified in 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 be made and maintained as specified in subsection (v)(1) of this section.

(9) All reciprocal recognition of certificates of registration by the department are granted as specified in §289.226(s) of this chapter.

(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 be licensed as specified in §289.252 of this subchapter.

(B) In addition to the licensing requirements in §289.252 of this subchapter, an application for a license must include.

(i) A schedule or description of the program for training radiographic personnel specifying:

(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 employed in industrial radiographic assignments.

(ii) Written operating, safety, and emergency procedures 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 document each individual operating a sealed source in radiographic operations has read the operating and safety procedures and must maintain this documentation for inspection by the department. The documentation must include:

(-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 include the items listed in subsection (x)(3) of this section.

(iii) A description of the internal audit program to ensure 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.

(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 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 for radioactive material; and

(III) methods for restricting access to radiation areas.

(ix) Procedures verifying and documenting the certification status of radiographers and 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 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 include a description of the procedures to be followed. The description must include:

(I) instruments to be used;

(II) methods of performing the analysis; and

(III) pertinent experience of the individual or individuals analyzing the wipe samples.

(xii) If the applicant intends to perform "in-house" calibrations of survey instruments, the applicant must describe methods to be used and the relevant experience of the individual or individuals performing the calibrations. All calibrations must be performed as specified in subsection (j) of this section.

(C) A license is issued if the requirements of this paragraph and §289.252 of this subchapter 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 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 be kept locked and, if a keyed lock, the key removed except when under the direct visual surveillance of a radiographer or an individual specifically authorized by the department, except at a permanent radiographic installation.

(B) Each radiographic exposure device, storage container, and source changer must be locked and the key removed from any keyed lock before being transported from one location to another and before 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 sealed sources must be secured while in storage to prevent tampering or removal by unauthorized individuals.

(B) Radiographic exposure devices, source changers, or transport containers containing radioactive material must not be stored in residential locations unless specifically authorized by the department.

(5) Performance requirements for industrial radiography equipment. Equipment used in industrial radiographic operations must meet the following minimum criteria.

(A) Each radiographic exposure device, source assembly, sealed source, and associated equipment must 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 comply with the requirements of this section.

(ii) All radiographic exposure devices and associated equipment in use after January 1, 1996, must 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 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 may find this an acceptable alternative to actual testing of the component as specified in 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 meet the applicable requirements of §289.257 of this subchapter.

(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 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 the source to move outside the device must meet the following criteria.

(i) The source assembly must be designed so the source does not become disconnected if cranked outside the guide tube. The source assembly cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.

(ii) The control cable must 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 automatically secure the source assembly when it is cranked back into the fully shielded position within the radiographic exposure device. This

securing system may 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 be equipped with safety plugs or covers installed during storage and transportation to protect the source assembly from damage and from other foreign matter, such as water, mud, or sand.

(v) Each sealed source or source assembly must 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 be used when moving the source out of the radiographic exposure device.

(vii) Guide tubes must be able to withstand a crushing test closely approximating the crushing forces likely to be encountered during use, and be able to withstand a kinking resistance test closely approximating the kinking forces 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 be attached to the outermost end of the guide tube during radiographic operations.

(ix) The guide tube exposure head connection must be able to withstand the tensile test for control units as specified in ANSI N432-1980.

(x) Source changers must provide a system for ensuring the source is not 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 be performed according to the following criteria.

(A) Leak testing of sealed sources must be done as specified in §289.201(g) of this chapter, except records of leak tests must be maintained as specified in subsection (v)(1) of this section.

(B) The replacement, leak testing analysis, repair, opening, or any modification of a sealed source must be performed only by persons specifically authorized to do so by the department, the NRC, or another agreement state.

(C) Each exposure device using DU shielding and an "S" tube configuration must be tested for DU contamination.

(i) Tests for DU contamination must be performed at intervals not to exceed 12 months.

(ii) The analysis must be capable of detecting the presence of 0.005 microcuries (185 becquerels (Bq)) of radioactive material on the test sample and must be performed by a person specifically authorized by the department, the NRC, or an agreement state to perform the analysis.

(iii) Should such testing reveal the presence of DU contamination, the exposure device must be removed from use until an evaluation of the wear of the S-tube has been made.

(iv) Should the evaluation reveal the S-tube is worn through, the device may not be used again.

(v) DU-shielded devices do not have to be tested for DU contamination while in storage and not in use.

(vi) The device must be tested for DU contamination before using or transferring the device, if the interval of storage exceeds 12 months.

(D) A record of the DU leak test must be made and maintained as specified in subsection (v)(1) of this section.

(7) Labeling and storage.

(A) Each transport container must have permanently attached to it a durable, legible, clearly visible label having, at 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 meet applicable requirements of the DOT.

(B) Radiographic exposure devices, source changers, and storage containers must be physically secured to prevent tampering or removal by unauthorized personnel. The licensee must store radioactive material in a manner that will minimize danger from explosion or fire.

(C) The licensee must 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 be prominently displayed with a durable, legible, and clearly visible label on both sides of all vehicles used to transport radioactive material for temporary job site use.

(E) The licensee must ensure each radiographic exposure device has attached to it a durable, legible, and clearly visible label bearing:

(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 a minimum, the standard radiation caution symbol as defined in §289.202 of this chapter, 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 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 conduct an internal audit program to ensure 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 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 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 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 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.

(H) Collimators must be used in industrial radiographic operations using crank-out devices except when physically impossible.

(I) Individuals other than a radiographer or a radiographer trainee, under the personal supervision of a radiographer trainer, must not 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.

(K) Records of annual refresher training and audits of job performance specified in this subsection must be made and maintained as specified in subsection (v)(1) of this section.

(L) Records of annual refresher safety training and audits of job performance made as specified in this subsection must include:

(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 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 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 be made after each radiographic exposure to determine 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 be surveyed. If the radiographic exposure device has a source guide tube, the survey must also include the source guide tube and any collimator.

(C) All potential radiation areas where industrial radiographic operations are performed must be posted as specified in subsection (r) of this section, based on calculated dose rates, before industrial radiographic operations begin. An area survey must be performed during the first radiographic exposure (for example, with the sealed source in the exposed position) to confirm 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 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 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 be performed.

(G) Surveys must be performed in the storage area to ensure radiation levels do not exceed the limits specified in §289.202(n)(1) of this chapter. These surveys must be performed initially with the maximum amount of radioactive material present in the storage area 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 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 be made and maintained as specified in 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 be maintained for inspection by the department until disposal is authorized by the department.

(10) Requirements for shielded rooms containing sealed sources.

(A) Shielded rooms containing sealed sources must comply with all applicable requirements of this section.

(B) Shielded rooms containing sealed sources must 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.

(C) Tests for proper operation of interlocks must be conducted and recorded as specified in subsection (n) of this section.

(D) Records of evaluations required by subparagraph (B) of this paragraph must be made and maintained as specified in subsection (v)(1) of this section.

(E) Records of interlock tests required by subparagraph (C) of this paragraph must be made and maintained as specified in subsection (v)(1) of this section.

(11) Underwater, offshore platform, and lay-barge radiography.

(A) Underwater, offshore platform, and lay-barge radiography must not be performed unless specifically authorized in a license issued by the department as specified in 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 20 curies (Ci) (nominal) (740 gigabecquerels) and iridium-192 sources with activities more than 100 Ci (nominal) (3.7 terabecquerels) must not be used in the performance of offshore platform or lay-barge radiography.

(ii) Collimators must be used for all industrial radiographic operations performed on offshore platforms or lay-barges.

(12) Prohibitions.

(A) Industrial radiography performed with a sealed source not fastened to or contained in a radiographic exposure device (fishpole technique) is prohibited unless specifically authorized in a license issued by the department.

(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 not be performed unless specifically authorized by a license condition.

(13) All reciprocal recognition of licenses by the department are granted as specified in §289.252(ee) of this subchapter.

(v) Record/document requirements. Each licensee and registrant must maintain the following records/documents at each site at the time intervals specified and make them available to the department for inspection.

(1) Time requirements for record keeping. The following are time requirements for record keeping.
Figure: 25 TAC §289.255(v)(1)

(2) Records and documents required at field stations .

(A) Each licensee or registrant maintaining field stations where industrial radiography operations are performed must maintain copies of the following records and documents specific to that site available at each site for inspection by the department 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 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 subsection (i) of this section;

(v) records of the latest survey instrument calibrations in use at the site as specified in subsection (j) of this section;

(vi) records of the latest calibrations of alarming ratemeters and operational checks of pocket dosimeters and electronic personal dosimeters as specified in subsection (p) of this section;

(vii) inventories as specified in subsection (k) of this section;

(viii) utilization records for each radiographic exposure device and radiation machine dispatched from that location as specified in subsection (l) of this section;

(ix) records of equipment problems identified in daily checks of equipment as specified in subsection (m) of this section, if applicable;

(x) records of alarm systems and entrance control checks as specified in subsection (n) of this section;

(xi) training records as specified in subsection (f) of this section;

(xii) records of direct-reading dosimeter readings as specified in subsection (p) of this section;

(xiii) audits as specified in subsections (t)(5)(A) - (C) and (u)(8)(A) - (C) of this section;

(xiv) latest radiation survey records as specified in subsections (t)(6)(D) and (u)(9)(I) of this section;

(xv) records of interlock testing as specified in 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 subsection (t)(7)(C) of this section;

(xvii) records of leak tests for specific devices and sources at the additional site as specified in subsection (u)(6) of this section;

(xviii) shipping papers for the transportation of sources of radiation as specified in §289.257 of this subchapter;

(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 §289.226 of this chapter and §289.252 of this subchapter; and

(xx) individual monitoring records as specified in subsection (p) of this section.

(B) The following records required for each field station as specified in this subsection must 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 subsection (i) of this section;

(ii) inventories as specified in subsection (k) of this section; and

(iii) individual monitoring records as specified in 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 have the following records available at that site for 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 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 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 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 attached to the devices or survey instruments and decay charts for sources 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 §289.226 of this chapter or §289.252 of this subchapter.

(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.

(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 be presented on a formal basis. The training must include the following subjects.

(A) Fundamentals of radiation safety, including:

(i) characteristics of radiation;

(ii) units of radiation dose in rem (sieverts) and quantity of radioactivity in curies (becquerels);

(iii) significance of radiation dose, including:

(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:

(I) working time;

(II) working distances; and

(III) shielding.

(B) Radiation detection instrumentation, including:

(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:

(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 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 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.

(C) Control cables and drive mechanisms must 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.

(D) Pipeliners must 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 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 include instructions in:

(A) handling and use of sources of radiation for industrial radiography so no individual is likely to be exposed to radiation doses more than the limits established in §289.202 of this chapter;

(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 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) 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 subsections (e) and (f) of this section; and

(M) source recovery 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 medical and veterinary use of radioactive material and the issuance of specific licenses authorizing medical and veterinary use of radioactive material. Unless otherwise exempted, persons must not 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 this section.

(2) A person who manufactures, produces, receives, possesses, uses, transfers, owns, or acquires radioactive material before 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 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 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 (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) §289.252 of this subchapter (relating to Licensing of Radioactive Material); and

(G) §289.257 of this subchapter (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 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) Parts 160 and 164) may be subject to privacy standards governing how information identifying 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) 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 have the following meaning unless the context clearly indicates otherwise.

(1) Address of use--The building or buildings identified on the license where radioactive material may be prepared, received, used, or stored.

(2) Area of use--A portion of an address of use 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:

(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:

(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:

(A) meets the requirements in subsections (k) and (m) of this section; or

(B) is identified as an authorized nuclear pharmacist on:

(i) a specific license issued by the department, the NRC, or an agreement state authorizing medical use or the practice of nuclear pharmacy;

(ii) a permit issued by an NRC master material licensee authorizing 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 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 medical use or the practice of nuclear pharmacy; or

(C) is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy authorized to identify authorized nuclear pharmacists; or

(D) is designated as an authorized nuclear pharmacist as specified in §289.252(r) of this subchapter; 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:

(I) a department, NRC, or agreement state license authorizing the medical use of radioactive material;

(II) a permit issued by an NRC master material licensee authorizing 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 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 subsections (gg), (jj), (nn) - (qq), (zz), (aaa), (ccc), and (ttt) of this section as applicable; or

(iii) is identified as an authorized user on:

(I) a department, NRC, or agreement state license authorizing the veterinary use of radioactive material;

(II) a permit issued by an NRC master material licensee authorizing 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 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 designed to deliver a therapeutic dose within a distance of a few centimeters.

(9) High dose-rate remote afterloader--A device remotely delivering a dose rate more than 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 remotely delivering 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 in close proximity to a treatment site or directly in the tissue volume.

(14) Medical event--An event meeting 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 remotely delivering 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, 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 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 the directions of the authorized user for procedures in subsections (ff) and (hh) of this section.

(26) Prescribed dose--Prescribed dose means:

(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 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 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:

(i) a specific license issued by the department, the NRC, or an agreement state authorizing the medical or veterinary use of radioactive material; or

(ii) a permit issued by an NRC master material licensee authorizing the medical or veterinary use of radioactive material.

(29) Sealed source and device registry--The national registry containing all registration certificates, generated by both the NRC and agreement states, summarizing the radiation safety information for sealed sources and devices and describing 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 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 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 tissue intended to receive a radiation dose, as described in a written directive.

(36) Type of use--Use of radioactive material as specified under:

(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:

(A) the research is conducted, funded, supported, or regulated by a federal agency implementing the Federal Policy for the Protection of Human Subjects as required by 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 obtain:

(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) as required by 45 CFR Part 46, and 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 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 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.

(3) Licensees must continue to comply with any license condition requiring implementation of procedures required by subsections (ggg) and (mmm) - (ooo) of this section until there is a license amendment or renewal modifying the license condition.

(f) Specific requirements for the issuance of licenses. In addition to the requirements in §289.252(e) of this subchapter and subsections (n) - (q) of this section, as applicable, a license is issued if the department determines:

(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 information submitted by the applicant is approved, including:

(A) an operating, safety, and emergency procedures manual to include 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;

(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 requested by the department to assist in its review of the application; and

(C) qualifications of the:

(i) RSO as specified in subsection (c)(28) of this section;

(ii) authorized users as specified in subsection (c)(6) of this section as applicable to the uses being requested;

(iii) authorized medical physicist as specified in subsection (c)(4) of this section, if applicable;

(iv) authorized nuclear pharmacist as specified in subsection (c)(5) of this section, if applicable;

(v) ophthalmic physicist as specified in subsection (c)(19) of this section, if applicable;

(vi) Radiation Safety Committee (RSC), as specified in subsection (i) of this section, if applicable; and

(vii) ARSO as specified in 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, a licensee's management must approve in writing:

(A) requests for a license application, renewal, or amendment before submittal to the department; and

(B) any individual before being allowed to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist.

(2) A licensee's management must appoint an RSO who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the RSO, must ensure radiation safety activities are being performed according to 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 not delegate the authority or responsibilities for implementing the radiation protection program.

(3) Every licensee must establish in writing the authority, duties, and responsibilities of the RSO and ensure 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 procedures are current and conform with this chapter;

(B) ensure required radiation surveys and leak tests are performed and documented as specified in this chapter, including any corrective measures when levels of radiation exceed established limits;

(C) ensure individual monitoring devices are used properly by occupationally exposed personnel, records are kept of the monitoring results, and timely notifications are made as specified in §289.203 of this chapter;

(D) investigate and report an individual or radiation level detected over the limits established by this chapter and each theft or loss of sources of radiation, to determine the causes, and take steps to prevent a recurrence;

(E) investigate and report to the department for each known or suspected case of release of radioactive material to the environment over the 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 records are maintained as required by this chapter;

(K) ensure proper storing, labeling, transport, use, and disposal of sources of radiation, storage, and transport containers;

(L) ensure inventories are performed in accordance with the activities for which the license application is submitted;

(M) ensure 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 ensure duties listed in paragraph (3)(A) - (N) of this subsection are performed.

(5) The RSO must be onsite 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 be capable of physically arriving at the licensee's authorized use sites 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 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 subsection (r)(5) of this section. Records of qualifications and dates of service must be maintained as specified in subsection (xxx) of this section for inspection by the department.

(8) A licensee may simultaneously appoint more than one temporary RSO as specified in paragraph (7) of this subsection, if needed to ensure the licensee has a temporary RSO satisfying 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 maintain records, as specified in subsection (xxx) of this section, as follows.

(A) A licensee must retain a record of actions taken by the licensee's management as specified in 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 require the individual fulfilling the responsibilities of an RSO or an individual assigned duties and tasks as an ARSO as specified in 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 recognized by the department, the NRC, or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page.

(A) To have its certification process recognized, a specialty board must 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 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 require all candidates for certification to:

(i) hold a master's or doctoral 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 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 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 knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

(2) has:

(A) completed a structured educational program consisting of both:

(i) 200 hours of classroom and laboratory training in:

(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, NRC, or agreement state license or on a permit issued by an NRC master material licensee authorizing similar types of use of radioactive material. An ARSO may provide supervision for those areas for which the ARSO is authorized on a department, NRC, or an agreement state license or a permit issued by an NRC master material licensee. The full-time radiation safety experience must involve:

(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 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) obtained written attestation, signed by a preceptor RSO or ARSO experienced 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 written attestation must state 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 certified by a specialty board whose certification process has been recognized by the department, the NRC, or an agreement state as specified in subsection (j)(1) of this section, has experience with the radiation safety aspects of similar types of use of radioactive material for which the licensee is seeking approval of the individual as the RSO or ARSO, and 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, NRC, or another agreement state's license; a permit issued by an 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 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 NRC master material licensee. 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 supervised by an RSO, an ARSO, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the types 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 subsections (q), (kk), (rr), and (ddd) of this section, or two or more types of therapeutic units under subsections (q) and (ddd) of this section, must establish an RSC to oversee all uses of radioactive material permitted by the license.

(1) The RSC must be composed of the following individuals:

(A) an authorized user of each type of use permitted by 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) other members as the licensee deems appropriate.

(2) Duties and responsibilities of the RSC.

(A) For licensees without broad scope authorization, the duties and responsibilities of the RSC include:

(i) meeting as often as necessary to conduct business but no less than three times a year;

(ii) reviewing summaries of information presented by the RSO, including:

(I) doses over the occupational or public limits;

(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:

(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) Records documenting the RSC meetings must be made and maintained for inspection by the department as specified in subsection (xxx) of this section. The record must 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 require the authorized medical physicist to be:

(1) an individual 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 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 require all candidates to:

(A) hold a master's or doctoral 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 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 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 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:

(i) a master's or doctoral 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 the requirements for an authorized medical physicist for the types of use for which the individual is seeking authorization. This training and work experience must be conducted 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 and must 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 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 written attestation must be signed by a preceptor authorized medical physicist meeting 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 for the types of use for which authorization is sought, including 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 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 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 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 require all candidates for certification to:

(A) have graduated from a pharmacy program accredited by the Accreditation Council for Pharmacy Education or have passed the Foreign Pharmacy Graduate Examination Committee 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 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:

(A) completed a 700-hour structured educational program, including both:

(i) 200 hours of classroom and laboratory training in:

(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:

(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) obtained written attestation, signed by a preceptor authorized nuclear pharmacist, 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, 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, NRC, or agreement state license or NRC master material license permit for those materials and uses 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 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 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, 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, 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 an NRC master material broad scope license 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 these individuals performed on or before October 24, 2005, as follows:

(i) 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 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 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 specialization 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 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, 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, 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, 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 have been obtained within the seven years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

(n) Licenses for medical and veterinary 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 use of radioactive material as described in the applicable subsections (ff), (hh), (kk), (rr), (bbb), and (ddd) of this section is issued if the department approves documentation showing:

(1) the physicians or veterinarians designated on the application as the authorized users are qualified as specified in subsections (gg), (jj), (nn) - (qq), (zz), (aaa), (ccc), and (ttt) of this section, as applicable;

(2) the radiation detection and measuring instrumentation is appropriate for performing surveys and procedures for the uses involved;

(3) the radiation safety operating procedures are adequate for the handling and disposal of the radioactive material involved in the uses; and

(4) an RSC has been established as specified in subsection (i) 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 issued if the department approves documentation showing:

(1) the review of authorized user qualifications by the RSC is as specified in subsections (gg), (jj), (nn) - (qq), (zz), (aaa), (ccc), and (ttt) of this section, as applicable;

(2) the application is for a license authorizing unspecified forms or multiple types of radioactive material for medical research, diagnosis, and therapy;

(3) the radiation detection and measuring instrumentation is appropriate for performing surveys and procedures for the uses involved;

(4) the radiation safety operating procedures are adequate for the handling and disposal of the radioactive material involved in the uses;

(5) staff has substantial experience in the use of a variety of radioactive material for a variety of human and animal uses;

(6) the full-time RSO meets the requirements of subsection (h) of this section; and

(7) an RSC has been established as specified in 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 issued if the department approves documentation showing:

(1) the physicians designated on the application as the authorized users are qualified as specified in subsection (ttt) of this section;

(2) the radiation detection and measuring instrumentation is appropriate for performing surveys and procedures for the uses involved;

(3) the radiation safety operating procedures are adequate for the handling and disposal of the radioactive material involved in the uses;

(4) the radioactive isotopes to be possessed;

(5) the sealed source manufacturer names and the model numbers of the sealed sources to be installed;

(6) the maximum number of sealed sources of each isotope to be possessed, including the activity of each sealed source;

(7) the manufacturer and model designation of the following units, as applicable:

(A) remote afterloader unit;

(B) teletherapy unit; or

(C) gamma stereotactic radiosurgery unit;

(8) the authorized medical physicist designated on the application is qualified as specified in subsection (j) of this section;

(9) the safety procedures and instructions as required by subsection (ggg) of this section;

(10) the spot check procedures as required by subsections (mmm) - (ooo) of this section, as applicable; and

(11) an RSC has been established as specified in subsection (i) 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 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 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 applicable to radiation safety not addressed in, or different from, requirements in this section;

(B) identification of and commitment to follow the applicable radiation safety program requirements in this section 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 be filed as specified in §289.252(aa) of this subchapter.

(2) A licensee must apply for and must receive a license amendment before:

(A) receiving or using radioactive material for a type of use authorized by this section, but not authorized on their current license issued under 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, NRC, or agreement state license or other equivalent permit or license recognized by the department authorizing 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, NRC, or agreement state specific license of broad scope 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 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 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 the amount or in a different form, or receiving a different radionuclide than authorized on the license;

(E) adding or changing the areas where radioactive material is used or stored and identified in the application or on the license, including areas used as specified in 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 areas of use where radioactive material is used only as specified in either subsection (ff) or (hh) of this section, are exempt;

(F) changing the addresses 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 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, 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 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 as an authorized user, authorized medical physicist, ophthalmic physicist, or authorized nuclear pharmacist providing 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 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 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 radioactive material is used as specified in 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:

(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:

(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 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 be dated and signed by an authorized user before any administration of sodium iodide I-131 greater than 30 microcuries (μCi) (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 to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive must be documented in writing as soon as possible in the patient's record. A written directive must be prepared and signed by the authorized user within 48 hours of the oral directive.

(2) The written directive must 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 μCi (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 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 retain the written directive as specified in 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 develop, implement, and maintain written procedures to provide high confidence:

(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, at a minimum, address the following items applicable for the licensee's use of radioactive material:

(i) verifying the identity of the patient or human research subject;

(ii) verifying the administration is in accordance with the treatment plan, if applicable, and the written directive;

(iii) checking both manual and computer-generated dose calculations;

(iv) verifying 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 maintain a copy of the procedures required by subparagraph (A) of this paragraph as specified in 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 a license issued under §289.252(o) of this subchapter 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 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 subsection (x) of this section, the licensee must 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 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 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 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 maintain a record of each instrument calibration as specified in subsection (xxx) of this section. The record must include:

(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 calibrate the survey instruments used to show compliance with this subsection and with §289.202 of this chapter before first use, annually, and following a repair affecting the calibration. A licensee must:

(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 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 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 determine and record the activity of each dosage.

(2) For a unit dosage, this determination must be made by:

(A) direct measurement of radioactivity; or

(B) a decay correction, based on the activity or activity concentration determined by:

(i) a manufacturer or preparer licensed as specified in §289.252(r) of this subchapter, 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 §289.252(kk) of this subchapter or equivalent NRC or agreement state requirements.

(3) For other than unit dosages, this determination must 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 §289.252(r) of this subchapter, or under an equivalent NRC or agreement state license; or

(ii) a PET radioactive drug producer licensed as specified in §289.252(kk) of this subchapter or equivalent NRC or agreement state requirements.

(4) Unless otherwise directed by the authorized user, a licensee must 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 §289.252(r) of this subchapter 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 maintain a record of the dosage determination required by this subsection as specified in subsection (xxx) of this section for inspection by the department. The record must include:

(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 the total activity is less than 30 μCi (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 or equivalent NRC or agreement state regulations;

(B) sealed sources, not exceeding 30 mCi (1.11 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 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 μCi (7.4 MBq) or 1000 times the quantities in §289.202(ggg)(3) of this chapter; and

(E) technetium-99m in amounts as needed.

(2) Radioactive material in sealed sources authorized by this subsection must not be:

(A) used for medical or veterinary use as defined in subsection (c) of this section except as specified in 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 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:

(1) follow the radiation safety and handling instructions supplied by the manufacturer and the leakage test requirements as specified in §289.201(g) of this chapter and reporting requirements in §289.202(bbb) of this chapter; 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 be made and maintained for inspection by the department as specified in subsection (xxx) of this section and must include:

(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 of the individual who performed the inventory.

(aa) Labeling of vials and syringes. Each syringe and vial containing a radiopharmaceutical must be labeled to identify the radioactive drug. Each syringe shield and vial shield must 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 and except as provided in paragraph (2) of this subsection, a licensee must 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 perform the surveys required by paragraph (1) of this subsection in an area where patients or human research subjects are confined when they cannot be released as specified in 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 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 be retained as specified in subsection (xxx) of this section for inspection by the department. The record must include:

(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 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).

(2) The licensee must 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 include:

(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 maintain for inspection by the department, a record as specified in subsection (xxx) of this section of each patient released according to paragraph (1) of this subsection. The record must include:

(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 issued if the department approves the documentation submitted by the applicant as specified in the requirements of subsections (f) and (n) of this section. The clients of the mobile nuclear medicine service must 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:

(A) obtain a letter signed by the management of each client for which services are rendered permitting the use of radioactive material at the client's address and clearly delineating 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 a minimum, the check for proper function required by this subparagraph must include a constancy check;

(C) have at least one fixed facility where records are maintained and radioactive material is delivered by manufacturers or distributors each day before the mobile nuclear medicine licensee dispatches its vehicles 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.

(2) A mobile nuclear medicine service must 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 be received and handled in conformance with the client's license.

(3) A licensee providing mobile nuclear medicine services must maintain records, for inspection by the department, as specified in 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:

(A) monitors radioactive material at the surface before disposal and determines 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 within containers and handled as biomedical waste after it has been released from the licensee.

(2) The licensee must retain a record of each disposal as required by paragraph (1) of this subsection as specified in subsection (xxx) of this section for inspection by the department. The record must include:

(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 not requiring a written directive. Except for quantities that require a written directive as specified in 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:

(1) obtained from:

(A) a manufacturer or preparer licensed as specified in §289.252(r) of this subchapter or equivalent NRC or agreement state requirements; or

(B) a PET radioactive drug producer licensed as specified in §289.252(kk) of this subchapter 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) 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) 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 require an authorized user of unsealed radioactive material for the uses authorized in subsection (ff) of this section to be:

(1) a physician certified by a medical specialty board whose certification process is recognized by the department, the NRC, or an agreement state. The names of board certifications 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 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 knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(2) an authorized user as specified in subsections (jj) or (nn) of this section or equivalent NRC or agreement state requirements; or

(3) a physician or veterinarian who:

(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 include:

(i) classroom and laboratory training in:

(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 the requirements of this subsection, subsections (l), (jj), or (nn) of this section, or equivalent NRC or agreement state requirements involving:

(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 written attestation 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 in writing 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, 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 not requiring a written directive. Except for quantities requiring a written directive as specified in subsection (t) of this section, a licensee may use any unsealed radioactive material prepared for medical or veterinary use for imaging and localization studies:

(1) obtained from:

(A) a manufacturer or preparer licensed as specified in §289.252(r) of this subchapter or equivalent NRC or agreement state requirements; or

(B) a PET radioactive drug producer licensed as specified in §289.252(kk) of this subchapter 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) 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) 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:

(A) more than 0.15 μCi 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 μCi 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 μCi 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 molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical must measure the molybdenum-99 concentration in each eluate from a generator to demonstrate compliance with paragraph (1) of this subsection.

(3) The licensee using a strontium-82/rubidium-82 generator for preparing a rubidium-82 radiopharmaceutical must, 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 retain a record of each measurement as specified in subsection (xxx) of this section for inspection by the department. The record must include:

(A) for each measured elution of technetium-99m:

(i) the ratio of the measures expressed as µCi 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 µCi of strontium-82 per mCi of rubidium (kBq of strontium-82 per MBq of rubidium-82);

(ii) the ratio of the measures expressed as µCi 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 report any measurement that exceeds the limits in paragraph (1) of this subsection at the time of generator elution, as specified in subsection (www) of this section.

(jj) Training for imaging and localization studies. Except as provided in subsection (l) of this section, the licensee must require an authorized user of unsealed radioactive material for the uses authorized in subsection (hh) of this section to be:

(1) a physician certified by a medical specialty board whose certification process is recognized by the department, the NRC, or an agreement state. The names of board certifications 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 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 knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(2) an authorized user as specified in 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:

(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 include:

(i) classroom and laboratory training in:

(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:

(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 written attestation 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 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 in writing the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user meeting the requirements in subsections (l), (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, 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 a written directive. A licensee may use any unsealed radioactive material iden-

tified in subsection (nn)(2)(A)(ii)(VI) of this section prepared for medical or veterinary use requiring a written directive:

(1) obtained from:

(A) a manufacturer or preparer licensed as specified in §289.252(r) of this subchapter or equivalent NRC or agreement state requirements;

(B) a PET radioactive drug producer licensed as specified in §289.252(kk) of this subchapter 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 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) 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) 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 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 subsection (cc) of this section. The instruction must be appropriate to the personnel's assigned duties and include:

(A) patient or human or animal research subject control; and

(B) visitor control, including:

(i) routine visitation to hospitalized individuals or animals as specified in §289.202(n) of this chapter;

(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 maintain a record for inspection by the department, as specified in subsection (xxx) of this section, of individuals receiving instruction. The record must include:

(A) list of the topics covered;

(B) date of the instruction or training;

(C) names of the attendees; and

(D) names of the personnel who provided the instruction.

(mm) Safety precautions. For each human patient or human research subject who cannot be released as specified in subsection (cc) of this section, the licensee must:

(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 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 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 a written directive. Except as provided in subsection (l) of this section, the licensee must require an authorized user of unsealed radioactive material for the uses authorized in subsection (kk) of this section to be:

(1) a physician certified by a medical specialty board whose certification process is 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 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 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 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 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 Training of the American Osteopathic Association; and

(B) pass an examination, administered by diplomates of the specialty board assessing 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:

(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 include:

(i) classroom and laboratory training in:

(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 the requirements of subsection (l) of this section, this subsection, or equivalent NRC or agreement state requirements. A supervising authorized user meeting the requirements of this paragraph must 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 involve:

(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 work experience must involve a minimum of three cases in:

(-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 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 written attestation 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 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 residency program director affirming in writing the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user meeting 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 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, 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 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:

(1) a physician certified by a medical specialty board whose certification process includes all the requirements of paragraph (3)(A) of this subsection and whose certification is recognized by the department, the NRC, or an agreement state (names of board certifications recognized by the department, the NRC, or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page); or

(2) an authorized user as specified in 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:

(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 include:

(i) classroom and laboratory training, including:

(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 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 the requirements in subsection (nn)(2) of this section must 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 involve:

(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 written attestation 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 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 in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user meeting 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 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, 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 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:

(1) a physician certified by a medical specialty board whose certification process includes all the requirements in paragraph (3)(A) of this subsection and whose certification is recognized by the department, the NRC, or an agreement state (names of board certifications recognized by the department, the NRC, or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page); or

(2) an authorized user as specified in 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:

(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 include:

(i) classroom and laboratory training, including:

(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 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 the requirements of subsection (nn)(2) of this section must also have experience in administering dosages as specified in subsection (nn)(2)(A)(ii)(VI)(-b-) of this section. The work experience must involve:

(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 written attestation 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 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 in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user meeting the requirements in subsections (l), (nn), 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)(-b-) of this section, and concurring 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, 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 require an authorized user for the parenteral administration of unsealed radioactive materials requiring a written directive to be:

(A) an authorized user as specified in 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) an authorized user under subsections (zz) or (ttt) of this section or equivalent NRC or agreement state requirements and meeting the requirements of paragraph (2) of this subsection; or

(C) a physician certified by a medical specialty board whose certification process is recognized by the department, the NRC, or an agreement state as specified in subsections (zz) or (ttt) of this section, and meets the requirements of paragraph (2) of this subsection.

(2) The physician or veterinarian must also:

(A) successfully complete 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 training and experience to include:

(i) classroom and laboratory training, including:

(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 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 the requirements of subsection (nn) of this section, this subsection, or equivalent NRC or agreement state requirements must have experience in administering dosages in the same category or categories as the individual requesting authorized user status. The work experience must involve:

(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 written attestation 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 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 the requirements in subsection (nn) of this section, this section, or equivalent agreement state requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status; or

(ii) a residency program director affirming in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user meeting 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 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, 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 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 not explicitly listed in the Sealed Source and Device Registry, but must be used according to 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 perform a survey to locate and account for all sealed sources not implanted.

(2) Immediately after removing the last temporary implant sealed source from a patient or a human or animal research subject, the licensee must perform a survey of the patient or the human or animal research subject with a radiation detection survey instrument to confirm all sealed sources are removed.

(3) A record of each survey must be retained, for inspection by the department, as specified in subsection (xxx) of this section. The record must include:

(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 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 return brachytherapy sealed sources to a secure storage area.

(3) The licensee must maintain a record of the brachytherapy sealed source accountability as specified in subsection (xxx) of this section for inspection by the department.

(A) When removing temporary implants from storage, the licensee must 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 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 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 provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human or animal research subjects receiving brachytherapy and who cannot be released as specified in subsection (cc) of this section or animals that are confined.

(1) The instruction must be appropriate to the personnel's assigned duties and include:

(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 visitation to hospitalized patients as specified in §289.202(n) of this chapter; 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 maintain a record, for inspection by the department, as specified in subsection (xxx) of this section, of individuals receiving instruction. The record must include:

(A) list of the topics covered;

(B) date of the instruction or training;

(C) names of the attendees; and

(D) names of the personnel who provided the instruction.

(vv) Safety precautions for the use of brachytherapy.

(1) For each patient or human research subject receiving brachytherapy and who cannot be released as specified in subsection (cc) of this section the licensee must:

(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 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 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, the licensee must:

(A) determine the sealed source output or activity using a dosimetry system meeting 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 made as specified in paragraph (1) of this subsection.

(3) The licensee must 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 retain a record of each calibration as specified in subsection (xxx) of this section for inspection by the department. The record must include:

(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 strontium-90 for ophthalmic treatments must ensure 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 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 identified in paragraph (1) of this subsection must:

(A) calculate the activity of each strontium-90 source 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 the administration is in accordance with the written directive. These procedures must include the frequencies 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 the administrations were in accordance with the written directives.

(3) A licensee must maintain a record of the activity of a strontium-90 source as specified in subsection (xxx) of this section for inspection by the department. The record must include:

(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 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 include, as applicable, verification of:

(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 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 recognized by the department, the NRC, or an agreement state. The names of board certifications 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 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 Training of the American Osteopathic Association; and

(B) pass an examination administered by diplomates of the specialty board assessing knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or

(2) has:

(A) completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources, including:

(i) 200 hours of classroom and laboratory training in:

(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 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:

(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 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 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) obtained written attestation 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 preceptor authorized user meeting the requirements of subsection (l) of this section, this subsection, or equivalent NRC or agreement state requirements; or

(ii) a residency program director affirming in writing that the attestation represents the consensus of the residency pro-

gram faculty where at least one faculty member is an authorized user meeting the requirements in subsection (l) of this section, this subsection, or equivalent NRC or agreement state requirements, and concurring 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, 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 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 include:

(i) classroom training in:

(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. This supervised clinical training must involve:

(I) examination of each patient 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 case history; and

(3) has obtained written attestation, signed by a preceptor authorized user meeting 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 use only sealed sources 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 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 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 ensure installation or exchange of sealed sources in medical imaging equipment is performed only by the manufacturer or persons specifically authorized to perform these services by the department, the NRC, or another agreement state. The licensee must maintain a record for each installation or exchange for inspection by the department as specified in subsection (xxx) of this section. The record must 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 require the authorized user of a diagnostic sealed source or a device authorized as specified in subsection (bbb) of this section to be a physician, dentist, podiatrist, or veterinarian who:

(1) is certified by a specialty board whose certification process includes all the requirements of paragraphs (3) and (4) of this subsection and whose certification is recognized by the department, the NRC, or an agreement state (names of board certifications 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 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 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 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 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 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 the sealed source or sources have been removed from the patient or human research subject and returned to the safe shielded position.

(2) The licensee must maintain a record of the surveys as specified in subsection (xxx) of this section for inspection by the department. The record must include:

(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 install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the sealed source shielding, the sealed source 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, or compromise the radiation safety of the unit or the sealed source or sources.

(2) Except for low dose-rate remote afterloader units, only a person specifically licensed by the department, the NRC, or an agreement state may 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 install, replace, relocate, or remove a sealed source contained in the unit.

(4) The licensee must 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 subsection (xxx) of this section for inspection by the department. For each installation, maintenance, adjustment, and repair, the record must include the date, description of the service, and names of the individuals who performed the work.

(ggg) Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

(1) A licensee must:

(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;

(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 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 include:

(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 post instructions at the unit console to inform the operator of:

(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 the operation and safety of the unit:

(A) a licensee must ensure 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 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 ensure operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

(6) A licensee must maintain records of the procedures required by paragraphs (1)(D) and (4)(B)(ii) of this subsection as specified in subsection (xxx) of this section for inspection by the department.

(7) A licensee must maintain records of individuals receiving instruction and participating in drills required by paragraphs (4) and (5) of this subsection as specified in subsection (xxx) of this section for inspection by the department. The record must include:

(A) a list of the topics covered;

(B) date of the instruction or drill;

(C) names of the attendees; and

(D) names of the personnel who provided the instruction.

(hhh) Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. The licensee must:

(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:

(A) prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

(B) cause the sealed source or sources to be shielded promptly when an entrance door is opened; and

(C) prevent the sealed source or sources from being exposed following an interlock interruption until all treatment room entrance doors are closed and the sealed source "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, 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 sealed sources are placed within the patient's or human research subject's body, only conduct treatments allowing expeditious removal of a decoupled or jammed sealed source;

(6) in addition to the requirements specified in paragraphs (1) - (5) of this subsection, require:

(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, 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, trained to remove the sealed source applicator 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, 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 an authorized user and an authorized medical physicist be physically present throughout all patient treatments; 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 have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions are required:

(A) the system was 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 performed within the previous two years and after any servicing that may have affected system calibration; or

(B) the system was calibrated within the previous four years. Eighteen to 30 months after that calibration, the system was intercompared with another dosimetry system 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 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 used for calibrating sealed sources for therapeutic units, the licensee must 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 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 calibrated as specified in paragraph (1) of this subsection. This comparison must 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 retain a record of each calibration, intercomparison, and comparison of dosimetry equipment as specified in subsection (xxx) of this section for inspection by the department. The record must include:

(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 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 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 include determination of:

(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 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 relative dose rates.

(4) The licensee must 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 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 be performed by an authorized medical physicist.

(7) The licensee must retain a record of each calibration as specified in subsection (xxx) of this section for inspection by the department. The record must include:

(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 perform full calibration measurements on each unit:

(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 include, as applicable, determination of:

(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 use the dosimetry system described in subsection (iii)(1) of this section to measure the output.

(4) A licensee must 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 perform an autoradiograph of the sealed source or sources to verify inventory and sealed source 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 paragraphs (1) - (5) of this subsection.

(7) The licensee must 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 be performed by an authorized medical physicist.

(9) The licensee must retain a record of each calibration as specified in subsection (xxx) of this section for inspection by the department. The record must include:

(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; 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 perform full calibration measurements on each gamma stereotactic radiosurgery unit:

(A) before the first medical use of the unit;

(B) before medical use under the following conditions:

(i) whenever spot check measurements indicate 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 include determination of:

(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 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 relative dose rates.

(4) The licensee must 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 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 be performed by an authorized medical physicist.

(7) The licensee must retain a record of each calibration as specified in subsection (xxx) of this section for inspection by the department. The record must include:

(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 perform output spot checks on each teletherapy unit once in each calendar month, including determination of:

(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 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 maintain a copy of the written procedures as specified in subsection (xxx) of this section for inspection by the department.

(3) The licensee authorized to use a teletherapy unit for medical use must perform safety spot checks of each teletherapy facility once in each calendar month and after each sealed source installation to assure proper operation of:

(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."

(4) The licensee must 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 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 retain a record of each spot check required by paragraphs (1) and (3) of this subsection, as specified in subsection (xxx) of this section for inspection by the department. The record must include:

(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 perform spot checks of each remote afterloader facility and on each unit:

(A) before the first use each day 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 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 maintain a copy of the written procedures as specified in subsection (xxx) of this section for inspection by the department.

(3) The licensee must 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, at a minimum, assure proper operation of:

(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 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 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 maintain a record, as specified in subsection (xxx) of this section for inspection by the department, of each check required by paragraph (4) of this subsection. The record must include, 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 perform spot checks of each gamma stereotactic radiosurgery facility and on each unit:

(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 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 maintain a copy of the written procedures as specified in subsection (xxx) of this section for inspection by the department.

(3) The licensee must 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, at a minimum, achieve:

(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:

(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 assure proper operation of:

(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 arrange for prompt repair of any system identified in paragraph (4) of this subsection 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 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 retain a record of each check required by paragraphs (4) and (5) of this subsection as specified in subsection (xxx) of this section for inspection by the department. The record must include:

(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 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:

(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 perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the operation of:

(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 ensure overall proper opera-

tion 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 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 maintain a record for inspection by the department, as specified in subsection (xxx) of this section, of each check required by paragraph (2) of this subsection. The record must include:

(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, a person licensed to use sealed sources in this section must make surveys to ensure the maximum radiation levels and average radiation levels, from the surface of the main sealed source safe with the sealed source or sources in the shielded position, do not exceed the levels stated in the Sealed Source and Device Registry.

(2) The licensee must make the survey required by paragraph (1) of this subsection at installation of a new sealed source and following repairs to the sealed source shielding, the sealed source 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, or compromise the radiation safety of the unit or the sealed source or sources.

(3) The licensee must maintain a record for inspection by the department, as specified in subsection (xxx) of this section, of the radiation surveys required by paragraph (1) of this subsection. The record must 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 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 not exceed five years for each teletherapy unit and must not exceed seven years for each gamma stereotactic radiosurgery unit.

(2) This inspection and servicing must only be performed by persons specifically licensed to do so by the department, the NRC, or an agreement state.

(3) The licensee must maintain a record of the inspection and servicing as specified in subsection (xxx) of this section for inspection by the department. The record must include:

(A) date of inspection;

(B) manufacturer's name, 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 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 include, as applicable, verification of:

(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 require an authorized user of a sealed source for a use authorized in subsection (ddd) of this section to be:

(1) a physician who is certified by a medical specialty board whose certification process is 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 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 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 Training of the American Osteopathic Association; and

(B) pass an examination, administered by diplomates of the specialty board, assessing 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 physician who:

(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:

(i) 200 hours of classroom and laboratory training in:

(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 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 in subsection (ddd) of this section involving:

(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 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 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 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 the requirements in subsection (l) of this section, this subsection, or equivalent NRC or agreement state requirements for the types of therapeutic medical units for which the individual is requesting authorized user status; or

(ii) a residency program director affirming in writing the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user meeting the requirements in subsection (l) of this section, this subsection, or equivalent NRC or agreement state requirements, for the types of therapeutic medical units for which the individual is requesting authorized user status, and concurring 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, 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 physician who has received training in device operation, safety procedures, and clinical use for the types 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, authorized for the types of use for which the individual is seeking authorization.

(uuu) Report and notification of a medical event.

(1) The licensee must report any event as a medical event, except for an event resulting from patient intervention, in which the administration of radioactive material, or radiation from radioactive material, except permanent implant brachytherapy, results in:

(A) a dose differing from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 5 rem (0.05 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:

(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:

(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 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 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:

(i) the wrong radionuclide;

(ii) the wrong individual or human research subject;

(iii) sealed source or sources 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 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 notify the department by telephone no later than the next calendar day after discovery of the medical event.

(5) The licensee must submit a written report to the department within 15 calendar days after discovery of the medical event. The written report must include, excluding 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 who received the administration;

(G) actions, if any, taken or planned to prevent recurrence; and

(H) certification the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

(6) The licensee must notify the referring physician and 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, 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 notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care resulting from the medical event, due to a 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 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 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 annotate a copy of the report provided to the department with:

(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 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 retain a copy of the annotated report of the medical event as specified in 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 report any dose to an embryo/fetus greater than 5 rem (50 mSv) dose equivalent resulting from an administration of radioactive material or radiation from radioactive material to a woman, unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

(2) The licensee must report any dose to a nursing child resulting from an administration of radioactive material to a breastfeeding woman:

(A) greater than 5 rem (50 mSv) TEDE; or

(B) resulting in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

(3) The licensee must 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 a report as specified in paragraphs (1) or (2) of this subsection.

(4) The licensee must 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 paragraphs (1) or (2) of this subsection. The written report must include, 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 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, taken or planned to prevent recurrence; and

(H) certification that the licensee notified the pregnant woman (or the pregnant woman's or child's responsible relative or guardian), and if not, why not.

(5) The licensee must notify the referring physician and also notify the pregnant woman, hereafter referred to as the mother, no later than 24 hours after discovery of an event requiring reporting as specified in 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, 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 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 the event, due to a 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 appropriate. If a verbal notification is made, the licensee must 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 provide such a written description if requested.

(6) The licensee must annotate a copy of the report provided to the department with:

(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 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 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 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 notify 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 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; 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 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)

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

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Cynthia Hernandez
General Counsel
Department of State Health Services
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TITLE 26. HEALTH AND HUMAN SERVICES

PART 1. HEALTH AND HUMAN SERVICES COMMISSION

CHAPTER 745. LICENSING

The Texas Health and Human Services Commission (HHSC) adopts amendments to §745.31 and §745.37; and new §§745.9051, 745.9053, 745.9055, 745.9057, 745.9059, 745.9061, 745.9063, 745.9065, 745.9067, 745.9069, 745.9071, 745.9073, 745.9075, 745.9077, 745.9085, 745.9087, 745.9089, 745.9091, 745.9093, 745.9095, and 745.9097.

Amended §745.31 and §745.37; and new §§745.9053, 745.9055, 745.9057, 745.9059, 745.9061, 745.9063, 745.9065, 745.9067, 745.9069, 745.9071, 745.9073, 745.9075, 745.9087, and 745.9089 are adopted with changes to the proposed text as published in the in the April 26, 2024, issue of the *Texas Register* (49 TexReg 2641). These rules will be republished.

New §§745.9051, 745.9077, 745.9085, 745.9091, 745.9093, 745.9095, and 745.9097 are adopted without changes to the proposed text as published in the April 26, 2024, issue of the *Texas Register* (49 TexReg 2641). These rules will not be republished.

BACKGROUND AND JUSTIFICATION

The amendments and new sections are necessary to comply with House Bill (H.B.) 3121, 87th Legislature, Regular Session, 2021, which created Texas Health and Safety Code Chapter 577A, Psychiatric Residential Youth Treatment Facilities. Chapter 577A mandates HHSC Child Care Regulation (CCR) to create a voluntary process whereby a general residential operation (GRO) may be certified as a psychiatric residential youth treat-

ment facility (PRYTF) to provide treatments and services to individuals 21 years of age or younger with a severe emotional disturbance. Section 577A.004 requires HHSC to adopt rules to implement the chapter. Accordingly, CCR is adopting amended rules in Chapter 745, Subchapter B to (1) clarify that CCR will also regulate PRYTFs that will care for young adults 18 to 21 years of age in addition to child care; and (2) update rules to meet current practice and to improve readability and understanding. In addition, CCR is adopting new rules in Chapter 745, Subchapter O to (1) define terms; (2) create an application process, including requiring accreditation and a current GRO license; (3) create a renewal process every two years; (4) establish application and renewal fees; (5) clarify how inspections, investigations, and confidentiality will apply to PRYTFs; and (6) establish the enforcement actions that HHSC may take against a PRYTF.

COMMENTS

The 31-day comment period ended May 28, 2024. During this period, HHSC received a comment regarding the proposed rules from one commenter representing Texas Alliance of Child and Family Services (the comment was developed from a committee of residential child-care operations, including child-placing agencies, GROs, and residential treatment centers). A summary of the comment relating to the rules and responses from HHSC follows.

Comment: Regarding §745.9053(a)(1), one commenter stated that because out-of-state providers would need to undergo a lengthy process of initial and then full licensure as a GRO, to attract out-of-state providers there should be recognition in standards for qualified providers from out-of-state that can demonstrate they meet comparable requirements in their state.

Response: HHSC disagrees with the comment and declines to revise §745.9053(a)(1). Texas Health and Safety Code §577A.054(a) states that for HHSC may only issue a PRYTF certificate to a GRO that is licensed under Chapter 42, Texas Human Resources Code. Out-of-state providers do not meet this requirement.

CCR updated §§745.9055(a)(2), 745.9057(a), 745.9063(1), and 745.9065 to clarify the GROs responsibility to continue to meet the Texas Human Resources Code §42.0461, regarding public notice and hearing requirements, and §42.252, regarding operational plan requirements.

In addition, HHSC made minor editorial changes to update the term "Licensing" by modifying the rule title at §745.31 and §745.37 without changing the meaning of the rule titles, and by changing "Licensing" to "Child Care Regulation" at §§745.9053(a)(2) and (3)(D), 745.9059, 745.9061, 745.9063, 745.9065, 745.9071 (in the title and at (b)(3)(B)), and 745.9087(2); modify the language to exclude usage of first- and second-person pronouns in §§745.31, 745.37, 745.9055, 745.9057, 745.9059, 745.9061, 745.9063, 745.9065, 745.9067, 745.9069, 745.9071, 745.9073, 745.9075, 745.9087, and 745.9089, but without changing the meaning of the rules; add an "and" at §745.9053(b)(1)(B); and corrected two punctuation errors at §745.9089. HHSC also updated the title of Subchapter B, changing "Child Care and Other Operations That We Regulate" to "Child Care and other Operations That Are Subject to Regulation," and titles in Subchapter O, changing Division 1 from "Definitions for Licensing" to "Licensing" and Division 3 from "Renewals" to "Certificate Renewals."

SUBCHAPTER B. CHILD CARE AND OTHER OPERATIONS THAT ARE SUBJECT TO REGULATION

26 TAC §745.31, §745.37

STATUTORY AUTHORITY

The amendments are adopted under 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, as well as Texas Government Code §531.033, which requires the Executive Commissioner to adopt rules necessary to carry out the duties of HHSC under Chapter 531 of the Texas Government Code. In addition, Texas Health and Safety Code §577A.004 requires HHSC to adopt rules necessary to implement Chapter 577A. Finally, amendments to current rules adopted under Texas Human Resources Code §42.042 are authorized under that section.

§745.31. What operations are subject to regulation under this chapter and corresponding minimum standards?

(a) Child day care and residential child care are subject to regulation under this chapter and corresponding minimum standards, unless Child Care Regulation (CCR) determines the operation is exempt from regulation.

(b) Residential child-care operations include:

(1) Child-placing agencies that verify foster homes and approve adoptive homes; and

(2) General residential operations, which CCR may also certify as a psychiatric residential youth treatment facility (PRYTF) as defined at §745.9051 of this chapter (relating to What do the following words and terms mean when used in this subchapter?).

(c) For a PRYTF, CCR regulates the operation's care of young adults 18 to 21 years of age in addition to child care.

§745.37. What specific types of operations are subject to regulation under this chapter and corresponding minimum standards?

The charts in paragraphs (1) and (2) of this section list the types of operations for child day care and residential child care that are subject to regulation under this chapter and corresponding minimum standards.

(1) Types of Child Day-Care Operations:
Figure: 26 TAC §745.37(1)

(2) Types of Residential Child-Care Operations:
Figure: 26 TAC §745.37(2)

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

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Karen Ray
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SUBCHAPTER O. PSYCHIATRIC RESIDENTIAL YOUTH TREATMENT FACILITY

DIVISION 1. LICENSING

26 TAC §745.9051

STATUTORY AUTHORITY

The new section is adopted under 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, as well as Texas Government Code §531.033, which requires the Executive Commissioner to adopt rules necessary to carry out the duties of HHSC under Chapter 531 of the Texas Government Code. In addition, Texas Health and Safety Code §577A.004 requires HHSC to adopt rules necessary to implement Chapter 577A. Finally, amendments to current rules adopted under Texas Human Resources Code §42.042 are authorized under that section.

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DIVISION 2. APPLICATION PROCESS

26 TAC §§745.9053, 745.9055, 745.9057, 745.9059, 745.9061, 745.9063, 745.9065

STATUTORY AUTHORITY

The new sections are adopted under 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, as well as Texas Government Code §531.033, which requires the Executive Commissioner to adopt rules necessary to carry out the duties of HHSC under Chapter 531 of the Texas Government Code. In addition, Texas Health and Safety Code §577A.004 requires HHSC to adopt rules necessary to implement Chapter 577A. Finally, amendments to current rules adopted under Texas Human Resources Code §42.042 are authorized under that section.

§745.9053. What requirements must a general residential operation meet before applying for a psychiatric residential youth treatment facility (PRYTF) certificate?

(a) Before applying for a PRYTF certificate a general residential operation must:

(1) Have a current initial or full license as a general residential operation;

(2) Have Child Care Regulation's approval to provide treatment services to children with an emotional disorder, as provided in §748.63 of this title (relating to Can I provide each type of service that Licensing regulates?); and

(3) Be accredited by:

(A) The Joint Commission;

(B) The Commission on Accreditation of Rehabilitation Facilities;

(C) The Council on Accreditation; or

(D) Another accreditation organization whose standards relate to the care of children and young adults receiving mental health services in a residential setting and is approved by Child Care Regulation.

(b) To meet the accreditation requirement under subsection (a)(3) of this section, a general residential operation:

(1) May obtain accreditation for:

(A) The entire general residential operation, including the PRYTF; or

(B) Only the part of the general residential operation where the PRYTF will operate; and

(2) May have an initial, provisional, full, or other type of accreditation that is appropriate to the accreditation organization.

§745.9055. What does a completed application for a psychiatric residential youth treatment facility (PRYTF) certificate include?

(a) A general residential operation (GRO) must submit:

(1) A PRYTF certificate application (Form 2973, Psychiatric Residential Youth Treatment Facility Application);

(2) A General Residential Operations - Additional Operation Plan (Form 2960, Application for a License to Operate a Residential Child Care Facility, Attachment C) that describes and includes the capacity of the children to be served by the GRO, including any children and young adults that the PRYTF will serve and as required by Texas Human Resources Code §42.252;

(3) An updated floor plan of the building and surrounding space the entire operation will use, including dimensions of the indoor space and the specific areas to be used by the PRYTF;

(4) Additional written policies required in §748.4821 of this title (relating to What additional policies must a general residential operation (GRO) submit as part of the application process for a psychiatric residential youth treatment facility (PRYTF) certificate?); and

(5) The PRYTF certificate application fee.

(b) The GRO may submit an updated General Residential Operations - Additional Operation Plan (Form 2960, Attachment C) if the GRO is already licensed to provide treatment services to children with emotional disorders.

§745.9057. How do the public notice and hearing requirements apply to an application for a psychiatric residential youth treatment facility (PRYTF) certificate?

(a) A general residential operation (GRO) that is applying for a PRYTF certificate must comply with the rules in Subchapter D, Division 4 of this chapter (relating to Public Notice and Hearing Requirements for Residential Child-Care Operations) if the addition of the PRYTF causes the GRO to meet one of the exceptions in §745.273(b) of this chapter (relating to Which residential child care operations must meet the public notice and hearing requirements?).

(b) The initial public notice and hearing, or a subsequent public notice and hearing, of the GRO must describe and include the capacity of the children and young adults the PRYTF will serve.

(c) If the GRO does not comply with the public notice and hearing requirements, Child Care Regulation may deny the operation a PRYTF certificate.

§745.9059. How long does Child Care Regulation (CCR) have to review an application for a psychiatric residential youth treatment facility (PRYTF) certificate?

(a) CCR has 21 calendar days after receiving a general residential operation's (GRO's) application for a PRYTF certificate to review the paperwork, unless there is good cause to exceed this timeframe.

(b) After CCR reviews the GRO's application, CCR will notify the GRO in writing that:

(1) There is good cause to delay the timeframe for making a determination on the application, consistent with §745.327 of this chapter (relating to When does Licensing have good cause for exceeding its timeframes for processing my application?);

(2) The GRO is ineligible to receive a PRYTF certificate because it does not meet one or more of the requirements under §745.9053(a) of this division (relating to What requirements must a general residential operation meet before applying for a psychiatric residential youth treatment facility (PRYTF) certificate?);

(3) The GRO's application is complete and accepted for processing; or

(4) The GRO's application is incomplete. The notification letter will:

(A) Identify any application materials submitted that do not show compliance with relevant statutes, rules, or minimum standards; and

(B) Explain what the GRO must do to complete the application.

(c) If the GRO's application is not complete by the first anniversary of the date the GRO submitted its application for a PRYTF certificate, CCR will close the application and the GRO must submit a new application, materials, and a PRYTF certificate application fee.

§745.9061. How long does Child Care Regulation (CCR) have to determine whether to issue a psychiatric residential youth treatment facility (PRYTF) certificate after accepting the application?

(a) CCR determines whether to issue a PRYTF certificate no later than two months after CCR accepts the application, unless there is good cause to exceed this timeframe consistent with §745.327 of this chapter (relating to When does Licensing have good cause for exceeding its timeframes for processing my application?).

(b) The general residential operation may file a complaint regarding timeframes according to §745.325 of this chapter (relating to How do I file a complaint regarding timeframes for processing my application?).

§745.9063. What factors will Child Care Regulation (CCR) consider when evaluating an application for a psychiatric residential youth treatment facility (PRYTF) certificate?

CCR determines whether to issue a PRYTF certificate by considering:

(1) The application and any information submitted with the application, including any information noted in Texas Human Resources Code §42.252(f);

(2) The on-site inspection to determine compliance with relevant statutes, rules, and minimum standards;

(3) Any information that CCR gathers through the application process, including any written comments and written information submitted to CCR during the process that CCR considers to be relevant to the decision to issue the PRYTF certificate; and

(4) If a public hearing is required by the GRO under §745.273(b) of this chapter (relating to Which residential child-care operations must meet the public notice and hearing requirements?) any requirements under Texas Human Resources Code §42.0461, including the Verbatim Record and summary Report of Public Comment from the Community, as required in §745.275 of this chapter (relating to What are the specific requirements for a public notice and hearing?).

§745.9065. For what reason may Child Care Regulation (CCR) deny a psychiatric residential youth treatment facility (PRYTF) certificate based on the results of a required public hearing?

If a public hearing is required in §745.273 of this chapter (relating to Which residential child-care operations must meet the public notice and hearing requirements?), CCR may deny the general residential operation's request for a PRYTF certificate for a reason described in Texas Human Resources Code §42.0461(e).

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

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Karen Ray
Chief Counsel
Health and Human Services Commission
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DIVISION 3. CERTIFICATE RENEWALS

26 TAC §§745.9067, 745.9069, 745.9071, 745.9073

STATUTORY AUTHORITY

The new sections are adopted under 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, as well as Texas Government Code §531.033, which requires the Executive Commissioner to adopt rules necessary to carry out the duties of HHSC under Chapter 531 of the Texas Government Code. In addition, Texas Health and Safety Code §577A.004 requires HHSC to adopt rules necessary to implement Chapter 577A. Finally, amendments to current rules adopted under Texas Human Resources Code §42.042 are authorized under that section.

§745.9067. When does a psychiatric residential youth treatment facility (PRYTF) need to apply to renew the PRYTF certificate?

(a) A PRYTF must apply to renew the PRYTF certificate every two years after the date Child Care Regulation (CCR) issues the certificate.

(b) A PRYTF must timely apply to renew the PRYTF certificate, even if:

(1) There is a pending civil or administrative penalty against the PRYTF; or

(2) The general residential operation or PRYTF is under an enforcement action.

(c) During the year that the PRYTF renews the PRYTF certificate, the renewal period:

(1) Begins 60 calendar days before the anniversary of when CCR issued the PRYTF certificate; and

(2) Ends on the date of the anniversary.

(d) If the PRYTF is late in applying for renewal of the PRYTF certificate, the PRYTF has 30 additional calendar days after the renewal period to apply for renewal.

§745.9069. What does a completed renewal application for a psychiatric residential youth treatment facility (PRYTF) certificate include?

A PRYTF must submit a completed PRYTF renewal application, which includes:

(1) Timely submitting the renewal application as required by §745.9067 of this division (relating to When does a psychiatric residential youth treatment facility (PRYTF) need to apply to renew the PRYTF certificate?);

(2) Verification that the following information is current and accurate:

(A) The list of controlling persons at the operation; and

(B) The list of governing body's members, such as officers and owners, if applicable;

(3) A statement as to whether the operation continues to need any existing waivers and variances that the PRYTF will also want to apply to the care of children and young adults receiving psychiatric health treatments and services;

(4) Validation on the provider website the list of persons who require a background check because of their association with the operation;

(5) Verification of the ongoing accreditation of the PRYTF; and

(6) A PRYTF certificate renewal fee.

§745.9071. What happens after Child Care Regulation (CCR) receives a psychiatric residential youth treatment facility (PRYTF)renewal application?

(a) After receiving a PRYTF renewal application, CCR evaluates whether:

(1) The PRYTF completed the renewal application as required by §745.9069 of this division (relating to What does a completed renewal application for a psychiatric residential youth treatment facility (PRYTF) certificate include?);

(2) The general residential operation license is current and approved to provide treatment services to children with emotional disorders;

(3) The PRYTF has paid each administrative penalty that the PRYTF owes after waiving or exhausting any due process provided under Texas Health and Safety Code §571.025; and

(4) The PRYTF meets the statutory, rule, and minimum standard requirements after CCR inspects the PRYTF.

(b) Within 30 calendar days of receiving the renewal application, CCR will send written notice that:

(1) CCR has renewed the PRYTF certificate;

(2) The PRYTF renewal application is incomplete because it did not meet one or more of the renewal application requirements in subsection (a) of this section; or

(3) CCR refuses to renew the PRYTF certificate because:

(A) The PRYTF did not submit a completed PRYTF renewal application;

(B) The PRYTF is no longer accredited as required by §748.4823(a) of this title (relating to When must a psychiatric residential youth treatment facility (PRYTF) notify Child Care Regulation (CCR) about accreditation changes regarding the PRYTF?);

(C) The general residential operation does not have a license;

(D) The general residential operation is not approved to provide treatment services to children with emotional disorders;

(E) The PRYTF did not pay the PRYTF certificate renewal fee;

(F) The PRYTF did not pay an administrative penalty that the PRYTF owes after waiving or exhausting any due process provided under Texas Health and Safety Code §571.025; or

(G) After inspecting the PRYTF, CCR determined that it does not meet the statute, rule, and minimum standard requirements.

(c) If the PRYTF renewal application is incomplete, the written notice will include:

(1) CCR's determination that the PRYTF did not meet one or more of the renewal application requirements in subsection (a) of this section; and

(2) A list of the requirements that the PRYTF must complete before CCR can renew the PRYTF certificate.

(d) If the PRYTF submitted an incomplete renewal application during the renewal period, the PRYTF may attempt to submit the missing information until the PRYTF certificate expires.

(e) If the PRYTF submitted an incomplete renewal application during the late renewal period, the PRYTF has 15 calendar days to submit a completed application from the date CCR determined that the renewal application was incomplete.

§745.9073. When does a psychiatric residential youth treatment facility (PRYTF) certificate expire?

(a) A PRYTF certificate expires if:

(1) The PRYTF does not submit a renewal application during the renewal period or late renewal period;

(2) The PRYTF submits a renewal application during the renewal period, the PRYTF was notified that the application was incomplete, and the PRYTF did not submit a completed renewal application before the end of the late renewal period; or

(3) The PRYTF submits a renewal application during the late renewal period, the PRYTF was notified that the application was incomplete, and the PRYTF did not submit a completed renewal application within 15 calendar days after notification.

(b) If the PRYTF certificate expires:

(1) Within 24 hours, the general residential operation (GRO) must inform the following persons that the PRYTF certificate has expired;

(A) All parents of children receiving psychiatric health treatments and services; and

(B) Young adults and any guardians of the young adults receiving psychiatric health treatments and services;

(2) The GRO must immediately:

(A) Discharge and stop providing care to the young adults 18 to 21 years of age receiving psychiatric health treatments and services unless the young adult meets the requirements of §748.1931 of this title (relating to After a child in my care turns 18 years old, may the person remain in my care?);

(B) For children receiving psychiatric health treatments and services:

(i) Enroll the child into the general residential operation, if appropriate; or

(ii) Discharge the child to the child's parents.

(3) Before the GRO that had the PRYTF certificate can operate again as a PRYTF, the PRYTF must submit a new PRYTF application, materials, and PRYTF certificate application fee.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

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Karen Ray
Chief Counsel
Health and Human Services Commission
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DIVISION 4. FEES

26 TAC §745.9075

STATUTORY AUTHORITY

The new section is adopted under 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, as well as Texas Government Code §531.033, which requires the Executive Commissioner to adopt rules necessary to carry out the duties of HHSC under Chapter 531 of the Texas Government Code. In addition, Texas Health and Safety Code §577A.004 requires HHSC to adopt rules necessary to implement Chapter 577A. Finally, amendments to current rules adopted under Texas Human Resources Code §42.042 are authorized under that section.

§745.9075. What fees must a general residential operation (GRO) pay to apply for and maintain its psychiatric residential youth treatment facility (PRYTF) certificate?

In addition to the fees required by §745.509 of this chapter (relating to What fees must I pay to apply for and maintain a license for an operation?), the following chart contains non-refundable fees applicable to a PRYTF, when the fees are due, and the consequences for failure to pay on time:
Figure: 26 TAC §745.9075

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

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Karen Ray
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DIVISION 5. INSPECTIONS, INVESTIGATIONS, AND CONFIDENTIALITY

26 TAC §745.9077

STATUTORY AUTHORITY

The new section is adopted under 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, as well as Texas Government Code §531.033, which requires the Executive Commissioner to adopt rules necessary to carry out the duties of HHSC under Chapter 531 of the Texas Government Code. In addition, Texas Health and Safety Code §577A.004 requires HHSC to adopt rules necessary to implement Chapter 577A. Finally, amendments to current rules adopted under Texas Human Resources Code §42.042 are authorized under that section.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

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DIVISION 6. ENFORCEMENT

26 TAC §§745.9085, 745.9087, 745.9089, 745.9091, 745.9093, 745.9095, 745.9097

STATUTORY AUTHORITY

The new sections are adopted under 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, as well as Texas Government Code §531.033, which requires the Executive Commissioner to adopt rules necessary to carry out the du-

ties of HHSC under Chapter 531 of the Texas Government Code. In addition, Texas Health and Safety Code §577A.004 requires HHSC to adopt rules necessary to implement Chapter 577A. Finally, amendments to current rules adopted under Texas Human Resources Code §42.042 are authorized under that section.

§745.9087. Denial of certificate.

The Texas Health and Human Services Commission (HHSC) may deny a psychiatric residential youth treatment facility (PRYTF) certificate if HHSC determines ineligibility based on:

(1) A provision in Texas Health and Safety Code Chapter 577A; or

(2) HHSC's evaluation of the application under the criteria described in §745.9063 of this subchapter (relating to What factors will Child Care Regulation (CCR) consider when evaluating an application for a psychiatric residential youth treatment facility (PRYTF) certificate?).

§745.9089. Refusal To Renew.

The Texas Health and Human Services Commission (HHSC) may refuse to renew a psychiatric residential youth treatment facility (PRYTF) certificate for a reason listed in §745.8605 of this chapter (relating to When can Licensing recommend or impose an enforcement action against my operation?) or if:

(1) The PRYTF did not submit a complete renewal application, timely or otherwise, according to §745.9069 of this subchapter (relating to What does a completed renewal application for a psychiatric residential youth treatment facility (PRYTF) certificate include?);

(2) The PRYTF was not accredited at the time of the renewal;

(3) The general residential operation (GRO) does not have a current license to operate at the time of the renewal, including if:

(A) HHSC revokes the GRO's license;

(B) HHSC refuses to renew the GRO's license;

(C) The GRO voluntarily closes;

(D) HHSC suspends the GRO's license; or

(E) The GRO voluntarily suspends their license;

(4) The GRO is not approved to provide treatment services to children with an emotional disorder at the time of renewal;

(5) The PRYTF has not paid an administrative penalty after waiving or exhausting any due process provided under Texas Health and Safety Code §571.025;

(6) The PRYTF has not timely submitted the renewal fee to HHSC; or

(7) The PRYTF does not meet:

(A) A provision in Texas Health and Safety Code Chapter 577A;

(B) A rule in this subchapter; or

(C) A minimum standard in Chapter 748, Subchapter W of this title (relating to Additional Requirements for Operations that Provide Psychiatric Health Treatments and Services).

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

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CHAPTER 748. MINIMUM STANDARDS FOR GENERAL RESIDENTIAL OPERATIONS

The Texas Health and Human Services Commission (HHSC) adopts an amendment to §748.61; and new §§748.4801, 748.4803, 748.4805, 748.4807, 748.4809, 748.4821, 748.4823, 748.4825, 748.4831, 748.4833, 748.4841, 748.4843, 748.4845, 748.4847, 748.4851, 748.4861, 748.4863, 748.4865, 748.4867, 748.4869, and 748.4881.

Amended §748.61 and new §§748.4803, 748.4807, 748.4821, 748.4823, 748.4825, 748.4841, 748.4843, 748.4845, 748.4847, 748.4861, 748.4863, 748.4865, 748.4867, 748.4869, and 748.4881 are adopted with changes to the proposed text as published in the in the April 26, 2024, issue of the *Texas Register* (49 TexReg 2671). These rules will be republished.

New §§748.4801, 748.4805, 748.4809, 748.4831, 748.4833, and 748.4851 are adopted without changes to the proposed text as published in the April 26, 2024, issue of the *Texas Register* (49 TexReg 2671). These ruleswill not be republished.

BACKGROUND AND JUSTIFICATION

The amendment and new sections are necessary to comply with House Bill (H.B.) 3121, 87th Legislature, Regular Session, 2021, which created Texas Health and Safety Code Chapter 577A, Psychiatric Residential Youth Treatment Facilities. Chapter 577A mandates HHSC Child Care Regulation (CCR) to create a voluntary process whereby a general residential operation (GRO) may be certified as a psychiatric residential youth treatment facility (PRYTF) to provide treatments and services to individuals 21 years of age or younger with a severe emotional disturbance. Section 577A.004 requires HHSC to adopt rules to implement Chapter 577A; and Section 577A.101 requires HHSC to adopt minimum standards for a certified PRYTF. Accordingly, CCR is adopting an amended rule in Chapter 748, Subchapter B to update the types of services CCR regulates to include treatment services for individuals who are 21 of age or younger with a severe emotional disturbance that are admitted to a certified PRYTF. In addition, CCR is adopting new rules in Chapter 748, Subchapter W to (1) define terms and explain the scope of the rules; (2) add requirements for policies, notifications and postings, including requiring ongoing accreditation; (3) require a treatment director; (4) update the training requirements for a caregiver and certain employees; (5) update the child to caregiver ratio during night-sleeping hours; and (6) add admission criteria and specific requirements for plans of care.

COMMENTS

The 31-day comment period ended May 28, 2024. During this period, HHSC received comments regarding the proposed rules

from five commenters: Disability Rights Texas, Texas Medical Association, Texas Association of Health Plans, Texas Alliance of Child and Family Services (the comments were developed from a committee of residential child-care operations, including child-placing agencies, GROs, and Residential Treatment Centers), and an individual. A summary of the comments relating to the rules and responses from HHSC' follows.

Comment: Regarding §748.4821 and §748.4863, one commenter was concerned with mixing older residents with younger residents who may be easily manipulated or at risk of potentially more sophisticated and predatory residents. While the language of §748.4863 addresses separating the populations during therapeutic services and in living quarters, §748.4821 leaves up to the facility the development of a policy to protect the separation of the populations in relation to use of restrooms and indoor/outdoor activities. The commenter strongly recommended that HHSC provide more guidance to providers in terms of what the goal of the policy is and the expectation that staff will ensure the separation of the populations. As it relates to restrooms, the policy should address ensuring the restrooms are locked and unlocked by staff who monitor the use. In the activity areas, the policy should stipulate sufficient staff to supervise all the activity areas while in use to ensure the continued separation of the populations.

Response: HHSC agrees in part and disagrees in part with the comment. HHSC agrees that the standards can provide more guidance to support a stronger policy but does not agree that the policy must mandate locked restrooms and absolute separation of the populations in all instances. Accordingly, HHSC is enhancing the policy requirement at §748.4821(2) regarding the supervision of PRYTF young adults and children when sharing restrooms or indoor or outdoor activity areas. Although the PRYTF population and general population can mix for short periods of time, the enhanced policy now requires a schedule for PRYTF young adults and children to use restrooms and for indoor and outdoor activity times, and an outline for the specific staffing schedule caregivers will use and how caregivers will maintain supervision, based on the supervision needs in the young adults' and children's service plans. After the PRYTF submits the policy, CCR staff are required to review it to determine if the policy is consistent with minimum standards considering the operation's program and number of children in care and then provide feedback as needed.

Comment: Regarding §748.4833, one commenter recommended that non-physician health care professionals be removed as an option for being a treatment director because only physicians would be able to provide or oversee the level of care specified by the underlying Texas statue or other state or federal standards for psychiatric facilities, including federal psychiatric hospitals and psychiatric residential treatment facilities for individuals under the age of 21. The commenter stated that since a facility is required to admit or provide treatment services only when the individual "requires residential psychiatric treatment under the direction of a licensed physician to improve the individual's condition," the underlying statute contemplates those treatments be provided under the direction of a physician.

Response: HHSC disagrees and declines to revise the rule in response to the comment. A treatment director is not responsible for the direct treatment of an individual but, as noted in current §748.603, is responsible for the overall treatment program, including clinical responsibility for the management of therapeutic interventions, providing directions and overall management of the treatment program, and overseeing the treatment of all children receiving treatment services. Chapter 748 does not contemplate a treatment director making medical decisions that cannot be legally made. Instead, the service planning team is responsible for developing the service plan and new §748.4869(c) requires a psychiatrist or physician to be on the service planning team to develop an individual's service plan (which is another name for a treatment plan). These plans are also based on an individual's admission assessment; identification of medical needs and therapeutic needs, including a plan for a psychiatric evaluation; follow-up treatment; testing; and the use of psychotropic medications. A service plan also requires a list of emotional, physical, and social needs that require specific professional expertise, and plans to obtain the appropriate professional consultation and treatment for those needs. Also, the federal statutes do not apply to PRYTFs, and Texas Health and Safety Code §577A.002 explicitly exempts a PRYTF from state licensure requirements for a mental hospital, private mental hospital, or other mental health facility licensed under Texas Health and Safety Code Chapter 577.

Comment: Regarding §§748.4843, 748.4845, and 748.4847 related to training, one commenter strongly recommended that mandated training be competency-based. The training should include testing to provide evidence that the person heard, understood, and can apply the training to the work situation. Most training programs, including on line, require testing to demonstrate the individual's competence when the training is completed.

Response: HHSC agrees with the comment. The intent of the additional training is that it meets the current training requirements related to instructor requirements, being competency-based, curriculum requirements, timely completion of the training, appropriate types of training, and documentation. As such, the three training rules have been revised accordingly.

Comment: Regarding §748.4867 and additional specific services an initial service plan must include, one commenter recommended adding language that the services must be included "unless consultation with professionals, documented in the youth's treatment records, indicates that such services are inappropriate for the initial service plan" or similar language to account for the need for clinical judgement in identifying services.

Response: HHSC disagrees and declines to revise the rule in response to the comment. The added services are specifically required by Texas Health and Safety Code §577A.101.

Comment: Regarding §748.4869(a) and (b), one commenter had concerns whether the requirement that a licensed psychiatrist or physician be included in the care team when providing psychiatric health treatments and services extends to the service planning team as contemplated under Texas Health and Safety Code Chapter 577A. The commenter also had concerns that treatment services regarding medical needs would be outside the scope of practice of non-physician behavioral health professionals listed in proposed subsection (b) and recommended a psychiatrist or physician be included on the service planning team for children with primary medical needs.

Response: HHSC disagrees with the comment and declines to revise subsection (a) of the rule or make the suggested change to subsection (b) of the rule at this time. CCR specifically added the requirement that a licensed psychiatrist or physician be included in the service planning team to develop an initial ser-

vice plan for an individual that will be receiving psychiatric health treatments and services in subsection (c) in response to Texas Health and Safety Code Chapter 577A. Regarding children with primary medical needs, §748.4869 replaces §748.1339 for PRYTFs, but subsection (b) has not changed from what is in current §748.1339. Any change to §748.4869(b) would only impact PRYTFs and would not impact all GROs. HHSC will review the comment requiring a psychiatrist or a physician to be on the service planning team for a child with primary medical needs in the next comprehensive rule review, which will also ensure the public can comment on any more broadly proposed change.

Comment: Regarding §748.4869(c), one commenter recommended deleting a licensed or registered occupational therapist from the list of professionals that could be on the initial service planning team for an individual receiving psychiatric health treatments and services because the occupational therapist may not have the relevant skill set. The commenter did recommend keeping subparagraph (c)(6) for allowance of other disciplines and professions.

Response: HHSC agrees with the comment and has revised the rule as recommended.

There were also several general comments regarding the rules.

General Comment 1: Two commenters had three comments related to funding.

General Comment 1A: One commenter recognized the need for high quality settings to serve children with higher needs, but there doesn't seem to be a clear funding mechanism. The commenter encouraged the state to continue to search for options that are sufficiently funded, like Qualified Residential Treatment Programs (QRTPs), the Residential Treatment Center (RTC) Division Project, and the state's transition to the Texas Child-Centered Care (T3C) structure for rates and delivery of residential care.

General Comment 1B: One commenter stated that there is no rate structure to support the specialized PRYTF setting, so it is unlikely to attract qualified providers.

General Comment 1C: One commenter stated that there is a gap in Medicaid coverage for residential treatment for youth experiencing mental health challenges, especially after short-term crisis stabilization in a psychiatric hospital. The commenter recommended aligning the PRYTF standards with the federal Medicaid Psychiatric Residential Treatment Facilities (PRTFs) standards to create a pathway for Medicaid coverage for children with severe mental health needs.

Response to General Comments 1A, 1B, and 1C: The comments are outside the scope of this rule project. H.B. 3121 did not provide a funding mechanism or otherwise address funding for care in a PRYTF. Moreover, the alignment of PRYTF standards with PRTF standards would not make these individuals Medicaid eligible. Medicaid PRTF funding is not currently in the Texas Medicaid state plan, so funding would not be available even if the standards were aligned at this time. However, if Medicaid PRTF funding is made available later, HHSC can look at the option of aligning these standards. Finally, the comment to encourage the continued search for options that are sufficiently funded, like QRTPs, the RTC Division Project, and the state's transition to T3C structure for rates and delivery of residential care, will be forwarded to the appropriate persons associated with these options in HHSC and the Department of Family and Protective Services.

General Comment 2: One commenter found the PRYTF title confusing with Medicaid Psychiatric Residential Treatment Facilities (PRTFs) and preferred a different nomenclature, maybe Youth Treatment Facility.

Response: HHSC disagrees and declines to revise any rule in response to the comment. HHSC understands the nomenclature problem for this type of facility; however, HHSC does not find any alternative title for a PRYTF, including Youth Treatment Facility, any less confusing and the PRYTF title is specifically used in Texas Health and Safety Code Chapter 577A.

General Comment 3: One commenter expressed concern with mixing the PRYTF population with the general GRO population.

Response: HHSC disagrees and declines to revise any rule in response to the comment. There are already regulations in place that support the general GRO population of children in care. This includes training requirements, supervision requirements, and specific supervision requirements noted on each child's service plan that must be followed. In addition, a GRO is already required to be approved to provide treatment services to children with emotional disorders, so a GRO should be very aware of this population. If a GRO cannot ensure the safety of a child in a mixed population setting, then the GRO would have to find a different solution to protect the safety of the child. Finally, a GRO that does not want to mix the PRYTF population with the general GRO population is not required to.

General Comment 4: One commenter expressed concern with HHSC assuming jurisdiction over the adult PRYTF population as this may be a slippery slope into taking authority over the extended foster care population, which could lead to negative outcomes for those young adults if they are investigated and treated as perpetrators rather than young adults in care.

Response: HHSC disagrees and declines to revise any rule in response to the comment. While the Texas Health and Safety Code Chapter 577A gives HHSC jurisdiction over PRYTFs, including their care of young adults, HHSC has no authority to assume jurisdiction under the Texas Human Resources Code Chapter 42 for the extended foster care population.

General Comment 5: One commenter expressed strong support for the PRYTF rules to expand the current limited capacity for children and young adults seeking quality local mental health services.

Response: HHSC appreciates the support of Alec's Law and the PRYTF rules.

In addition, HHSC made several minor editorial changes to delete the term "Licensing" by modifying the rule title at §748.61 without changing the rule title meaning, and by replacing "Licensing" with "Child Care Regulation" at §748.4823; modify the language to exclude usage of first- and second-person pronouns in §§748.61, 748.4803, 748.4807, 748.4821, 748.4823, 748.4825, 748.4841, 748.4843, 748.4861, 748.4863, 748.4865, 748.4867, 748.4869, and 748.4881, but without changing the meaning of the rules; update a citation at §748.61(3)(E); correct punctuation and add an "and" at §748.4821(1); correct the term "psychiatric health treatments and services" in several places at §748.4843(b)(1) and (2) and §748.4847(b)(2)(A) and (B) and (d)(1) and (2); and correct the spelling of "may" at §748.4863(c).

SUBCHAPTER B. DEFINITIONS AND SERVICES

DIVISION 2. SERVICES

26 TAC §748.61

STATUTORY AUTHORITY

The amendment is adopted under 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, as well as Texas Government Code §531.033, which requires the Executive Commissioner to adopt rules necessary to carry out the duties of HHSC' under Chapter 531 of Texas Government Code. In addition, Texas Health and Safety §577A.004 requires HHSC to adopt rules necessary to implement Chapter 577A and §577A.101 requires HHSC to adopt minimum standards for a certified PRYTF. Finally, amendments to current rules adopted under Texas Human Resources Code §42.042 are authorized under that section.

§748.61. What types of services are subject to regulation under this chapter?

The following types of services are subject to regulation under this chapter:

(1) Child-Care Services--Services that meet a child's basic need for shelter, nutrition, clothing, nurture, socialization and interpersonal skills, care for personal health and hygiene, supervision, education, and service planning;

(2) Treatment Services--In addition to child-care services, a specialized type of child-care services designed to treat and support children:

(A) With an Emotional Disorder who have a:

(i) Current Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5) diagnosis, such as mood disorders, psychotic disorders, or dissociative disorders, and demonstrate two or more of the following:

(I) Major self-injurious actions, including a suicide attempt within the last 12 months;

(II) Difficulties that present a significant risk of harm to others, including frequent or unpredictable physical aggression; or

(III) An additional DSM-5 diagnosis of substance-related or addictive disorder with severe impairment; or

(ii) Severe emotional disturbance as defined by §748.4801 of this chapter (relating to What do the following terms mean when used in this subchapter?) who are admitted to a certified psychiatric residential youth treatment facility also defined at §748.4801 of this chapter, in addition to young adults 18 to 21 years of age who also qualify for these services;

(B) With a DSM-5 diagnosis of Intellectual Disability that is characterized by prominent, severe deficits and pervasive impairment in one or more of the following areas:

(i) Conceptual, social, and practical adaptive skills to include daily living and self-care;

(ii) Communication, cognition, or expressions of affect;

(iii) Self-care activities or participation in social activities;

(iv) Responding appropriately to an emergency; or

(v) Multiple physical disabilities, including sensory impairments;

(C) With a DSM-5 diagnosis of Autism Spectrum Disorder that is characterized by prominent, severe deficits and pervasive impairment in one or more of the following areas of development:

(i) Conceptual, social, and practical adaptive skills to include daily living and self-care;

(ii) Communication, cognition, or expressions of affect;

(iii) Self-care activities or participation in social activities;

(iv) Responding appropriately to an emergency; or

(v) Multiple physical disabilities, including sensory impairments;

(D) With Primary Medical Needs, who cannot live without mechanical supports or the services of others because of life-threatening conditions, including:

(i) The inability to maintain an open airway without assistance, which does not include the use of inhalers for asthma;

(ii) The inability to be fed except through a feeding tube, gastric tube, or a parenteral route;

(iii) The use of sterile techniques or specialized procedures to promote healing, prevent infection, prevent cross-infection or contamination, or prevent tissue breakdown; or

(iv) Multiple physical disabilities including sensory impairments; and

(E) Determined to be a trafficking victim, including a child:

(i) Determined to be a trafficking victim as the result of a criminal prosecution or who is currently alleged to be a trafficking victim in a pending criminal investigation or prosecution;

(ii) Identified by the parent or agency that placed the child in the operation as a trafficking victim; or

(iii) Determined by the operation to be a trafficking victim based on reasonably reliable criteria, including one or more of the following:

(I) The child's own disclosure as a trafficking victim;

(II) The assessment of a counselor or other professional; or

(III) Evidence that the child was recruited, harbored, transported, provided to another person, or obtained for the purpose of forced labor or commercial sexual activity; and

(3) Additional Programmatic Services, which include:

(A) Emergency Care Services--A specialized type of child-care services designed and offered to provide short-term child care to children who, upon admission, are in an emergency constituting an immediate danger to the physical health or safety of the child or the child's offspring;

(B) Transitional Living Program--A residential services program designed to serve children 14 years old or older for whom the service or treatment goal is basic life skills development toward independent living, which includes basic life skills training and the opportunity for children to practice those skills and is not an independent living program;

(C) Assessment Services Program--Services to provide an initial evaluation of the appropriate placement for a child to ensure that appropriate information is obtained to facilitate service planning;

(D) Therapeutic Camp Services--A camping program to augment an operation's treatment services with an experiential curriculum exclusively for a child with an emotional disorder who has difficulty functioning in his home, school, or community and is only available to children 13 years old and older; and

(E) Respite Child-Care Services--See §748.73 of this chapter (relating to What are respite child-care services?).

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

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SUBCHAPTER W. ADDITIONAL REQUIREMENTS FOR OPERATIONS THAT PROVIDE PSYCHIATRIC HEALTH TREATMENTS AND SERVICES

DIVISION 1. DEFINITIONS AND SCOPE

26 TAC §§748.4801, 748.4803, 748.4805, 748.4807, 748.4809

STATUTORY AUTHORITY

The new sections are adopted under 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, as well as Texas Government Code §531.033, which requires the Executive Commissioner to adopt rules necessary to carry out the duties of HHSC' under Chapter 531 of Texas Government Code. In addition, Texas Health and Safety §577A.004 requires HHSC to adopt rules necessary to implement Chapter 577A and §577A.101 requires HHSC to adopt minimum standards for a certified PRYTF. Finally, amendments to current rules adopted under Texas Human Resources Code §42.042 are authorized under that section.

§748.4803. When is a general residential operation (GRO) required to meet the additional rules of this subchapter?

A GRO that is a certified psychiatric residential youth treatment facility must meet the additional rules in this subchapter when providing psychiatric health treatments and services to an individual.

§748.4807. How do the rules in this subchapter apply to the care of a young adult 18 to 21 years of age at a psychiatric residential treatment facility (PRYTF)?

The rules in this chapter that apply to a PRYTF as noted in §748.4805 of this division (relating to In addition to the rules in this subchapter, what other rules in this chapter apply to a psychiatric residential youth treatment facility (PRYTF)?) also apply to the care of a young adult 18 to 21 years of age whom the PRYTF has admitted for psychiatric health treatments and services.

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DIVISION 2. POLICIES, NOTIFICATIONS, AND POSTINGS

26 TAC §§748.4821, 748.4823, 748.4825

STATUTORY AUTHORITY

The new sections are adopted under 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, as well as Texas Government Code §531.033, which requires the Executive Commissioner to adopt rules necessary to carry out the duties of HHSC' under Chapter 531 of Texas Government Code. In addition, Texas Health and Safety §577A.004 requires HHSC to adopt rules necessary to implement Chapter 577A and §577A.101 requires HHSC to adopt minimum standards for a certified PRYTF. Finally, amendments to current rules adopted under Texas Human Resources Code §42.042 are authorized under that section.

§748.4821. What additional policies must a general residential operation (GRO) submit as part of the application process for a psychiatric residential youth treatment facility (PRYTF) certificate?

A GRO must develop written policies that address:

(1) How the PRYTF will provide 24-hour medical and emergency services, including 24-hour nursing services; and

(2) How caregivers will supervise young adults 18 to 21 years of age receiving psychiatric health treatments and services and children in the GRO, including the PRYTF, when sharing restrooms or indoor or outdoor activity areas. The policy must:

(A) Include a schedule for the young adults and children to use restrooms, for indoor activity time, including cafeteria usage, and outdoor activity time; and

(B) Outline the specific staffing schedule caregivers will use and how the caregivers will maintain supervision, based on the supervision needs in the young adults' and children's service plans.

§748.4823. When must a psychiatric residential youth treatment facility (PRYTF) notify Child Care Regulation (CCR) about accreditation changes regarding the PRYTF?

(a) A PRYTF must always meet the accreditation requirement of §745.9053 of this title (relating to What requirements must a general

residential operation meet before applying for a psychiatric residential youth treatment facility (PRYTF) certificate?).

(b) A PRYTF must notify CCR within two days if the accreditation organization informs the PRYTF that it has taken or will take an action that will result in the PRYTF no longer meeting the accreditation requirement of §745.9053 of this title for any period. Such an action includes revoking, suspending, or refusing to renew the PRYTF's accreditation.

§748.4825. Where must a psychiatric residential youth treatment facility (PRYTF) post the PRYTF certificate?

The PRYTF must post the PRYTF certificate in a prominent and publicly accessible place where employees, children, young adults, parents, and others will be able to view it easily.

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DIVISION 3. PERSONNEL

26 TAC §748.4831, §748.4833

STATUTORY AUTHORITY

The new sections are adopted under 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, as well as Texas Government Code §531.033, which requires the Executive Commissioner to adopt rules necessary to carry out the duties of HHSC' under Chapter 531 of Texas Government Code. In addition, Texas Health and Safety §577A.004 requires HHSC to adopt rules necessary to implement Chapter 577A and §577A.101 requires HHSC to adopt minimum standards for a certified PRYTF. Finally, amendments to current rules adopted under Texas Human Resources Code §42.042 are authorized under that section.

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DIVISION 4. TRAINING

26 TAC §§748.4841, 748.4843, 748.4845, 748.4847

STATUTORY AUTHORITY

The new sections are adopted under 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, as well as Texas Government Code §531.033, which requires the Executive Commissioner to adopt rules necessary to carry out the duties of HHSC' under Chapter 531 of Texas Government Code. In addition, Texas Health and Safety §577A.004 requires HHSC to adopt rules necessary to implement Chapter 577A and §577A.101 requires HHSC to adopt minimum standards for a certified PRYTF. Finally, amendments to current rules adopted under Texas Human Resources Code §42.042 are authorized under that section.

§748.4841. What are the pre-service experience requirements for a caregiver providing psychiatric health treatments and services?

(a) A caregiver responsible for an individual receiving psychiatric health treatments and services must have a minimum of 40 hours of supervised caregiver experience in:

(1) The current general residential operation providing treatment services to children with an emotional disorder;

(2) Another general residential operation providing treatment services to children with an emotional disorder;

(3) A psychiatric residential youth treatment facility providing psychiatric health treatments and services to children or young adults; or

(4) A residential or hospital setting providing direct care, supervision, guidance, and protection of children or young adults with a severe emotional disturbance.

(b) Until a caregiver has the minimum amount of supervised child-care experience as specified in subsection (a) of this section, the caregiver:

(1) May not be assigned as the only caregiver responsible for a group of individuals if any individual in the group is receiving psychiatric health treatments and services;

(2) Must be always supervised by another caregiver who has already satisfied the 40-hour experience requirement; and

(3) Must have their supervised child-care experience documented in the appropriate personnel record.

§748.4843. What additional pre-service training requirements apply to a caregiver or an employee at a psychiatric residential youth treatment facility (PRYTF)?

(a) In addition to the types of pre-service training and hours at §748.863(a) of this chapter (relating to What are the pre-service training requirements for a caregiver?), a caregiver must complete four hours of suicide prevention training before the caregiver may be counted in the child to caregiver ratio if any individual in the group is receiving psychiatric health treatments and services.

(b) In addition to the types of pre-service training and hours at §748.864(a) of this chapter (relating to What are the pre-service training requirements for an employee?), a child-care administrator, professional level service provider, treatment director, and case manager

must complete four hours of suicide prevention training within 90 days of beginning job duties that include:

(1) Providing services to or planning services for individuals receiving psychiatric health treatments and services; or

(2) Managing or overseeing employees that provide services to or plans services for individuals receiving psychiatric health treatments and services.

(c) To meet the pre-service training requirements, the suicide prevention training must meet:

(1) The instructor requirements at §748.869(a) and (b) of this chapter (relating to How must pre-service training be conducted?); and

(2) The curriculum requirements at §748.125(c)(1) of this chapter (relating to What is the model suicide prevention, intervention, and postvention policy?).

(d) A caregiver or employee (child-care administrator, professional level service provider, treatment director, and case manager) does not have to complete the four hours of suicide prevention training if the caregiver or employee has documentation that it was completed during the last 12 months.

(e) The PRYTF must document the exemption factor in the appropriate personnel record.

§748.4845. Who must have first-aid and CPR training in a psychiatric residential youth treatment facility?

(a) Caregivers providing psychiatric health treatments and services to individuals must have a current certificate of training with an expiration or renewal date in:

(1) First-aid with rescue breathing and choking, which may be through instructor-led training or self-instructional training; and

(2) Pediatric and adult cardiopulmonary resuscitation (CPR).

(b) Each caregiver must be certified in first aid and CPR within 90 days of employment.

(c) At least one person counted in the child to caregiver ratio must be certified in first aid and CPR at all times.

(d) To meet the first-aid and CPR training requirements, the training must meet:

(1) The CPR training requirements at §748.913 of this chapter (relating to What are the requirements for CPR training?); and

(2) The documentation requirements at §748.915 of this chapter (relating to What documentation must I maintain for the first aid and CPR certifications?).

§748.4847. What additional annual training requirements apply to a caregiver or an employee at a psychiatric residential youth treatment facility (PRYTF)?

(a) A caregiver providing psychiatric health treatments and services to an individual in a PRYTF must complete 50 annual training hours.

(b) In addition to the one hour of annual suicide prevention training required in §748.125(c) of this chapter (relating to What is the model suicide prevention, intervention, and postvention policy?):

(1) A caregiver must complete four additional hours of annual suicide prevention training for a total of five hours of annual suicide prevention training if the caregiver provides care to an individual receiving psychiatric health treatments and services; and

(2) A child-care administrator, professional level service provider, treatment director, and case manager must complete four additional hours of annual suicide prevention training for a total of five hours of annual suicide prevention training if the employee is or will be:

(A) Providing services to or planning services for individuals receiving psychiatric health treatments and services; or

(B) Managing or overseeing other employees that provide services to or plans services for individuals receiving psychiatric health treatments and services.

(c) In addition to the specific types of annual training and hours required in §748.930(b) of this chapter (relating to What are the annual training requirements for a caregiver?), a caregiver providing psychiatric health treatments and services to an individual must complete two hours of annual training on administering psychotropic medication.

(d) In addition to the specific types of annual training and hours required in §748.931(b) and (c) of this chapter (relating to What are the annual training requirements for an employee), a child-care administrator, professional level service provider, treatment director, and case manager must complete two hours of annual training on administering psychotropic medication if the employee is or will be:

(1) Providing services to or planning services for individuals receiving psychiatric health treatments and services; or

(2) Managing or overseeing other employees that provide services to or plans services for individuals receiving psychiatric health treatments and services.

(e) To meet the annual training requirements, the annual training must meet the requirements in:

(1) §748.935 of this chapter (relating to When must an employee or caregiver complete the annual training?);

(2) §748.937 of this chapter (relating to What types of hours or instruction can be used to complete the annual training requirements?);

(3) §748.941 of this chapter (relating to How must annual training be conducted?);

(4) §748.945 of this chapter (relating to What curriculum components must be included in the annual training for administering psychotropic medication?);

(5) §748.125(c)(1) of this chapter (relating to What is the model suicide prevention, intervention, and postvention policy?), relating to the curriculum components for suicide prevention training; and

(6) §748.949 of this chapter (relating to What documentation must I maintain for annual training?).

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DIVISION 5. CHILD TO CAREGIVER RATIO

26 TAC §748.4851

STATUTORY AUTHORITY

The new section is adopted under 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, as well as Texas Government Code §531.033, which requires the Executive Commissioner to adopt rules necessary to carry out the duties of HHSC' under Chapter 531 of Texas Government Code. In addition, Texas Health and Safety §577A.004 requires HHSC to adopt rules necessary to implement Chapter 577A and §577A.101 requires HHSC to adopt minimum standards for a certified PRYTF. Finally, amendments to current rules adopted under Texas Human Resources Code §42.042 are authorized under that section.

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DIVISION 6. ADMISSION AND SERVICE PLANS

26 TAC §§748.4861, 748.4863, 748.4865, 748.4867, 748.4869

STATUTORY AUTHORITY

The new sections are adopted under 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, as well as Texas Government Code §531.033, which requires the Executive Commissioner to adopt rules necessary to carry out the duties of HHSC' under Chapter 531 of Texas Government Code. In addition, Texas Health and Safety §577A.004 requires HHSC to adopt rules necessary to implement Chapter 577A and §577A.101 requires HHSC to adopt minimum standards for a certified PRYTF. Finally, amendments to current rules adopted under Texas Human Resources Code §42.042 are authorized under that section.

§748.4861. Whom may a psychiatric residential youth treatment facility (PRYTF) admit for psychiatric health treatments and services?

A PRYTF may only admit an individual for psychiatric health treatments and services who:

(1) Is 21 years of age or younger;

(2) Has been diagnosed with a severe emotional disturbance by a licensed mental health professional;

(3) Requires residential psychiatric treatment under the direction of a licensed physician to improve the individual's condition; and

(4) Was referred for treatment or services in a PRYTF by a licensed mental health professional.

§748.4863. May individuals receiving different types of service live in the same living quarters?

(a) Except as provided by subsections (c) and (d) of this section, children receiving different types of service may reside in the same living quarters as long as:

(1) A professional level service provider completes an evaluation of the living quarters for each child that the psychiatric residential youth treatment facility (PRYTF) places in the living quarters; and

(2) In each evaluation, the professional level service provider ensures that:

(A) There is no conflict of care with the best interests of any of the children placed in the living quarters;

(B) Placing the child with different service or treatment needs in the living quarters will not adversely impact the other children in the living quarters;

(C) The number of children in the living quarters is appropriate at all times based on the needs of all children in the living quarters;

(D) Caregivers can appropriately supervise all children in the living quarters at all times; and

(E) The PRYTF can meet the needs of all children in the living quarters.

(b) If the treatment or service needs of any child in the living quarters changes, the professional level service provider must evaluate the needs of each child in the living quarters to ensure there is no conflict of care.

(c) Children admitted for emergency care services must receive any therapeutic services (such as group therapy or art therapy) separately from children admitted for non-emergency care and must have separate living quarters, such as a separate wing of an operation, or a separate cottage. The PRYTF may combine children admitted for emergency care services with children in non-emergency care for meals, recreation, and transportation.

(d) Young adults 18 to 21 years of age receiving psychiatric health treatments and services that are not in the care of the Texas Department of Family and Protective Services and did not come immediately from another residential child-care operation:

(1) Must receive therapeutic services (such as group therapy or art therapy) separately from children admitted to the operation, including the PRYTF;

(2) Must have separate living quarters, such as a separate wing of an operation, or a separate cottage; and

(3) Must not use an area of the general residential operation's building or grounds at the same time with children admitted to the operation, including the PRYTF, except restrooms and indoor and outdoor activity areas may be shared under a policy required by §748.4821 of this subchapter (relating to What additional policies must a general residential operation (GRO) submit as part of the application process for a psychiatric residential youth treatment facility (PRYTF) certificate?).

§748.4865. Are there additional requirements for a preliminary service plan when a psychiatric residential youth treatment facility (PRYTF) admits an individual for psychiatric health treatments and services?

When a PRYTF admits an individual for psychiatric health treatments and services, in addition to the requirements listed in §748.1331 of this chapter (relating to What are the requirements for a preliminary service plan?), the preliminary service plan for an individual receiving psychiatric health treatments and services must include:

(1) Therapeutic needs, including plans for psychiatric evaluation, the use of psychotropic medications, and one-to-one therapy;

(2) Family engagement activities;

(3) Plans to consult with qualified professionals, including case managers, primary care professionals, community-based mental health providers, school staff, and other support planners; and

(4) Nursing care.

§748.4867. Are there additional requirements for an initial service plan when a psychiatric residential youth treatment facility (PRYTF) admits an individual for psychiatric health treatments and services?

(a) In addition to the requirements listed in (b)(2) in Figure: 26 TAC §748.1337(b) of this chapter (relating to What must a child's initial service plan include?), the initial service plan for an individual receiving psychiatric health treatments and services must include:

(1) One-to-one therapy;

(2) Family engagement activities;

(3) Consultation services with qualified professionals, including case managers, primary care professionals, community-based mental health providers, school staff, and other support planners;

(4) 24-hour nursing services, though services do not need to be onsite; and

(5) Direct care and supervision services, supportive services for daily living and safety, and positive behavior management services.

(b) A PRYTF must document all professional consultations, examinations, recommendations, and treatment in the individual's record.

§748.4869. Who must be involved in developing an initial service plan?

(a) A service planning team must develop the service plan. The team must consist of:

(1) At least one of the individual's current caregivers;

(2) For a child, a person designated to make decisions regarding a child's participation in childhood activities; and

(3) At least one professional level service provider who provides direct services to the individual.

(b) Except as provided by subsection (c) of this section, if a general residential operation is providing treatment services to a child, the team must also include two of the following professions:

(1) A licensed professional counselor;

(2) A psychologist;

(3) A psychiatrist or physician;

(4) A licensed registered nurse;

(5) A licensed masters level social worker;

(6) A licensed or registered occupational therapist; or

(7) Any other person in a related discipline or profession that is licensed or regulated in accordance with state law.

(c) If a psychiatric residential youth treatment facility is providing psychiatric health treatments and services to an individual, the team must also include a licensed psychiatrist or physician and one of the following professionals:

(1) A licensed professional counselor;

(2) A psychologist;

(3) A licensed registered nurse;

(4) A licensed masters level social worker; or

(5) Any other person in a related discipline or profession that is licensed or regulated in accordance with state law.

(d) The individual and parents or guardian must be invited to a service planning meeting, so that they may participate and provide input into the development of the service plan.

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For further information, please call: (512) 438-3269

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DIVISION 7. PROVIDING CARE TO CHILDREN AND ADULTS

26 TAC §748.4881

STATUTORY AUTHORITY

The new sections are adopted under 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, as well as Texas Government Code §531.033, which requires the Executive Commissioner to adopt rules necessary to carry out the duties of HHSC' under Chapter 531 of Texas Government Code. In addition, Texas Health and Safety §577A.004 requires HHSC to adopt rules necessary to implement Chapter 577A and §577A.101 requires HHSC to adopt minimum standards for a certified PRYTF. Finally, amendments to current rules adopted under Texas Human Resources Code §42.042 are authorized under that section.

§748.4881. After a child in the care of a psychiatric residential youth treatment facility (PRYTF) turns 18 years old, may the young adult remain in care?

A child who turns 18 years old in the care of a PRYTF may remain in care until the young adult's 22nd birthday.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on September 18, 2024.

TRD-202404503
Karen Ray
Chief Counsel
Health and Human Services Commission
Effective date: October 15, 2024
Proposal publication date: April 26, 2024
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TITLE 28. INSURANCE

PART 1. TEXAS DEPARTMENT OF INSURANCE

CHAPTER 21. TRADE PRACTICES

SUBCHAPTER F. ELECTRONIC TRANSACTIONS

28 TAC §21.501

The commissioner of insurance adopts new 28 TAC Subchapter F, §21.501, concerning notices of termination of insurance policies. New §21.501 implements House Bill 1040, 88th Legislature, 2023. The rule is adopted without changes to the proposed text published in the May 24, 2024, issue of the *Texas Register* (49 TexReg 3695) and will not be republished.

REASONED JUSTIFICATION. The new subchapter and section clarify that nonrenewals and discontinuations of insurance policies are considered forms of termination that require insurance companies and other regulated entities to notify a party both electronically and by paper or another nonelectronic form.

HB 1040 amended Insurance Code §35.003 and §35.004 to allow regulated entities to do business electronically without obtaining consent from the other party. Before HB 1040, a regulated entity had to obtain an agreement from a party to an insurance transaction to do business or deliver documents electronically. Under HB 1040, no express agreement is required, and the regulated entity can simply notify the party that it will conduct business electronically. After receiving notice, the party has a right to withdraw consent from doing business electronically.

HB 1040 also added to §35.004 new subsection (l), which requires a regulated entity to send notices in both electronic form and in paper or another nonelectronic form to a party when cancelling or terminating a policy. With the proliferation of electronic transactions, entities may be sending notices in only electronic form. The 88th Legislature included new subsection (l) to make sure that regulated entities send notices in nonelectronic form as well as electronic. New §21.501 defines "termination" to include nonrenewal, a refusal to renew, or discontinuation by a regulated entity for the purposes of Insurance Code §35.004.

SUMMARY OF COMMENTS AND AGENCY RESPONSE. TDI provided an opportunity for public comment on the rule proposal. The comment period ended on June 24, 2024.

Commenters: TDI received two comments. One from the Office of Public Insurance Counsel in support of the proposal and one from the American Property and Casualty Insurance Association asking for clarification

Comments on §21.501

Comment. One commenter expresses support for TDI's proposal, saying that it "increases transparency, updates the rules in accordance with statutory changes, and helps ensure that companies give the required notice to those inured."

Agency Response. TDI appreciates the commenter's support.

Comment. Another commenter wanted to know if they are required to send notices to non-renewals that are customer initiated, such as when a renewal proposal is made to the insured, but the insured declines to pay the new premium to renew the policy.

Agency Response. 28 TAC §21.501 clarifies that if a notice of nonrenewal is delivered electronically, then it must also be delivered by paper or another nonelectronic form. 28 TAC §21.501 does not address what circumstances require a notice of nonrenewal.

STATUTORY AUTHORITY. The commissioner adopts new §21.501 under Insurance Code §§35.0045, 551.001, 1202.051, 1271.307, and 36.001.

Insurance Code §35.0045 requires the commissioner to adopt rules necessary to implement and enforce Insurance Code Chapter 35.

Insurance Code §551.001 authorizes the commissioner to adopt rules related to the cancellation and nonrenewal of insurance policies issued under specified provisions of the Insurance Code.

Insurance Code §1202.051 requires the commissioner to adopt necessary rules related to the renewal and continuation of individual health insurance policies.

Insurance Code §1271.307 authorizes the commissioner to adopt necessary rules related to the renewal of managed care individual health care plans and conversion contracts.

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.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on September 23, 2024.

TRD-202404551
Jessica Barta
General Counsel
Texas Department of Insurance
Effective date: October 13, 2024
Proposal publication date: May 24, 2024
For further information, please call: (512) 676-6555

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TITLE 40. SOCIAL SERVICES AND ASSISTANCE

PART 20. TEXAS WORKFORCE COMMISSION

CHAPTER 800. GENERAL ADMINISTRATION

The Texas Workforce Commission (TWC) adopts amendments to the following sections of Chapter 800, relating to General Administration:

Subchapter B. Allocations, §§800.52, 800.63, 800.71, 800.74, 800.75, and 800.77

TWC adopts the repeal of the following section of Chapter 800, relating to General Administration:

Subchapter B. Allocations, §800.65

Amended §§800.52, 800.63, 800.71, 800.74, 800.75, and 800.77 are adopted without changes to the proposal, as published in the July 19, 2024, issue of the *Texas Register* (49 TexReg 5340), and, therefore, the adopted rule text will not be published.

PART I. PURPOSE, BACKGROUND, AND AUTHORITY

The purpose of the Chapter 800 rule change is to amend Subchapter B, Allocations, to:

--update rule language to conform with current federal program requirements, particularly those relating to the Workforce Innovation and Opportunity Act (WIOA); and

--repeal §800.65 relating to Project Reintegration of Offenders (Project RIO) to align with the Commission's repeal of Texas Administrative Code (TAC), Title 40, Chapter 847, Project RIO Employment Activities and Support Services. Though Project RIO is no longer operational, Local Workforce Development Boards (Boards) continue their ongoing efforts to serve ex-offenders through other program activities and services, as appropriate.

PART II. EXPLANATION OF INDIVIDUAL PROVISIONS

(Note: Minor editorial changes are made that do not change the meaning of the rules and, therefore, are not discussed in the Explanation of Individual Provisions.)

SUBCHAPTER B. ALLOCATIONS

TWC adopts the following amendments to Subchapter B:

§800.52. Definitions

Section 800.52 is amended to align language and references with current federal programs.

§800.63. Workforce Investment Act (WIA) Allocations

Section 800.63 is amended to align language with current federal programs and update statutory references. Section 800.63(i) is amended, and (j) and (k) are removed, to align WIOA statewide funding methodologies with federal regulations. Removal of subsection (k) further clarifies the Commission's ability to use and transmit statewide funds to Boards as needed, including use of funds to address emerging needs in regions throughout Texas.

Section 800.63 is amended to change the section name from "Workforce Investment Act (WIA) Allocations" to "Workforce Innovation and Opportunity Act (WIOA) Allocations."

§800.65. Project Reintegration of Offenders

Section 800.65 is repealed to align with the Commission's repeal of Chapter 847, Project RIO Employment Activities and Support Services.

§800.71. General Deobligation and Reallocation Provisions

Section 800.71 is amended to remove inactive programs and add WIOA formula funding. Additionally, statewide funds references are removed from deobligation and reallocation processes, enhancing statutory flexibility provided to the Commission in determining use of these funds, and further aligning rule with federal regulations.

§800.74. Midyear Deobligation of Funds

Section 800.74 is amended to remove inactive programs. Additionally, statewide funds references are removed from deobligation and reallocation processes, enhancing statutory flexibility provided to the Commission in determining use of these funds, and further aligning rule with federal regulations.

§800.75. Second-Year WIA Deobligation of Funds

Section 800.75 is amended to align language with current federal programs.

Section 800.75 is amended to change the section name from "Second-Year WIA Deobligation of Funds" to "Second-Year WIOA Deobligation of Funds."

§800.77. Reallocation of Funds

Section 800.77 is amended to remove inactive programs and include WIOA formula funding. Additionally, statewide funds references are removed from deobligation and reallocation processes, enhancing statutory flexibility provided to the Commission in determining use of these funds, and further aligning rule with federal regulations.

PART III. PUBLIC COMMENTS

The comment period ended on August 19, 2024. No comments were received.

SUBCHAPTER B. ALLOCATIONS

40 TAC §§800.52, 800.63, 800.71, 800.74, 800.75, 800.77

STATUTORY AUTHORITY

The adopted rules implement provisions of WIOA by making conforming changes to TWC rules to align with current federal program requirements.

The rules are adopted under Texas Labor Code §301.0015(a)(6) and §302.002(d), which provide TWC with the general authority to adopt, amend, or repeal such rules as it deems necessary for the effective administration of TWC services and activities.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on September 17, 2024.

TRD-202404468

Les Trobman
General Counsel
Texas Workforce Commission
Effective date: October 7, 2024
Proposal publication date: July 19, 2024
For further information, please call: (512) 850-8356

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40 TAC §800.65

The repeal is adopted under Texas Labor Code §301.0015(a)(6) and §302.002(d), which provide TWC with the general authority to adopt, amend, or repeal such rules as it deems necessary for the effective administration of TWC services and activities.

The repeal relates to Texas Labor Code, particularly Chapters 301, 302, and 306; Texas Education Code, Chapter 19; and Texas Government Code, Chapter 552.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

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TRD-202404469
Les Trobman
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Effective date: October 7, 2024
Proposal publication date: July 19, 2024
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