Proposed rules include new rules, amendments to existing rules, and repeals of existing rules. A state agency shall give at least 30 days' notice of its intention to adopt a rule before it adopts the rule. A state agency shall give all interested persons a reasonable opportunity to submit data, views, or arguments, orally or in writing (Government Code, Chapter 2001).

Symbols in proposed rule text. Proposed new language is indicated by underlined text. [~~Square brackets and strikethrough~~] indicate existing rule text that is proposed for deletion. "(No change)" indicates that existing rule text at this level will not be amended.

TITLE 16. ECONOMIC REGULATION

PART 2. PUBLIC UTILITY COMMISSION OF TEXAS

CHAPTER 25. SUBSTANTIVE RULES APPLICABLE TO ELECTRIC SERVICE PROVIDERS

SUBCHAPTER D. RECORDS, REPORTS, AND OTHER REQUIRED INFORMATION

16 TAC §25.98

The Public Utility Commission of Texas (commission) proposes new §25.98, relating to Permian Basin Reliability Plan Reporting Requirements and Monitor. This proposed rule will implement Public Utility Regulatory Act (PURA) §39.166 and §39.167 as enacted by House Bill (HB) 5066 during the Texas 88th Regular Legislative Session. The proposed rule will create reporting requirements associated with implementing the reliability plan for the Permian Basin region, establish the responsibilities of a third-party monitor, and require that the Transmission Service Providers implementing the reliability plan for the Permian Basin region pay for the monitor. The reporting requirements created by the proposed rule will enable the monitor to identify schedule and cost components that may impact the timely development and approval of necessary transmission service improvements. Additionally, the proposed rule will provide transparency related to costs for the projects that comprise the Permian Basin Reliability Plan.

Growth Impact Statement

The agency provides the following governmental growth impact statement for the proposed rule, as required by Texas Government Code §2001.0221. The agency has determined that for each year of the first five years that the proposed rule is in effect, the following statements will apply:

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

(2) implementation of the proposed rule will not require the creation of new employee positions and will not require the elimination of existing employee positions;

(3) implementation of the proposed rule will not require an increase and will not require a decrease in future legislative appropriations to the agency;

(4) the proposed rule will require an increase in fees paid to the agency for purposes of paying the invoiced costs for a monitor;

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

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

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

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

Fiscal Impact on Small and Micro-Businesses and Rural Communities

There is no adverse economic effect anticipated for small businesses, micro-businesses, or rural communities as a result of implementing the proposed rule. Accordingly, no economic impact statement or regulatory flexibility analysis is required under Texas Government Code §2006.002(c).

Takings Impact Analysis

The commission has determined that the proposed rule will not be a taking of private property as defined in chapter 2007 of the Texas Government Code.

Fiscal Impact on State and Local Government

Jessie Horn, Senior Counsel, Rules and Projects Division, has determined that for the first five--year period the proposed rule is in effect, there will be no fiscal implications for the state but there will be fiscal implications for units of local government under Texas Government Code §2001.024(a)(4) as a result of enforcing or administering the section. Under the proposed rule, a municipally owned utility may be apportioned costs for the monitor.

Public Benefits

Ms. Horn has determined that for each year of the first five years the proposed section is in effect the public benefit anticipated as a result of enforcing the section will be greater transparency related to implementation of the reliability plan for the Permian Basin region. In accordance with Texas Government Code §2001.024(a)(5), Ms. Horn has determined that the economic costs to persons required to comply with the proposed rule will vary on an individual basis, depending on the number of projects that must be reported on.

Local Employment Impact Statement

For each year of the first five years the proposed section is in effect, there should be no effect on a local economy; therefore, no local employment impact statement is required under Texas Government Code §2001.022.

Costs to Regulated Persons

Texas Government Code §2001.0045(b) does not apply to this rulemaking because the commission is expressly excluded under subsection §2001.0045(c)(7).

Public Hearing

The commission staff will conduct a public hearing on this rulemaking if requested in accordance with Texas Government Code §2001.029. The request for a public hearing must be received by March 27, 2025. If a request for public hearing is received, commission staff will file in this project a notice of hearing.

Public Comments

Interested persons may file comments electronically through the interchange on the commission's website. Comments must be filed by March 27, 2025. Comments should be organized in a manner consistent with the organization of the proposed rule. The commission invites specific comments regarding the costs associated with, and benefits that will be gained by, implementation of the proposed rule. The commission will consider the costs and benefits in deciding whether to modify the proposed rule on adoption. All comments should refer to Project Number 57602.

Each set of comments should include a standalone executive summary as the last page of the filing. This executive summary must be clearly labeled with the submitting entity's name and should include a bulleted list covering each substantive recommendation made in the comments.

Statutory Authority

The new rule is proposed under the following provisions of PURA: §14.001, which grants the commission the general power to regulate and supervise the business of each public utility within its jurisdiction and to do anything specifically designated or implied by this title that is necessary and convenient to the exercise of that power and jurisdiction; §14.002, which authorizes the commission to adopt and enforce rules reasonably required in the exercise of its powers and jurisdiction; §14.003, which authorizes the commission to require a public utility to report to the commission information relating to the utility, establish the form for a report, and determine the time and frequency for a report; §14.151, which authorizes the commission to prescribe any form, record, and memorandum to be kept by a public utility, including a municipally owned utility, that the commission considers necessary to carry out Title II, Texas Utilities Code; §39.166, which requires the commission to develop a plan to implement each reliability plan adopted under §39.166(a); and §39.167, which requires the commission to direct the Electric Reliability Council of Texas, Inc. (ERCOT) to develop a reliability plan under PURA §39.166 for the Permian Basin region.

Cross Reference to Statute: Public Utility Regulatory Act §§14.001, 14.002, 14.003, 14.151, 39.166, and 39.167.

§25.98. Permian Basin Reliability Plan Reporting Requirements and Monitor.

(a) Purpose and applicability. This section sets forth the reporting requirements for a transmission service provider (TSP) responsible for the ownership, construction, and operation of a Permian Basin Reliability Plan (PBRP) common local project or import path (PBRP project) approved by the commission's order issued on October 7, 2024 in Project No. 55718, relating to Reliability Plan for the Permian Basin Under PURA §39.167. These requirements are in addition to the reporting requirements set forth in §25.83 of this title (relating to Transmission Construction Reports). This section also establishes the duties of the commission's monitor to oversee the completion of the PBRP.

(b) Initial implementation schedule requirements. Within 30 days of an order issued by the commission, identifying a TSP as responsible for the ownership, construction, and operation of a PBRP project, the TSP must file with the commission an initial implementation schedule, using a form prescribed by the commission, that identifies the following information:

(1) name of the PBRP project;

(2) PBRP project ID, as identified in the ERCOT Permian Basin Reliability Plan Study Report;

(3) upgrade ID;

(4) transmission upgrade;

(5) voltage;

(6) facilities;

(7) counties affected;

(8) the initial estimated start and completion dates for each of the following milestones, as applicable:

(A) CCN application,

(B) right-of-way and land acquisition,

(C) engineering and design,

(D) materials and equipment procurement, and

(E) construction of facilities; and

(9) the initial estimated energization date of the PBRP project.

(c) Quarterly progress report requirements. The first of January, April, July, and October is the start of a new quarter. On the fifteenth of each new quarter, a TSP must file a report with the commission, detailing progress during the previous quarter, for each PBRP project through energization of the PBRP project.

(1) PBRP projects that require a certificate of convenience and necessity (CCN). For each PBRP project that requires a CCN, a TSP must file a quarterly progress report with the commission beginning the fifteenth day of a new quarter following the date that the commission approves the TSP's CCN application for the PBRP project.

(2) PBRP projects that do not require a CCN. For each PBRP project that does not require a CCN, a TSP must file a quarterly progress report with the commission beginning the fifteenth day of a new quarter following the date that the TSP files an initial implementation schedule for the PBRP project.

(3) PBRP project description and summary. For each PBRP project, a TSP must provide a description and summary of the PBRP project in its quarterly progress report that identifies the following, as applicable:

(A) name of the PBRP project;

(B) assigned docket number that is associated with the TSP's CCN application for the PBRP project;

(C) PBRP project ID, as identified in the ERCOT Permian Basin Reliability Plan Study Report;

(D) upgrade ID;

(E) transmission upgrade;

(F) voltage;

(G) facilities;

(H) counties affected;

(I) a brief summary of the PBRP project progress to date; and

(J) the percentage of engineering and design that is complete to date;

(K) the percentage of procurement that is complete to date;

(L) the percentage of construction that is complete to date.

(4) Costs. For each PBRP project, a TSP must identify in its quarterly progress report cost estimates using the most up-to-date information available, and actual costs as costs are incurred for each of the following, as applicable:

(A) CCN acquisition;

(B) right-of-way and land acquisition;

(C) engineering and design;

(D) material and equipment procurement;

(E) construction of facilities; and

(F) the total to complete the PBRP project.

(5) Implementation schedule. For each PBRP project, a TSP must identify in its quarterly progress report estimated dates, using the most up-to-date information available, and actual dates for each of the following milestones, as applicable:

(A) start and completion of right-of-way and land acquisition;

(B) start and completion of engineering and design;

(C) start and completion of materials and equipment procurement;

(D) start and completion of construction of facilities; and

(E) PBRP project energization.

(6) Form. A TSP must submit its quarterly progress report using a form prescribed by the commission.

(d) Reporting significant changes. Within 10 days of becoming aware of a significant change, a TSP must provide a detailed explanation of the reasons for the significant change and report that information to the commission's monitor in writing. A significant change includes the following:

(1) an increase of more than 10 percent to the total cost estimate that was included in the TSP's initial quarterly progress report;

(2) a change of more than 60 days from the initial estimated date to complete a milestone in the TSP's initial implementation schedule;

(3) a delay to the TSP's energization date of a PBRP project that is caused by the incomplete status of another PBRP project; and

(4) circumstances that pose a risk to the energization date of a PBRP project.

(e) Requests for additional information. Within 10 working days of receiving a request from commission staff or the commission's monitor for additional information relating to the progress or implementation of a PBRP project, a TSP must provide responsive information to the requestor, including applicable supporting documentation. A TSP may seek, and the requestor may agree to, an extension to the deadline for a TSP to provide responsive information.

(f) Confidential Information. Information that is submitted confidentially must be included in a redacted and unredacted form. The redacted form must be redacted only to the minimum extent necessary to ensure confidentiality. The unredacted form must include a memorandum prescribed by the commission that specifies the reasons and legal basis for submitting the information confidentially. Information submitted confidentially may only be accessed by commission staff or the monitor upon signing a protective order certification.

(g) Monitor. The commission delegates authority to the Executive Director to award, negotiate pricing and performance requirements, and execute and administer a contract for a third-party monitor for the PBRP. Before commencing its duties, the monitor must sign a protective order certification to access confidential information submitted by a TSP under this section. The monitor's duties include:

(1) monitor and review the reports that TSPs are required to file under this section;

(2) communicate with TSPs, as needed to fulfill the monitor's responsibilities under this section;

(3) request additional information from TSPs, as needed;

(4) provide regular status updates to the commission;

(5) inform commission staff of a significant change to a PBRP project; and

(6) any other function deemed appropriate by the Executive Director or the Executive Director's designee.

(h) Monitor cost assignment and apportionment. A TSP identified through a commission order as responsible for the ownership, construction, and operation of a PBRP project, must pay the invoiced costs approved by the Executive Director or the Executive Director's designee for the monitor.

(1) The funding of the monitor must be sufficient to ensure the selection of a monitor in accordance with the scope and activities set forth in subsection (g) of this subsection.

(2) The apportionment of costs among TSPs and the payment mechanisms will be established by the Executive Director or the Executive Director's designee.

(3) A TSP may seek recovery of the amounts paid under this paragraph as part of the overall PBRP project costs.

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

Filed with the Office of the Secretary of State on February 20, 2025.

TRD-202500649
Adriana Gonzales
Rules Coordinator
Public Utility Commission of Texas
Earliest possible date of adoption: April 6, 2025
For further information, please call: (512) 936-7322

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TITLE 19. EDUCATION

PART 2. TEXAS EDUCATION AGENCY

CHAPTER 66. STATE ADOPTION AND DISTRIBUTION OF INSTRUCTIONAL MATERIALS

SUBCHAPTER CC. COMMISSIONER'S RULES CONCERNING INSTRUCTIONAL MATERIALS AND TECHNOLOGY ALLOTMENT

19 TAC §66.1307

The Texas Education Agency (TEA) proposes the repeal of §66.1307, concerning the Instructional Materials and Technology Allotment. The proposed repeal would move the Instructional Materials and Technology Allotment rule to proposed new 19 TAC §67.1001, which is presented in a separate rule action in the Proposed Rules section of this issue of the *Texas Register*.

BACKGROUND INFORMATION AND JUSTIFICATION: House Bill (HB) 1605, 88th Texas Legislature, Regular Session, 2023, significantly revised Texas Education Code, Chapter 31, related to instructional materials. The proposed repeal of §66.1307 would remove provisions related to the Instructional Materials and Technology Allotment that are being replaced by proposed new 19 TAC §67.1001. Proposed new §67.1001 would clarify the allowable uses of funds in alignment with HB 1605.

FISCAL IMPACT: Todd Davis, associate commissioner of instructional strategy, has determined that for the first five-year period the proposal is in effect, there are no additional costs to state or local government, including school districts and open-enrollment charter schools, required to comply with the proposal.

LOCAL EMPLOYMENT IMPACT: The proposal has no effect on local economy; therefore, no local employment impact statement is required under Texas Government Code, §2001.022.

SMALL BUSINESS, MICROBUSINESS, AND RURAL COMMUNITY IMPACT: The proposal has no direct adverse economic impact for small businesses, microbusinesses, or rural communities; therefore, no regulatory flexibility analysis, specified in Texas Government Code, §2006.002, is required.

COST INCREASE TO REGULATED PERSONS: The proposal does not impose a cost on regulated persons, another state agency, a special district, or a local government and, therefore, is not subject to Texas Government Code, §2001.0045.

TAKINGS IMPACT ASSESSMENT: The proposal does not impose a burden on private real property and, therefore, does not constitute a taking under Texas Government Code, §2007.043.

GOVERNMENT GROWTH IMPACT: TEA staff prepared a Government Growth Impact Statement assessment for this proposed rulemaking. During the first five years the proposed rulemaking would be in effect, it would repeal an existing regulation to move information related to the Instructional Materials and Technology Allotment to proposed new 19 TAC §67.1001.

The proposed rulemaking would not create or eliminate a government program; would not require the creation of new employee positions or elimination of existing employee positions; would not require an increase or decrease in future legislative appropriations to the agency; would not require an increase or decrease in fees paid to the agency; would not create a new regulation; would not expand or limit an existing regulation; would not increase or decrease the number of individuals subject to its applicability; and would not positively or adversely affect the state's economy.

PUBLIC BENEFIT AND COST TO PERSONS: Mr. Davis has determined that for each year of the first five years the proposal is in effect, the public benefit anticipated as a result of enforcing the proposal would be to repeal a rule that is being replaced by proposed new §67.1001. There is no anticipated economic cost to persons who are required to comply with the proposal.

DATA AND REPORTING IMPACT: The proposal would have no data and reporting impact.

PRINCIPAL AND CLASSROOM TEACHER PAPERWORK REQUIREMENTS: TEA has determined that the proposal would not require a written report or other paperwork to be completed by a principal or classroom teacher.

PUBLIC COMMENTS: The public comment period on the proposal begins March 7, 2025, and ends April 7, 2025. A request for a public hearing on the proposal submitted under the Administrative Procedure Act must be received by the commissioner of education not more than 14 calendar days after notice of the proposal has been published in the *Texas Register* on March 7, 2025. A form for submitting public comments is available on the TEA website at https://tea.texas.gov/About_TEA/Laws_and_Rules/Commissioner_Rules_(TAC)/Proposed_Commissioner_of_Education_Rules/.

STATUTORY AUTHORITY. The repeal is proposed under Texas Education Code (TEC), §31.0211, as amended by House Bill (HB) 1605 and HB 4595, 88th Texas Legislature, Regular Session, 2023, which permits the commissioner to adopt rules regarding the instructional materials and technology allotment, including the amount of the per-student allotment, the authorization of juvenile justice alternative education program allotments, allowed expenditures, required priorities, and adjustments to the number of students for which a district's allotment is calculated; TEC, §31.0212, as amended by HB 1605, 88th Texas Legislature, Regular Session, 2023, which addresses the documentation required for requisitions and disbursements to be approved, districts' online instructional materials ordering system accounts, and school district submission to the commissioner of the title and publication information for any materials the districts purchase with their allotments; TEC, §31.0214, as transferred and amended by HB 1605, 88th Texas Legislature, Regular Session, 2023, which permits the commissioner to establish procedures to adjust the instructional materials and technology allotment of school districts experiencing high enrollment growth; TEC, §31.0215, as amended by HB 1605, 88th Texas Legislature, Regular Session, 2023, which addresses allotment purchases, including announcing to districts the amount of their allotments and delayed payment options; TEC, §31.029, which requires the commissioner to adopt rules regarding instructional materials for use in bilingual education classes; TEC, §31.031, which requires the commissioner to adopt rules regarding the purchase of college preparatory instructional materials with the allotment; TEC, §31.076, as amended by HB 1605, 88th Texas Legislature, Regular Session, 2023, which permits the commissioner to adopt rules necessary to implement TEC, Chapter 31, Subchapter B-1, and states that a decision made by the commissioner under the subchapter is final and may not be appealed; and TEC, §31.104, which requires the commissioner to adopt rules that include criteria for determining whether instructional materials and technological equipment are returned in an acceptable condition.

CROSS REFERENCE TO STATUTE. The repeal implements Texas Education Code (TEC), §31.0211, as amended by House Bill (HB) 1605 and HB 4595, 88th Texas Legislature, Regular Session, 2023; §31.0212, as amended by HB 1605, 88th Texas Legislature, Regular Session, 2023; §31.0214, as transferred and amended by HB 1605, 88th Texas Legislature, Regular Session, 2023; §31.0215, as amended by HB 1605, 88th Texas Legislature, Regular Session, 2023; §31.029; §31.031; §31.076, as amended by HB 1605, 88th Texas Legislature, Regular Session, 2023; and §31.104.

§66.1307. Instructional Materials and Technology Allotment.

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

Filed with the Office of the Secretary of State on February 24, 2025.

TRD-202500682
Cristina De La Fuente-Valadez
Director, Rulemaking
Texas Education Agency
Earliest possible date of adoption: April 6, 2025
For further information, please call: (512) 475-1497

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CHAPTER 67. STATE REVIEW AND APPROVAL OF INSTRUCTIONAL MATERIALS SUBCHAPTER AA. INSTRUCTIONAL MATERIALS AND TECHNOLOGY ALLOTMENT

19 TAC §§67.1001, 67.1003, 67.1004

The Texas Education Agency (TEA) proposes new §§67.1001, 67.1003, and 67.1004, concerning the Instructional Materials and Technology Allotment. The proposed new sections would establish the requirements for the Instructional Materials and Technology Allotment and establish guidance regarding the use of the additional state aid for state-approved instructional materials and open education resource instructional materials.

BACKGROUND INFORMATION AND JUSTIFICATION: Proposed new §67.1001, Instructional Materials and Technology Allotment, would clarify the allowable uses of funds for the Instructional Materials and Technology Allotment that previously existed in 19 TAC §66.1307. This section would also clarify the commissioner's authority to set the allotment amounts for each school district and open-enrollment charter school and special school districts.

House Bill 1605, 88th Texas Legislature, Regular Session, 2023, established two new entitlements from the Foundation School Program. The bill also established requirements in Texas Education Code (TEC), Chapter 48, for the access to the funding.

Proposed new §67.1003, Additional State Aid for State-Approved Instructional Materials, would clarify the allowable uses of funds for the entitlement in TEC, §48.307, pertaining to additional state aid for state-approved instructional materials.

Proposed new §67.1004, Additional State Aid for Open Education Resource Instructional Materials, would clarify the allowable uses of funds for the entitlement in TEC, §48.308, pertaining to additional state aid for open education resource instructional materials.

FISCAL IMPACT: Todd Davis, associate commissioner of instructional strategy, has determined that for the first five-year period the proposal is in effect, there are no additional costs to state or local government, including school districts and open-enrollment charter schools, required to comply with the proposal.

LOCAL EMPLOYMENT IMPACT: The proposal has no effect on local economy; therefore, no local employment impact statement is required under Texas Government Code, §2001.022.

SMALL BUSINESS, MICROBUSINESS, AND RURAL COMMUNITY IMPACT: The proposal has no direct adverse economic impact for small businesses, microbusinesses, or rural communities; therefore, no regulatory flexibility analysis, specified in Texas Government Code, §2006.002, is required.

COST INCREASE TO REGULATED PERSONS: The proposal does not impose a cost on regulated persons, another state agency, a special district, or a local government and, therefore, is not subject to Texas Government Code, §2001.0045.

TAKINGS IMPACT ASSESSMENT: The proposal does not impose a burden on private real property and, therefore, does not constitute a taking under Texas Government Code, §2007.043.

GOVERNMENT GROWTH IMPACT: TEA staff prepared a Government Growth Impact Statement assessment for this proposed rulemaking. During the first five years the proposed rulemaking would be in effect, it would create new regulations regarding the requirements for the Instructional Materials and Technology Allotment and establish guidance regarding the use of the additional state aid for state-approved instructional materials and open education resource printing entitlements by implementing HB 1605, 88th Texas Legislature, Regular Session, 2023.

The proposed rulemaking would not create or eliminate a government program; would not require the creation of new employee positions or elimination of existing employee positions; would not require an increase or decrease in future legislative appropriations to the agency; would not require an increase or decrease in fees paid to the agency; would not expand, limit, or repeal an existing regulation; would not increase or decrease the number of individuals subject to its applicability; and would not positively or adversely affect the state's economy.

PUBLIC BENEFIT AND COST TO PERSONS: Mr. Davis has determined that for each year of the first five years the proposal is in effect, the public benefit anticipated as a result of enforcing the proposal would be to clarify the allowable uses of funding for instructional materials purchases and eligibility for new funding from the Foundation School Program. There is no anticipated economic cost to persons who are required to comply with the proposal.

DATA AND REPORTING IMPACT: The proposal would have no data and reporting impact.

PRINCIPAL AND CLASSROOM TEACHER PAPERWORK REQUIREMENTS: TEA has determined that the proposal would not require a written report or other paperwork to be completed by a principal or classroom teacher.

PUBLIC COMMENTS: The public comment period on the proposal begins March 7, 2025, and ends April 7, 2025. A request for a public hearing on the proposal submitted under the Administrative Procedure Act must be received

by the commissioner of education not more than 14 calendar days after notice of the proposal has been published in the *Texas Register* on March 7, 2025. A form for submitting public comments is available on the TEA website at https://tea.texas.gov/About_TEA/Laws_and_Rules/Commissioner_Rules_(TAC)/Proposed_Commissioner_of_Education_Rules/.

STATUTORY AUTHORITY. The new sections are proposed under Texas Education Code (TEC), §31.003(b), as added by House Bill (HB) 1605, 88th Texas Legislature, Regular Session, 2023, which authorizes the commissioner of education to adopt rules consistent with TEC, Chapter 31, as necessary to implement a provision of the chapter that the commissioner or the agency is responsible for implementing; TEC, §31.0211, as amended by HB 1605 and HB 4595, 88th Texas Legislature, Regular Session, 2023, which permits the commissioner to adopt rules regarding the instructional materials and technology allotment, including the amount of the per-student allotment, the authorization of juvenile justice alternative education program allotments, allowed expenditures, required priorities, and adjustments to the number of students for which a district's allotment is calculated; TEC, §31.0212, as amended by HB 1605, 88th Texas Legislature, Regular Session, 2023, which addresses the documentation required for requisitions and disbursements to be approved, districts' online instructional materials ordering system accounts, and school district submissions to the commissioner of the title and publication information for any materials the districts purchase with their allotments; TEC, §31.0215, as amended by HB 1605, 88th Texas Legislature, Regular Session, 2023, which addresses allotment purchases, including announcing to districts the amount of their allotments and delayed payment options; TEC, §31.029, which requires the commissioner to adopt rules regarding instructional materials for use in bilingual education classes; TEC, §31.031, which requires the commissioner to adopt rules regarding the purchase of college preparatory instructional materials with the allotment; TEC, §31.071, as amended by HB 1605, 88th Texas Legislature, Regular Session, 2023, which addresses state-developed open-source instructional materials; TEC, §31.076, as amended by HB 1605, 88th Texas Legislature, Regular Session, 2023, which permits the commissioner to adopt rules necessary to implement TEC, Chapter 31, Subchapter B-1, and states that a decision made by the commissioner under the subchapter is final and may not be appealed; TEC, §31.104, which requires the commissioner to adopt rules that include criteria for determining whether instructional materials and technological equipment are returned in an acceptable condition; and TEC, §48.004, which requires the commissioner to adopt rules, act, and require reports consistent with Chapter 48 as necessary to implement and administer the Foundation School Program.

CROSS REFERENCE TO STATUTE. The new sections implement Texas Education Code (TEC), §31.003(b), as added by House Bill (HB) 1605, 88th Texas Legislature, Regular Session, 2023; §31.0211, as amended by HB 1605 and HB 4595, 88th Texas Legislature, Regular Session, 2023; §31.0212, as amended by HB 1605, 88th Texas Legislature, Regular Session, 2023; §31.0215, as amended by HB 1605, 88th Texas Legislature, Regular Session, 2023; §31.029; §31.031; §31.071, as amended by HB 1605, 88th Texas Legislature, Regular Session, 2023; §31.076, as amended by HB 1605, 88th Texas Legislature, Regular Session, 2023; §31.104, as amended by HB 1605, 88th Texas Legislature, Regular Session, 2023; and §48.004.

§67.1001. Instructional Materials and Technology Allotment.

(a) The commissioner of education shall determine the amount of the Instructional Materials and Technology Allotment for a school district or an open-enrollment charter school based on Texas Student Data System Public Education Information Management System (TSDS PEIMS) student enrollment data from the fall snapshot collection of the school year preceding the first year of each biennium.

(b) The commissioner shall determine the amount of the allotment for Texas Juvenile Justice Department facilities.

(c) The commissioner shall determine the amount of the allotment for bilingual education based on TSDS PEIMS bilingual enrollment data from the fall collection of the school year preceding the first year of each biennium.

(d) The amount of the allotments determined by the commissioner in this section is final and may not be appealed.

(e) Allotment funds may be used to pay for:

(1) any approved uses outlined in Texas Education Code (TEC), §31.0211(c);

(2) formats of instructional materials that are fully accessible to students with disabilities;

(3) activities related to the local review and adoption of instructional materials; and

(4) software for analyzing the use and effectiveness of instructional materials.

(f) Allotment funds may not be used to pay for:

(1) services for installation;

(2) the physical conduit that transmits data, such as cabling and wiring, or electricity;

(3) office and school supplies;

(4) items that are not directly related to student instruction, such as furniture, athletic equipment, extension cords, temporary contractors, or video surveillance equipment;

(5) travel expenses;

(6) equipment used for moving or storing instructional materials;

(7) instructional material that contains obscene or harmful content or would otherwise cause the school district to which the funds were allotted to be unable to submit the certification required under TEC, §31.11011(a)(1)(B); or

(8) instructional material that incorporates three-cueing in the phonics curriculum required under TEC, Chapter 28.

(g) The allotments for each biennium will be made available for school district and open-enrollment charter school use through the state's online instructional materials ordering system as early as possible in the fiscal year preceding the beginning of the biennium for which the funds have been appropriated.

(h) A school district or an open-enrollment charter school may access its allotment funds for an upcoming school year after submitting to the commissioner:

(1) certification that the school district or open-enrollment charter school has instructional materials that cover all the required Texas Essential Knowledge and Skills (TEKS), except those for physical education, as required by TEC, §31.1011;

(2) certification that the school district or open-enrollment charter school has used its allotment for only the allowable expenditures provided in subsection (e) of this section; and

(3) information regarding the instructional materials used by the district during the previous school year, including the cost of each material as required by TEC, §31.1012.

(i) Upon completion of the requirements listed in subsection (h) of this section, school districts and open-enrollment charter schools may access their allotment funds by correctly providing all the information required in the state ordering system.

(j) Information required in the state ordering system may include verification of TEKS coverage for certain disbursement requests.

§67.1003. Additional State Aid for State-Approved Instructional Materials.

(a) The commissioner of education shall determine annually the amount of additional state aid for State Board of Education (SBOE)-approved instructional materials, as outlined in Texas Education Code (TEC), §48.307, for a school district or an open-enrollment charter school based on Texas Student Data System Public Education Information Management System (TSDS PEIMS) student enrollment data from the fall snapshot collection of the current school year.

(b) Before TSDS PEIMS student enrollment data from the fall snapshot collection of the current school year is available, a school district or an open-enrollment charter school will have an expected allotment amount that is based on 90% of the TSDS PEIMS student enrollment data from the fall snapshot collection of the previous school year.

(c) The Texas School for the Blind and Visually Impaired and the Texas School for the Deaf qualify for this funding under TEC, §30.025 and §30.056, respectively, for funding purposes under TEC, §48.307.

(d) Special purpose school districts authorized by the SBOE qualify for this funding. Texas Tech University K-12 and The University of Texas at Austin High School qualify for this funding under TEC, §48.307, for all free public education students. The University of Texas at Rio Grande Valley qualifies under TEC, §79.10(f). Texas A&M International University qualifies for this funding under TEC, §87.505(g). Lamar University qualifies for this funding under TEC, §96.707(k). The University of North Texas qualifies for this funding under TEC, §101.301(e)(3).

(e) Windham School District qualifies for this funding under TEC, §19.007(b) and (e), for funding purposes under TEC, §48.307.

(f) The Texas Juvenile Justice Department (TJJD) and juvenile justice alternative education programs operated by TJJD do not qualify for this funding under TEC, §48.307.

(g) Funds from TEC, §48.307, will be made available for school district and open-enrollment charter school use through the state's online instructional materials ordering system as early as possible each year in the fiscal year for which the funds have been appropriated.

(h) The Texas Education Agency (TEA) will make payment for any remaining balance for a school district's or an open-enrollment charter school's order under this section as the TEC, §48.307, funds become available.

(i) A school district is entitled to the amount of state aid provided by subsection (a) of this section each school year, regardless of whether the district uses the amount during the school year for which the amount was provided.

(j) Texas Government Code, Chapter 2251, does not apply to requisitions placed under this section, per TEC, §31.0215(e).

(k) The additional state aid for SBOE-approved instructional materials outlined in TEC, §48.307, may be used to purchase:

(1) instructional material products placed on the list of approved materials outlined in TEC, §31.022, including any non-text components of the approved product, such as manipulative kits or digital licenses; or

(2) instructional material components from a product on the list of approved materials outlined in TEC, §31.022, only after an initial purchase of all components of the product.

(l) SBOE-Approved Instructional Materials Allotment funds may not be used to purchase:

(1) instructional material or material components not on the list of approved instructional materials as outlined in TEC, §31.022;

(2) instructional material placed on the rejected list of instructional materials; or

(3) instructional material that promotes three-cueing as defined in TEC, §28.0062(a-1).

(m) Subject to TEA approval, the commissioner may exempt, under TEC, §7.056, a school district or an open-enrollment charter school from an initial purchase of each component of an approved product outlined in subsection (k)(2) of this section if the district or charter school can demonstrate that it already possesses an identical or nearly identical component for each student and/or teacher as indicated by the product design.

§67.1004. Additional State Aid for Open Education Resource Instructional Materials.

(a) The commissioner of education shall determine the amount of the additional state aid for open education resource (OER) instructional materials for a school district or an open-enrollment charter school based on Texas Student Data System Public Education Information Management System (TSDS PEIMS) student enrollment data from the fall snapshot collection of the current school year.

(b) Before TSDS PEIMS student enrollment data from the fall snapshot collection of the current school year is available, a school district or an open-enrollment charter school will have an expected allotment amount that is based on 90% of the TSDS PEIMS student enrollment data from the fall snapshot collection of the previous school year.

(c) The Texas School for the Blind and Visually Impaired and the Texas School for the Deaf qualify for this funding under TEC, §30.025 and §30.056, respectively, for funding purposes under TEC, §48.308.

(d) Special purpose school districts authorized by the State Board of Education (SBOE) qualify for this funding. Texas Tech University K-12 and The University of Texas at Austin High School qualify for this funding under TEC, §48.308, for all free public education students. The University of Texas at Rio Grande Valley qualifies under TEC, §79.10(f). Texas A&M International University qualifies for this funding under TEC, §87.505(g). Lamar University qualifies for this funding under TEC, §96.707(k). The University of North Texas qualifies for this funding under TEC, §101.301(e)(3).

(e) Windham School District qualifies for this funding under TEC, §19.007(b) and (e), for funding purposes under TEC, §48.308.

(f) The Texas Juvenile Justice Department (TJJD) and juvenile justice alternative education programs operated by TJJD do not qualify for this funding under TEC, §48.308.

(g) Funds may only be used for the costs incurred or for which the district is obligated to pay during the school year in which the aid is provided.

(h) Requisitions for funding must be submitted in the online requisition and disbursement system required in TEC, §31.0212(e), before August 31 of the fiscal year in which the aid is provided.

(i) The entitlements for each year will be made available for school district and open-enrollment charter school use through the state's online instructional materials ordering system as early as possible in the fiscal year for which the funds have been appropriated.

(j) Texas Government Code, Chapter 2251, does not apply to requisitions placed under this section per TEC, §31.0125(e).

(k) The additional state aid for OER instructional materials outlined in TEC, §48.308, may be used to purchase:

(1) OER instructional material made available under TEC, Chapter 31, Subchapter B-1, and placed on the list of approved materials outlined in TEC, §31.022, including any non-text components of the approved product, such as manipulative kits; and

(2) OER instructional material components made available under TEC, Chapter 31, Subchapter B-1, and placed on the list of approved materials outlined in TEC, §31.022, only after an initial purchase of all components of the product.

(l) The additional state aid for OER instructional materials outlined in TEC, §48.308, may not be used to purchase or reimburse for:

(1) instructional material or material components not on the list of approved instructional materials as outlined in TEC, §31.022;

(2) instructional material placed on the rejected list of instructional materials;

(3) instructional material that promotes three-cueing as defined in TEC, §28.0062(a-1); or

(4) printing of SBOE-approved OER material, which may be otherwise procured through a requisition in EMAT.

(m) The commissioner may grant a waiver under TEC, §7.056, to exempt a school district or an open-enrollment charter school from an initial purchase of each component of an approved product outlined in subsection (k)(2) of this section if the district or charter school can demonstrate that it already possesses an identical or near-identical component for each student and/or teacher as indicated by the product design.

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

Filed with the Office of the Secretary of State on February 24, 2025.

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Cristina De La Fuente-Valadez
Director, Rulemaking
Texas Education Agency
Earliest possible date of adoption: April 6, 2025
For further information, please call: (512) 475-1497

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CHAPTER 149. COMMISSIONER'S RULES CONCERNING EDUCATOR STANDARDS

SUBCHAPTER AA. TEACHER STANDARDS

19 TAC §149.1001

The Texas Education Agency (TEA) proposes the repeal of §149.1001 and new §149.1001, concerning teacher standards. The proposed repeal and new rule would reflect alignment with recent updates to State Board for Educator Certification (SBEC) rules in 19 Texas Administrative Code (TAC) Chapter 235, Subchapters A-D, as required by House Bill (HB) 1605, 88th Texas Legislature, Regular Session, 2023.

BACKGROUND INFORMATION AND JUSTIFICATION: Section 149.1001 identifies the performance standards to be used to inform the training, appraisal, and professional development of Early Childhood-Grade 12 pre-service and in-service teachers in Texas.

The proposed repeal of and new §149.1001 would align with recent updates to SBEC rules in 19 TAC Chapter 235, Subchapters A-D, as required by HB 1605.

The proposed repeal of and new §149.1001 would reflect a reorganization of the teacher standards and would also include definitions that provide clarity for educators and promote a common understanding of terms used within the updated teacher standards.

The standards included in proposed new §149.1001 would outline the necessary knowledge and skills related to instructional preparation, instructional delivery and assessment, content pedagogy for all teachers and for teachers leading English language arts and reading and math classes, learning environments, and professional practices and responsibilities.

FISCAL IMPACT: Kelvey Oeser, deputy commissioner of educator support, has determined that for the first five-year period the proposal is in effect, there are no additional costs to state or local government, including school districts and open-enrollment charter schools, required to comply with the proposal.

LOCAL EMPLOYMENT IMPACT: The proposal has no effect on local economy; therefore, no local employment impact statement is required under Texas Government Code, §2001.022.

SMALL BUSINESS, MICROBUSINESS, AND RURAL COMMUNITY IMPACT: The proposal has no direct adverse economic impact for small businesses, microbusinesses, or rural communities; therefore, no regulatory flexibility analysis, specified in Texas Government Code, §2006.002, is required.

COST INCREASE TO REGULATED PERSONS: The proposal does not impose a cost on regulated persons, another state agency, a special district, or a local government and, therefore, is not subject to Texas Government Code, §2001.0045.

TAKINGS IMPACT ASSESSMENT: The proposal does not impose a burden on private real property and, therefore, does not constitute a taking under Texas Government Code, §2007.043.

GOVERNMENT GROWTH IMPACT: TEA staff prepared a Government Growth Impact Statement assessment for this proposed rulemaking. During the first five years the proposed rulemaking would be in effect, it would repeal an existing regulation and create a new regulation to align with recent updates to SBEC rules in 19 TAC Chapter 235, Subchapters A-D, as required by HB 1605.

The proposed rulemaking would not create or eliminate a government program; would not require the creation of new employee positions or elimination of existing employee positions;

would not require an increase or decrease in future legislative appropriations to the agency; would not require an increase or decrease in fees paid to the agency; would not expand or limit an existing regulation; would not increase or decrease the number of individuals subject to its applicability; and would not positively or adversely affect the state's economy.

PUBLIC BENEFIT AND COST TO PERSONS: Ms. Oeser has determined that for each year of the first five years the proposal is in effect, the public benefit anticipated as a result of enforcing the proposal would be to identify the performance standards to be used to inform the training, appraisal, and professional development of Early Childhood-Grade 12 pre-service and in-service teachers in Texas; to reflect a reorganization of the teacher standards; to include definitions that provide clarity for educators; and to align the rule with recent updates to SBEC rules in 19 TAC Chapter 235, Subchapters A-D, as required by HB 1605. There is no anticipated economic cost to persons who are required to comply with the proposal.

DATA AND REPORTING IMPACT: The proposal would have no data and reporting impact.

PRINCIPAL AND CLASSROOM TEACHER PAPERWORK REQUIREMENTS: TEA has determined that the proposal would not require a written report or other paperwork to be completed by a principal or classroom teacher.

PUBLIC COMMENTS: The public comment period on the proposal begins March 7, 2025, and ends April 7, 2025. A request for a public hearing on the proposal submitted under the Administrative Procedure Act must be received by the commissioner of education not more than 14 calendar days after notice of the proposal has been published in the *Texas Register* on March 7, 2025. A form for submitting public comments is available on the TEA website at https://tea.texas.gov/About_TEA/Laws_and_Rules/Commissioner_Rules_(TAC)/Proposed_Commissioner_of_Education_Rules/.

STATUTORY AUTHORITY. The repeal is proposed under Texas Education Code, §21.351, which authorizes the commissioner to adopt a recommended appraisal process and criteria on which to appraise the performance of teachers.

CROSS REFERENCE TO STATUTE. The repeal implements Texas Education Code, §21.351.

§149.1001. Teacher Standards.

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

Filed with the Office of the Secretary of State on February 24, 2025.

TRD-202500686
Cristina De La Fuente-Valadez
Director, Rulemaking
Texas Education Agency
Earliest possible date of adoption: April 6, 2025
For further information, please call: (512) 475-1497

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19 TAC §149.1001

STATUTORY AUTHORITY. The new section is proposed under Texas Education Code, §21.351, which authorizes the commissioner to adopt a recommended appraisal process and criteria on which to appraise the performance of teachers.

CROSS REFERENCE TO STATUTE. The new section implements Texas Education Code, §21.351.

§149.1001. Teacher Standards.

(a) Purpose. The standards identified in this section are performance standards used to inform the preparation, appraisal, and professional development of Early Childhood-Grade 12 pre-service and in-service teachers in Texas. The standards:

(1) emphasize the knowledge and skills required for teachers to select, evaluate, internalize, and implement high-quality instructional materials;

(2) assume that practicing teachers are aware of Open Educational Resource (OER) instructional materials, customize materials as directed by their district, and engage in initial lesson design when directed by their district;

(3) describe the knowledge and skills required for teachers to prepare, deliver, and assess instruction that results in positive outcomes for all students;

(4) describe the knowledge and skills required for teachers to build positive relationships with and among students in a safe and productive learning environment;

(5) reflect research- and evidence-based practices that ensure all students are held to rigorous grade-level academic and nonacademic standards; and

(6) define a teacher's role as a professional, ethical, and reflective practitioner.

(b) Definitions. The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Academic language--the oral, written, auditory, and visual language specific to a discipline. It includes vocabulary, grammar, punctuation, syntax, discipline-specific terminology, and rhetorical conventions that allow students to acquire knowledge and academic skills.

(2) Accelerated instruction--includes aligned research-driven strategies and supports within a multi-tiered instructional model that helps students make more than one year of growth in one year of time.

(3) Complex text--texts that provide students opportunities to work with new language, knowledge, and ways of thinking. Text complexity is evaluated along quantitative dimensions such as word and sentence length; qualitative dimensions such as text structure, levels of meaning, and language conventions; and considerations including the reader's background, motivation, and knowledge of the topic.

(4) Deliberate practice--practice that is systematic, requires focused attention, and is conducted with the specific goal of improving performance.

(5) Encoding--the process by which information is initially coded to be stored and retrieved. Encoding requires attention and is aided by reducing extraneous cognitive load or information in the learning environment.

(6) Engagement--a state in which students are cognitively and behaviorally connected to and involved in their learning experience, characterized by participation, curiosity, and perseverance.

(7) Evidence-based--a concept or strategy that has been evaluated as a whole and found to have positive effects when implemented with programmatic fidelity.

(8) Explanatory feedback--feedback that provides the learner with an explanation of strengths and weaknesses related to the learning activity or assignment.

(9) Explicit instruction--instruction in which the teacher's actions are clear, unambiguous, direct, and visible. Explicit instruction makes it clear what the students are to do and learn.

(10) Fixed personality traits--the misconception that personality traits become fixed at certain stages of an individual's development and do not change over time.

(11) Formative assessment--A deliberate process used by teachers during instruction that provides actionable feedback used to elicit and use evidence of student learning to improve students' attainment of learning targets.

(12) Hemispheric dominance--the misconception that each brain hemisphere is specialized to process information differently and that the dominant hemisphere determines a person's personality and way of thinking.

(13) High-quality instructional materials--instructional materials that ensure full coverage of Texas Essential Knowledge and Skills (TEKS); are aligned to evidence-based best practices in the relevant content areas; support all learners, including students with disabilities, emergent bilingual students, and students identified as gifted and talented; enable frequent progress monitoring through embedded and aligned assessments; include implementation supports for teachers; and provide teacher- and student-facing lesson-level materials.

(14) Instructional preparation--describes the process by which a teacher uses knowledge of students and student learning to prepare instructional delivery to a unique group of students. Instructional preparation may include activities such as lesson design, evaluation of instructional materials, and lesson internalization.

(15) Interleaving--an instructional technique that arranges practice of topics in such a way that consecutive problems cannot be solved by the same strategy.

(16) Just-in-time supports--a learning acceleration strategy that integrates small, timely supports to address gaps in the most critical prerequisite knowledge and skills that students will need to access grade-level content in upcoming units.

(17) Learning styles--the disproven theory that identifies learners by type (visual, auditory, reading and writing, and kinesthetic) and adapts instruction to the individual's learning style.

(18) Lesson design--describes the process by which a teacher develops the planned learning experiences and related instructional materials for a topic. Lesson design incorporates activities including developing objectives, learning experiences, sequencing, scaffolds, resources, materials, tasks, assessments, and planned instructional practices.

(19) Lesson internalization--an aspect of instructional preparation specific to teaching a lesson or unit. It includes activities such as evaluating sequencing, learning goals, and expected outcomes; using assessment data to identify prior knowledge; studying lesson content; rehearsing lesson delivery; identifying possible misconceptions; and planning instructional strategies, materials, and pacing.

(20) Metacognition--the awareness of how one's mind learns and thinks and the use of that awareness to optimize the efficiency of learning and cognition.

(21) Multiple means of engagement--a range of options provided to engage and motivate students in learning.

(22) Multiple means of representation--a range of options provided in the ways that information is presented to students.

(23) Multiple means of action and expression--a range of options provided in the ways that students express or demonstrate their learning.

(24) Open educational resource instructional materials--state-developed materials included on the list of approved instructional materials maintained by the State Board of Education under Texas Education Code (TEC), §31.022, where the underlying intellectual property is either owned by the state of Texas or can be freely used and modified by the state in perpetuity.

(25) Patterns of student thinking--common patterns in the ways in which students think about and develop understanding and skill in relation to particular topics and problems.

(26) Productive struggle--expending effort to understand a challenging situation and determine a course of action when no obvious strategy is stated and receiving support that encourages persistence without removing the challenge.

(27) Recall--also referred to as "retrieval," the mental process of retrieving information that was previously encoded and stored in the brain.

(28) Remediation--strategies that focus on the drilling of isolated skills that bear little resemblance to current curriculum. Activities connect to past standards and aim to master content from past years.

(29) Research-based--a concept or strategy with positive findings from studies effective in isolation or in combination with other researched strategies or evidence-based programs.

(30) Retrieval practice--also referred to as "testing effect" or "active recall," the finding that trying to remember previously learned material, including by responding to questions, tests, assessments, etc., leads to better retention than restudying or being retold the material for an equivalent amount of time.

(31) Science of learning--the summarized existing cognitive-science, cognitive psychology, educational psychology, and neuroscience research on how people learn, as it connects to practical implications for teaching.

(32) Second language acquisition--the process through which individuals leverage their primary language to learn a new language. A dynamic process of learning and acquiring proficiency in the English language, supported by exposure to comprehensible input, interaction, formal instruction, and access to resources and support in English and primary language.

(33) Spaced practice/distributed practice--practice opportunities for learning are sequenced in a way that students actively retrieve learned information from long-term memory through multiple opportunities over time with rest intervals in between.

(34) State Board of Education-approved instructional materials--materials included on the list of approved instructional materials maintained by the State Board of Education under TEC, §31.022.

(35) Summative assessment--medium- to high-stakes assessments, administered at the conclusion of an instructional period

that are used to evaluate student learning, knowledge, proficiency, or mastery of a learning target.

(c) Standards.

(1) Standard 1--Instructional Preparation. Teachers understand how students learn, and they prepare for instructional delivery by designing lessons, evaluating instructional materials, leveraging their knowledge of students, and engaging in a thorough process for lesson internalization.

(A) Teachers apply basic principles from the learning sciences to prepare for instruction.

(i) Teachers understand learning as an active and social process of meaning-making that results in changes in student knowledge and behavior based on connections between past and new experiences.

(ii) Teachers prepare instruction that uses research- and evidence-based teaching strategies for eliciting and sustaining attention and motivation, supporting memory encoding and recall, and deeply integrating new experiences with prior knowledge, such as interleaving, spacing, metacognition, and distributed practice.

(iii) Teachers recognize misconceptions about learning, the brain, and child and adolescent development, including myths such as learning styles, personality traits, and hemispheric dominance, and avoid unsupported instructional practices based on these misunderstandings.

(B) Teachers evaluate instructional materials and select or customize the highest quality district-approved option to prepare for instruction.

(i) Teachers identify the components of high-quality instructional materials, such as a logical scope and sequence, clear learning objectives, grade-level content, explicit instruction, student engagement, academic language, deliberate practice, and assessment, appropriate to the discipline.

(ii) Teachers identify the benefits of using high-quality instructional materials.

(iii) Teachers apply knowledge of the components of high-quality instructional materials to design, select, or customize materials when appropriate.

(iv) Teachers analyze instructional materials and digital resources to ensure quality, rigor, and access to grade-level content.

(v) Teachers use high-quality materials to plan instruction that connects students' prior understanding and real-world experiences to new content and contexts.

(C) Teachers understand initial lesson design and, when district-approved materials are not available and when directed by their district, engage in initial lesson design using science of learning concepts.

(i) Teachers design lessons based on the components of high-quality instructional materials, such as a logical scope and sequence, clear learning objectives, and grade-level content.

(ii) Teachers design lessons that effectively connect learning objectives with explicit instruction, student engagement, academic language, deliberate practice, and assessment.

(iii) Teachers design lessons that connect students' prior understanding and real-world experiences to new content and contexts.

(iv) Teachers plan for the use of digital tools and resources to engage students in active, deep learning.

(D) Teachers ensure lesson sequence and materials meet the needs of all learners and adapt methods when appropriate.

(i) Teachers plan for the use of multiple means to engage students, varied ways of representing information, and options for students to demonstrate their learning.

(ii) Teachers leverage student data to prepare flexible student groups that facilitate learning for all students.

(iii) Teachers differentiate instruction and align methods and techniques to diverse student needs, including acceleration, just-in-time supports, technology, intervention, linguistic supports, appropriate scaffolding, and implementation of individualized education programs.

(E) Teachers recognize students' backgrounds (familial, educational, linguistic, and developmental) as assets and apply knowledge of students to engage them in meaningful learning.

(i) Teachers plan to present information in a meaningful way that activates or provides any prerequisite knowledge to maximize student learning.

(ii) Teachers collaborate with other professionals, use resources, and plan research- and evidence-based instructional strategies to anticipate and respond to the unique needs of students, including disabilities, giftedness, bilingualism, and biliteracy.

(iii) Teachers plan instructional practices and strategies that support language acquisition so that language is comprehensible and instruction is fully accessible.

(iv) Teachers apply knowledge of how each category of disability under the Individuals with Disabilities Act (20 U.S.C. §1400, et seq.) and Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. §794) can affect student learning and development.

(F) Teachers engage in a thorough process of lesson internalization to prepare well-organized, sequential instruction that builds on students' prior knowledge.

(i) Teachers identify how the intentional sequencing of units, lessons, and learning tasks supports student knowledge and mastery throughout the year.

(ii) Teachers identify how the learning goals of units and lessons are aligned to state standards.

(iii) Teachers use assessment data to identify prior knowledge and plan for the learning needs of students.

(iv) Teachers internalize lesson content by reading the texts, completing learning tasks and assessments, rehearsing lesson delivery, and identifying any personal gaps in understanding.

(v) Teachers plan for pacing, use of teacher resources, and transitions between activities.

(vi) Teachers create or analyze and customize exemplar responses and anticipate potential barriers to learning.

(vii) Teachers strategically plan instructional strategies, formative assessments, technology, scaffolds, and enrichment to make learning accessible to all students.

(2) Standard 2--Instructional Delivery and Assessment. Teachers intentionally apply their knowledge of students and the learning process to implement high-quality instruction and assessment

practices that are research- and evidence-based and informed by student work.

(A) Teachers deliver research- and evidence-based instruction to meet the needs of all learners and adapt methods when appropriate.

(i) Teachers effectively communicate grade-level expectations, objectives, and goals to help all students reach high levels of achievement.

(ii) Teachers apply research- and evidence-based teaching strategies for eliciting and sustaining attention and motivation and supporting memory encoding and recall, such as interleaving, spacing, metacognition, and distributed practice.

(iii) Teachers ensure a high degree of student engagement through explicit instruction, student discussion, feedback, and opportunities for deliberate practice.

(iv) Teachers apply research- and evidence-based teaching strategies that connect students' prior understanding and real-world experiences to new content and contexts and invite student perspectives.

(v) Teachers implement appropriate scaffolds in response to student needs.

(vi) Teachers strategically implement tools, technology, and procedures that lead to increased participation from all students, elicit patterns of student thinking, and highlight varied responses.

(vii) Teachers provide multiple means of engagement to encourage all students to remain persistent in the face of challenges.

(viii) Teachers collaborate with other educational professionals, when appropriate, to deliver instruction that addresses students' academic and non-academic needs.

(B) Teachers scaffold instruction, from initial knowledge and skill development through automaticity, toward complex, higher-order thinking, providing opportunities for deeper learning.

(i) Teachers set high expectations and facilitate rigorous grade-level learning experiences for all students that encourage them to apply disciplinary and cross-disciplinary knowledge to real-world problems.

(ii) Teachers apply instructional strategies to deliberately engage all students in critical thinking and problem solving.

(iii) Teachers validate student responses, using them to advance learning for all students.

(iv) Teachers respond to student errors and misconceptions with prompts or questions that build new understanding on prior knowledge.

(v) Teachers use strategic questioning to build and deepen student understanding.

(vi) Teachers strategically incorporate technology that removes barriers and allows students to interact with the curriculum in more authentic, significant, and effective ways.

(C) Teachers consistently check for understanding, give feedback, and make lesson adjustments as necessary.

(i) Teachers use a variety of formative assessments during instruction to gauge and respond to student progress and address misconceptions.

(ii) Teachers implement frequent, low- or no-stakes assessments to promote retrieval of learned information.

(iii) Teachers continually monitor and assess students' progress to guide instructional outcomes and determine next steps to ensure student mastery of grade-level content.

(iv) Teachers build student capacity to self-monitor their progress.

(v) Teachers provide frequent, timely, and specific explanatory feedback that emphasizes effort and improvement and acknowledges students' strengths and areas for growth.

(vi) Teachers strategically implement instructional strategies, formative assessments, scaffolds, and enrichment to make learning accessible to all students.

(vii) Teachers set goals for each student in response to previous outcomes from formative and summative assessments.

(viii) Teachers involve all students in self-assessment, goal setting, and monitoring progress.

(D) Teachers implement formative and summative methods of measuring and monitoring student progress through the regular collection, review, and analysis of data.

(i) Teachers individually and collaboratively review and analyze student work to understand students' thinking, identify strengths and progress toward mastery, and identify gaps in knowledge.

(ii) Teachers combine results from different measures to develop a holistic picture of students' strengths and learning needs.

(iii) Teachers apply multiple means of assessing learning, including the use of digital tools, to accommodate according to students' learning needs, linguistic differences, and/or varying levels of background knowledge.

(iv) Teachers use assessment results to inform and adjust instruction and intervention.

(v) Teachers clearly communicate the results of assessments with students, including setting goals and identifying areas of strength and opportunities for improvement.

(3) Standard--Content Pedagogy Knowledge and Skills. Teachers show a full understanding of their content and related pedagogy and the appropriate grade-level TEKS.

(A) Teachers understand the major concepts, key themes, multiple perspectives, assumptions, processes of inquiry, structure, and real-world applications of their grade-level and subject-area content.

(i) Teachers demonstrate a thorough understanding of and competence in the use of open education resource instructional materials when available for the grade level and subject area.

(ii) Teachers have expertise in how their content vertically and horizontally aligns with the grade-level/subject-area continuum, leading to an integrated curriculum across grade levels and content areas.

(iii) Teachers identify gaps in students' knowledge of subject matter and communicate with their leaders and colleagues to ensure that these gaps are adequately addressed across grade levels and subject areas.

(iv) Teachers deliberately and regularly share multiple different examples of student representations and resolutions.

(v) Teachers stay current with developments, new content, new approaches, and changing methods of instructional delivery within their discipline.

(B) Teachers demonstrate content-specific pedagogy that meets the needs of diverse learners, using engaging instructional materials to connect prior content knowledge to new learning.

(i) Teachers teach the key content knowledge, the key skills of the discipline, and the requisite linguistic skills to construct, the information into usable knowledge and make it accessible to all learners by constructing it into usable knowledge.

(ii) Teachers make appropriate and authentic connections across disciplines, subjects, and students' real-world experiences to build knowledge from year to year.

(iii) Teachers provide multiple means of representation and engagement to promote literacy and ensure discipline-specific academic language is accessible for all students.

(iv) Teachers explicitly teach, encourage, and reinforce the use of academic language, including vocabulary, use of symbols, and labeling.

(v) Teachers prepare for and apply scaffolds in the lesson to make content accessible to all students, including diverse learners such as emergent bilingual students, students with disabilities, and students working above and below grade level.

(vi) Teachers engage students in productive struggle by allowing them time to work, asking questions to deepen their thinking, encouraging multiple approaches, and praising effort on successful and unsuccessful attempts.

(C) Teachers demonstrate research- and evidence-based best practices specific to planning, instruction, and assessment of mathematics.

(i) Teachers use multiple means of representation to communicate the relationship between mathematical concepts and mathematical procedures.

(ii) Teachers engage students in recursive lesson activities that reinforce automaticity in prerequisite knowledge and skills to mitigate the use of working memory when engaging those knowledge and skills as task complexity increases.

(iii) Teachers use multiple means of representation to engage students in mathematical tasks that deepen students' understanding of conceptual understanding, procedural fluency, and mathematical reasoning.

(iv) Teachers prepare and deliver instruction and questioning to deliberately solicit different explanations, representations, solutions, and reasoning from all students.

(v) Teachers prepare and deliver explicit instruction and modeling that links grade-level conceptual understanding with mathematical procedures and avoids shortcuts to problem solving.

(vi) Teachers analyze instructional plans to ensure an appropriate balance between conceptual understanding and procedural fluency.

(vii) Teachers facilitate discourse through regular opportunities for students to communicate the relationship between mathematical concepts and mathematical procedures.

(viii) Teachers provide time for students to collaboratively and independently apply conceptual understanding and procedural fluency to problem-solving.

(ix) Teachers communicate and model the connections between mathematics and other fields that use mathematics to problem solve, make decisions, and incorporate real-world applications in instruction.

(x) Teachers explicitly teach and model that math abilities are expandable and improvable.

(D) Teachers demonstrate research- and evidence-based best practices specific to planning, instruction, and assessment of language arts and reading.

(i) Teachers analyze instructional materials in preparation for instruction to ensure they provide grade-level appropriate, systematic, and explicit practice in foundational literacy skills.

(ii) Teachers analyze instructional materials in preparation for instruction to ensure that foundational literacy skills are reached at each grade level.

(iii) Teachers implement clear and explicit reading instruction aligned to the Science of Teaching Reading competencies and engage students in deliberate practice to make meaning from text.

(iv) Teachers identify and analyze grade-level and complex texts for quality in preparation for instruction.

(v) Teachers prepare and deliver explicit reading instruction that uses grade-level and complex texts to build student knowledge.

(vi) Teachers strategically plan and implement supports such as read-aloud and questioning at varied levels of complexity to support comprehension of high-quality complex texts.

(vii) Teachers engage students in writing practice, including text-based writing that builds comprehension and higher-order thinking skills.

(viii) Teachers engage students in speaking practice that builds comprehension, language acquisition, and higher-order thinking skills.

(ix) Teachers use high-quality assessments to monitor grade-level appropriate foundational skills development.

(x) Teachers implement and analyze a variety of high-quality literacy assessments to monitor grade-level appropriate comprehension and identify gaps.

(xi) Teachers apply just-in-time supports and intervention on prerequisite skills and continually monitor to determine the need for additional learning support.

(4) Standard 4--Learning Environment. Teachers maintain a safe and supportive learning environment that is characterized by respectful interactions with students, consistent routines, high expectations, and the development of students' self-regulation skills.

(A) Teachers establish, implement, and communicate consistent routines for effective classroom management, including clear expectations for student behavior and positive interventions, that maintain a productive learning environment for all students.

(i) Teachers arrange their classrooms and virtual learning spaces in an organized way that is safe, flexible, and accessible to maximize learning that accommodates all students' learning and physical needs.

(ii) Teachers implement consistent classroom and behavior management systems to maintain an environment where all students are engaged and can reach academic and nonacademic goals.

(iii) Teachers model and provide explicit instruction on effective behavior regulation skills to build students' resilience and self-discipline.

(iv) Teachers maintain a safe and positive culture of student ownership and group accountability that fosters engagement by all students in the classroom expectations, culture, and norms.

(B) Teachers lead and maintain classroom environments in which students are motivated and cognitively engaged in learning.

(i) Teachers maintain a classroom environment that is based on high expectations and student self-efficacy.

(ii) Teachers strategically use instructional time, including transitions, to maximize learning.

(iii) Teachers manage and facilitate strategic and flexible groupings to maximize student learning.

(5) Standard 5--Professional Practices and Responsibilities. Teachers are self-aware and consistently hold themselves to a high standard for individual development. They collaborate with other educational professionals; communicate regularly with stakeholders; maintain professional relationships; comply with federal, state, and local laws; and conduct themselves ethically and with integrity.

(A) Teachers model ethical and respectful behavior and demonstrate integrity in all settings and situations.

(i) Teachers understand and comply with applicable federal, state, and local laws pertaining to the professional behaviors and responsibilities of educators.

(ii) Teachers adhere to the Educators' Code of Ethics in §247.2 of this title (relating to Code of Ethics and Standard Practices for Texas Educators), including following policies and procedures at their specific school placement(s).

(iii) Teachers demonstrate understanding of their role in strengthening American democracy and are willing to support and defend the constitutions of the United States and Texas.

(iv) Teachers advocate for and apply knowledge of students' progress and learning plans through the maintenance of thorough and accurate records.

(v) Teachers model and promote for students the use of safe, ethical, and legal practices with digital tools and technology.

(B) Teachers actively self-reflect on their practice and collaborate with other educational professionals to deepen knowledge, demonstrate leadership, and improve their instructional effectiveness.

(i) Teachers apply consistent reflective practices, analysis of student work, and video evidence of teaching to identify and communicate professional learning needs.

(ii) Teachers seek and apply job-embedded feedback from colleagues, including supervisors, mentors, coaches, and peers.

(iii) Teachers establish and strive to achieve professional goals to strengthen their instructional effectiveness and better meet students' needs.

(iv) Teachers engage in relevant professional learning opportunities that align with their growth goals and student learning needs.

(v) Teachers seek to lead other adults on campus through professional learning communities, grade- or subject-level team leadership, committee membership, or other opportunities.

(vi) Teachers collaborate with educational professionals to ensure learning is accessible and enables all students to reach their academic and non-academic goals.

(C) Teachers communicate consistently, clearly, and respectfully with all community stakeholders, including students, parents and families, colleagues, administrators, and staff.

(i) Teachers clearly communicate the mission, vision, and goals of the school to students, colleagues, parents and families, and other community members.

(ii) Teachers communicate regularly, clearly, and appropriately with families about student progress, providing detailed and constructive feedback in a language that is accessible to families to support students' developmental and learning goals.

(iii) Teachers build mutual understanding of expectations with students, parents, and families through clear, respectful, and consistent communication methods.

(iv) Teachers communicate with students and families regularly about the importance of collecting data and monitoring progress of student outcomes, sharing timely and comprehensible feedback so they understand students' goals and progress.

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

Filed with the Office of the Secretary of State on February 24, 2025.

TRD-202500687
Cristina De La Fuente-Valadez
Director, Rulemaking
Texas Education Agency
Earliest possible date of adoption: April 6, 2025
For further information, please call: (512) 475-1497

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TITLE 22. EXAMINING BOARDS

PART 10. TEXAS FUNERAL SERVICE COMMISSION

CHAPTER 210. NON-TRANSPLANT WHOLE BODY DONATIONS

SUBCHAPTER B. AUTHORIZATION & REGISTRATION FOR THE RECEIPT, USE AND DISTRIBUTION OF DONOR WHOLE BODIES OR BODY PARTS

22 TAC §210.27

The Texas Funeral Service Commission (hereinafter referred to as "the Commission") proposes a new rule - 22 Texas Administrative Code §210.27. This proposed rule establishes licensing fees for regulated entities, including willed body programs, non-transplant anatomical donation organizations, and anatomical facilities.

BACKGROUND INFORMATION AND JUSTIFICATION

The proposed new 22 Texas Administrative Code §210.27 implements TEX. HEALTH & SAFETY CODE § 691.012, which authorizes the Commission to adopt rules necessary to set and administer fees. These fees are reasonable and necessary to cover the cost of regulating willed body programs, non-transplant anatomical donation organizations, and anatomical facilities. The rule is necessitated by the transfer of regulatory duties from the Anatomical Board of the State of Texas to the Commission under Senate Bill 2040 (88th (R)).

FISCAL NOTE

Staff Attorney Sarah Kemp has determined that, for each of the first five years that the rule is in effect, the additional estimated cost to the state and local governments will be primarily composed of licensing fees. State-affiliated programs, such as those operated by state universities, will bear these costs as part of their operational budgets. Licensing fees will include:

1. $2,790.00 for initial authorization, registration application, or change of ownership (including relocations);

2. additional inspection fees for inspection requests made within 30 days;

3. $1,789.00 for 12-month renewals; and

4. $1,789.00 for late applications submitted within 1-30 days after expiration.

The total annual fees for each regulated entity will depend on its licensing stage, whether it requires expedited inspections, and if late fees are applicable. The Commission's Legislative Appropriations Request has projected costs associated with its new and expanded statutory obligations. The additional revenue generated by these fees is designed to cover the costs of regulatory duties required by the General Appropriations Act.

PUBLIC BENEFIT

The proposed rule provides the financial support necessary to regulate willed body programs, non-transplant anatomical donation organizations, and anatomical facilities - thereby protecting public safety and welfare.

ECONOMIC COSTS TO PERSONS

Staff Attorney Sarah Kemp has determined that the economic cost to individuals and entities required to comply with the proposed rule comprises licensing fees detailed above.

ECONOMIC IMPACT ON LOCAL ECONOMY AND EMPLOYMENT

Staff Attorney Sarah Kemp has determined that the proposed rule will not impact local economies and employment.

FISCAL IMPACT ON SMALL BUSINESSES, MICRO-BUSINESSES, OR RURAL COMMUNITIES

The proposed rule is not expected to adversely impact small businesses, micro-businesses, or rural communities because these entities are not typically involved in the activities regulated by the rule. Accordingly, the preparation of an economic impact statement and a regulatory flexibility analysis is not required under TEX. GOV'T CODE § 2006.002.

TAKINGS IMPACT ASSESSMENT

The proposed rule does not constitute a taking as it does not impose a burden on private real property. TEX. GOV'T CODE § 2007.043.

GOVERNMENT GROWTH IMPACT STATEMENT

Pursuant to TEX. GOV'T CODE § 2001.0221, the Commission provides the following government growth impact statement:

1. The proposed rule does not create or eliminate a government program.

2. Implementation of the proposed rule does not require the creation or elimination of employee positions.

3. Implementation of the proposed rule may impact future appropriations, depending on actual regulatory costs and revenue.

4. The proposed rule requires an increase in fees paid to the Commission, based on reasonable and necessary administrative costs.

5. The proposed rule creates new regulations to fulfill responsibilities transferred under Senate Bill 2040, 88th regular legislative session (SB 2040).

6. The proposed rule does not expand an existing regulation but replaces prior rules of the Anatomical board.

7. The proposed rule does not increase the number of individuals or entities subject to the applicability of the Commission's rules but clarifies procedures for those now under the Commission's jurisdiction.

8. The proposed rule does not positively or adversely affect the state's economy.

REQUEST FOR PUBLIC COMMENTS

Comments on the proposed rule may be submitted to the Texas Funeral Service Commission by email to sarah.sanders@tfsc.texas.gov for 30 days following the date of publication in the *Texas Register*. To be considered for purposes of this rulemaking, comments must be e-mailed by midnight on the last day of the comment period. Comments should be organized in a manner consistent with the organization of the proposed new rule.

STATUTORY AUTHORITY

The proposed rule is authorized by TEX. HEALTH & SAFETY CODE § 691. 012 which gives the Commission authority to adopt rules to set and administer fees. Statutes affected by the proposed rule include TEX. HEALTH & SAFETY CODE §§ 691.012, 691.034.

§210.27. Fees.

(a) Initial establishment authorization, registration application, or change of ownership fee. The fee for an initial authorization or registration (includes change of ownership or relocation) is $2,790.00. The authorization or registration term shall not exceed 12 months. Additional fees may apply for inspection requests made within 30 days.

(b) Renewal fee. The fee for a renewal authorization or registration is $1,789.00. The renewal shall not exceed 12 months.

(c) Late fee. Applications submitted 1-30 days after the authorization or registration expired will incur an additional fee of $1,789.00 in addition to the renewal fee.

(d) Payment of fees. All fees shall be paid to the Texas Funeral Service Commission.

(e) Non-refundable fees. All fees are non-refundable and must be paid to the Texas Funeral Service Commission.

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

Filed with the Office of the Secretary of State on February 21, 2025.

TRD-202500680
Sarah Sanders
Staff Attorney
Texas Funeral Service Commission
Earliest possible date of adoption: April 6, 2025
For further information, please call: (512) 936-2469

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TITLE 25. HEALTH SERVICES

PART 1. DEPARTMENT OF STATE HEALTH SERVICES

CHAPTER 289. RADIATION CONTROL
SUBCHAPTER E. REGISTRATION REGULATIONS

Editor's Note: This proposed rulemaking was originally published in the February 21, 2025, issue of the Texas Register (50 TexReg 908). Due to an error by the Texas Register, numerous provisions in the original publication of the amendment were formatted incorrectly or were omitted from the original publication. Text of the corrected proposal follows.

The Executive Commissioner of the Texas Health and Human Services Commission (HHSC), on behalf of the Department of State Health Services (DSHS), proposes an amendment to §289.230, concerning Certification of Mammography Systems and Mammography Machines Used for Interventional Breast Radiography, and the repeal of §289.234, concerning Mammography Accreditation.

BACKGROUND AND PURPOSE

The purpose of the proposal is to amend §289.230, relating to requirements for the certification and use of radiation machines in mammography and interventional breast radiography. The amendment is necessary to align with the United States Food and Drug Administration (FDA) Mammography Quality Standards Act (MQSA) under 21 Code of Federal Regulations (CFR) Part 900.

Additionally, the proposal repeals §289.234, relating to mammography accreditation, because DSHS no longer accredits mammography facilities due to an expired contract which ended on August 31, 2024. With the contract's expiration, this rule is no longer valid.

SECTION-BY-SECTION SUMMARY

The proposed amendment to §289.230 updates the requirements concerning breast tissue density in mammography reports and plain language notification statements to patients. Three new outcome data reporting requirements for the interpreting physician and the facility have been added. The outcome data report must include calculations for positive predictive value, cancer detection rate, and recall rate.

Additional changes to §289.230 include reorganizing the rule to mirror the layout of other sections of this chapter, adding survey report requirements, and adding and clarifying definitions for various terms related to mammography machines. The proposal adopts 21 CFR Part 900 by reference for system design, screen-film, processor performance testing, equipment variances, and investigational device requirements. The proposed changes enhance clarity, safety, and regulatory compliance in the field of mammography. Other edits are made to improve grammar, formatting, and rule clarity.

The proposed repeal of §289.234 is necessary to delete an invalid rule.

FISCAL NOTE

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

GOVERNMENT GROWTH IMPACT STATEMENT

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

(1) the proposed rules will eliminate a government program;

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

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

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

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

(6) the proposed rules will expand and repeal existing regulations;

(7) the proposed rules will decrease the number of individuals subject to the rules; and

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

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

Christy Havel Burton has also determined that there will be an adverse economic effect on small businesses or micro-businesses, or rural communities because there may be a cost to comply with new data reporting requirements.

DSHS estimates that the number of mammography facilities subject to the proposal for §289.230 is 668. The projected economic impact cannot be determined because the impact is based on the size of the facility and the age of its current software.

DSHS determined that alternative methods to achieve the purpose of the proposed rules for small businesses, micro-businesses, or rural communities would not be consistent with ensuring the health and safety of the public, employees, and patients.

LOCAL EMPLOYMENT IMPACT

The proposed rules will not affect a local economy.

COSTS TO REGULATED PERSONS

Texas Government Code §2001.0045 does not apply to these rules because the rules are necessary to comply with federal law: 21 CFR Part 900, and to protect the health, safety, and welfare of the residents of Texas.

PUBLIC BENEFIT AND COSTS

Dr. Timothy Stevenson, Deputy Commissioner, Consumer Protection Division, has determined that for each year of the first five years the rules are in effect, the anticipated public benefit will be improved protection from unnecessary exposure to radiation for the public, patients, workers, and the environment.

Christy Havel Burton has also determined that for the first five years the rules are in effect, persons required to comply with the proposed rules may incur economic costs because new outcome data reporting requirements may require additional software or increase staff workload. The proposed rules do not increase registration fees or increase the frequency of fee payment.

TAKINGS IMPACT ASSESSMENT

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

PUBLIC COMMENT

Written comments on the proposal may be submitted to Rules Coordination Office, P.O. Box 13247, Mail Code 4102, Austin, Texas 78711-3247, or street address 4601 West Guadalupe Street, Austin, Texas 78751; or emailed to HHSRulesCoordinationOffice@hhs.texas.gov.

To be considered, comments must be submitted no later than 31 days after the date of this issue of the *Texas Register*. Comments must be (1) postmarked or shipped before the last day of the comment period; (2) hand-delivered before 5:00 p.m. on the last working day of the comment period; or (3) faxed or emailed before midnight on the last day of the comment period. If the last day to submit comments falls on a holiday, comments must be postmarked, shipped, or emailed before midnight on the following business day to be accepted. When faxing or emailing comments, please indicate "Comments on Proposed Rule 24R087" in the subject line.

25 TAC §289.230

STATUTORY AUTHORITY

The amendment is authorized by Texas Health and Safety Code Chapter 401 (the Texas Radiation Control Act), which provides for DSHS radiation control rules and regulatory program to be compatible with federal standards and regulations; §401.051, which provides the required authority to adopt rules and guidelines relating to the control of sources of radiation; §401.064, which provides for the authority to adopt rules relating to inspection of x-ray equipment; Chapter 401, Subchapter J, which authorizes enforcement of the Act; Chapter 401, Subchapter L, which provides for the Certification of Mammography Systems; and Texas Government Code §531.0055 and Texas Health and Safety Code §1001.075, which authorize the Executive Commissioner of HHSC to adopt rules and policies for the operation and provision of health and human services by DSHS and the administration of Texas Health and Safety Code Chapter 1001.

§289.230. Certification of Mammography Systems and X-Ray [~~Mammography~~] Machines Used for Interventional Breast Radiography.

(a) Purpose. This section establishes the requirements for using mammography systems and x-ray machines for interventional breast radiography.

(1) Requirements for the registration of a person using radiation machines for mammography.

(A) A person must not use radiation machines except as authorized in a certificate of registration issued by the Department of State Health Services (department) as specified in the requirements of this section.

(B) A person who receives, possesses, uses, owns, or acquires radiation machines before receiving a certificate of registration is subject to the requirements of this chapter.

[~~(1) This section provides for the certification of mammography systems and mammography machines used for interventional breast radiography. No person shall use radiation machines for mammography of humans or for interventional breast radiography except as authorized in a certification issued by the agency in accordance with the requirements of this section. Certification by this agency includes certification of mammography systems and facilities that have received accreditation by the agency accreditation body or by another United States Food and Drug Administration (FDA)-approved accreditation body and certification of mammography machines used for interventional breast radiography.~~]

(2) Mammography [~~The use of all mammography~~] machines certified under [~~in accordance with~~] this section must [~~shall~~] be used [~~by or~~] under the supervision of a physician licensed by the Texas Medical Board.

(3) Requirements for specific record keeping and general provisions for records and reports.

(b) Scope.

(1) This section applies to a person who receives, possesses, uses, or transfers radiation machines in mammography facilities. The facility is responsible for the administrative control and oversight of the mammography systems or x-ray machines used for interventional breast radiography.

(2) [~~(1)~~] In addition to the requirements of this section, all facilities [~~registrants~~] are subject to the requirements of:

(A) §289.203 of this chapter [~~title~~] (relating to Notices, Instructions, and Reports to Workers; Inspections);[~~,~~]

(B) §289.204 of this chapter [~~title~~] (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services);[~~,~~]

(C) §289.205 of this chapter [~~title~~] (relating to Hearing and Enforcement Procedures);[~~,~~]

(D) §289.226 of this subchapter [~~title~~] (relating to Registration of Radiation Machine Use and Services);[~~, and~~]

(E) §289.231 of this subchapter [~~title~~] (relating to General Provisions and Standards for Protection Against Machine-Produced Radiation); and

(F) 21 Code of Federal Regulations (CFR) Part 900, except for facilities subject to subsection (w) of this section. [~~Mammography facilities choosing to be accredited by the agency accreditation body will be subject to §289.234 of this title (relating to Mammography Accreditation).~~]

(3) [~~(2)~~] The procedures as specified [~~found~~] in §289.205 of this chapter relating to [~~title for~~] modifications, suspensions, revo-

cations, denials, and hearings regarding certificates of registration are applicable to certifications issued by the department [agency].

(4) [(3)] This section does not apply to an entity under the jurisdiction of the federal government.

(5) [(4)] An entity, [that is a "covered entity" as that term is] defined in [HIPAA (]the Health Insurance Portability and Accountability Act of 1996 (HIPAA) as a "covered entity" under[,] 45 [Code of Federal Regulations (]CFR[),] Parts 160 and 164[)], may be subject to privacy standards governing how information identifying [that identifies] a patient can be used and disclosed. Failure to follow HIPAA requirements may result in the department referring [making a referral of] a potential violation to the United States Department of Health and Human Services.

(c) Prohibitions.

(1) The department prohibits the use of radiographic equipment designed for general purpose or special non-mammography procedures for mammographic imaging. This includes systems that have been modified or equipped with special attachments for mammography.

(2) The department prohibits the use of mammography machines posing a significant threat or danger to occupational and public health and safety, as specified in §289.205 and §289.231 of this chapter.

(3) The department prohibits exposing an individual to the useful beam, except for healing arts imaging ordered by a practitioner. This provision specifically prohibits intentional exposure of an individual for:

(A) training, demonstration, or other non-healing arts purposes;

(B) healing arts screening, or self-referral mammography except as authorized by subsection (r) of this section; and

(C) research, except as authorized by subsection (s) of this section.

(4) The department prohibits remote operation of radiation machines.

(d) Exemptions.

(1) Mammography machines or cabinet x-ray machines used exclusively for examination of breast biopsy specimens are exempt from the requirements of this section. These machines are required to meet applicable provisions of §289.226 and §289.228 of this subchapter (relating to Radiation Safety Requirements for Industrial Radiation Machines).

(2) Machines used exclusively for interventional breast radiography are exempt from the requirements of this section except for those listed in subsection (w) of this section. These machines are not required to be accredited by a United States Food and Drug Administration (FDA)-approved accreditation body (AB).

(3) Loaner machines as described in subsection (g)(6) of this section are exempt from the inspection requirements in subsection (v)(1) of this section. These machines are not required to be accredited by an AB.

(4) Mammography machines with investigational device exemptions as described in subsection (s) of this section and used in clinical studies are exempt from the requirements of this chapter. These machines are not required to be accredited by an AB.

(5) All mammography and interventional breast radiography facilities are exempt from the posting of radiation area requirements of §289.231 of this subchapter if the operator has continuous surveillance and controls access to the radiation area.

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

(1) Accreditation--The approved use of a mammography machine by an AB [An approval of a mammography machine within a mammography facility by an accreditation body. A facility may be accredited by the agency accreditation body or another FDA-approved accreditation body].

(2) Act--Texas Radiation Control Act, Health and Safety Code[,] Chapter 401.

(3) Action limit--The minimum or maximum value of a quality assurance (QA) measurement representing acceptable performance. Values less than the minimum or greater than the maximum action limit indicate [that] corrective action must be taken by the facility.

(4) Additional mammography review (AMR)--A [(includes targeted clinical image reviews)--At the request of the agency certification body or an FDA-approved accreditation body, a] review [by the FDA-approved accreditation body] of clinical images and other relevant facility information necessary to assess compliance [conformation] with [the] accreditation standards. [The reviews include the following:]

[(A) clinical image review with interpretation; or]

[(B) clinical image review without interpretation.]

(5) Adverse event--An undesirable experience associated with mammography activities [within the scope of this section]. Adverse events include [but are not limited to]:

(A) poor image quality;

(B) failure to send mammography reports within 30 days to the referring physician or in a timely manner to the self-referred patient; and

(C) use of personnel who do not meet the applicable requirements of subsection (h) [(r)] of this section.

(6) Air kerma--The kinetic energy released in air by ionizing radiation. Kerma is the quotient of dE by dM, where dE is the sum of the initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles in air of mass dM. The System International (SI) unit of air kerma is joule per kilogram, and the special name for the unit of kerma is gray (Gy) [Agency accreditation body--For the purpose of this section, the agency as approved by the FDA under Title 21, CFR, §900.3(d) to accredit mammography facilities in the State of Texas].

(7) American Registry of Radiologic Technologists-Radiography (ARRT(R))--the credential issued by the American Registry of Radiologic Technologists in radiography [Agency certifying body--For the purpose of this section, the agency, as approved by FDA, under Title 21, CFR, §900.21, to certify facilities within the State of Texas to perform mammography services].

[(8) Air kerma--The kerma in a given mass of air. The unit used to measure the quantity of air kerma is the Gray (Gy). For x-rays with energies less than 300 kiloelectronvolts (keV), 1 Gy = 100 rad. In air, 1 Gy of absorbed dose is delivered by 114 roentgens (R) of exposure.]

(8) [(9)] Automatic exposure control (AEC)--A device [that] automatically controlling [controls] one or more technique factors [in order] to obtain the [at preselected locations a] required quantity of radiation at preselected locations.

(9) [(10)] Average glandular dose--The average absorbed dose [accruing] to the glandular tissue of the breast.

(10) [(11)] Beam-limiting device--A device providing [that provides] a means to restrict the dimensions of the x-ray field.

(11) [(12)] Breast implant--A prosthetic device implanted in the breast.

(12) [(13)] Calendar quarter--Any one of the following time periods during a given year: January 1 - March 31, April 1 - June 30, July 1 - September 30, or October 1 - December 31.

(13) [(14)] Calibration of instruments--The comparative response or reading of an instrument relative to a series of known radiation values over the range of the instrument.

(14) [(15)] Category I continuing medical education units (CMEU)--Educational activities designated as Category I and approved by the Accreditation Council for Continuing Medical Education, the American Osteopathic Association, a state medical society, or an equivalent organization.

(15) [(16)] Certification--An authorization for the use of a mammography system for mammography or x-ray [mammography] machines used for interventional breast radiography.

(16) [(17)] Clinical image--See the definition for mammogram.

(17) [(18)] Contact hour--An hour of training received through direct instruction.

(18) [(19)] Continuing education unit (CEU)--One contact hour of training.

(19) [(20)] Control panel--The [That] part of the radiation machine control upon which are mounted the [switches, knobs, push buttons, and other] hardware necessary for setting the technique factors.

(20) [(21)] Direct instruction--Instruction, including [that includes]:

(A) interaction between an instructor and student [face-to-face interaction between instructor(s) and student(s)], such as when the instructor provides a lecture, conducts demonstrations, or reviews student performance; or

(B) [the] administration and correction of student examinations by an instructor [instructor(s)] with subsequent feedback to the student [student(s)].

(21) [(22)] Direct supervision--Oversight of operations, including [that include] the following.

(A) During joint interpretation of mammograms, the supervising interpreting physician reviews, discusses, and confirms the interpretation [diagnosis] of the physician being supervised and signs the [resulting] report before it is entered into the patient's record.

(B) During performance of a mammography examination, the supervising medical radiologic technologist (MRT) is present to observe and correct, as needed, the individual [who is] performing the examination.

(C) During performance of a survey of the facility's [registrant's] equipment and QA [quality assurance] program, the supervising medical physicist is present to observe, and correct, as needed, the individual [who is] conducting the survey.

[(23) Established operating level--The value of a particular quality assurance parameter that has been established as an acceptable normal level by the registrant's quality assurance program.]

(22) [(24)] Facility--A hospital, outpatient department, clinic, radiology practice, mobile unit, an office of a physician, or other person conducting [that conducts] breast cancer screening or diagnosis through mammography activities, including [the following]:

(A) operating [the operation of] equipment to produce a mammogram;

(B) processing [of] film or digital images;

(C) interpreting [initial interpretation of] the mammogram; or

(D) maintaining the viewing conditions for [that] interpretation.

(23) [(25)] FDA-approved accreditation body (AB)--An entity approved by the FDA under [Title] 21[,] CFR[,] §900.3(d)[,] to accredit mammography facilities.

(24) [(26)] Final assessment categories--The overall final assessment of findings in a report of a mammography examination[,] classified in subsection (j)(3)(E) of this section. [one of the following categories:]

[(A) "negative" indicates nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained);]

[(B) "benign" is also a negative assessment;]

[(C) "probably benign" indicates a finding(s) that has a high probability of being benign;]

[(D) "suspicious abnormality" indicates a finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant;]

[(E) "highly suggestive of malignancy" indicates a finding(s) that has a high probability of being malignant;]

[(F) "known biopsy proven malignancy" indicates appropriate action should be taken;]

[(G) "post procedure mammogram" indicates a mammogram to confirm the deployment and position of a breast tissue marker; or]

[(H) "incomplete" indicates there is a need for additional imaging evaluation and/or prior mammograms for comparison. Reasons why no assessment can be made shall be stated by the interpreting physician.]

(25) [(27)] First allowable time--The earliest time a resident physician is eligible to take the diagnostic radiology boards from an FDA-designated certifying body.

(26) [(28)] Formal training--Attendance and participation in direct instruction. This does not include self-study programs.

(27) [(29)] Half-value layer (HVL)--The thickness of a specified material attenuating [that attenuates] the beam of radiation to the [an] extent [such that] the exposure rate is reduced to one-half of its original value. [In this definition, the contribution of all scattered radiation, other than any that might be present initially in the beam concerned, is deemed to be excluded.]

(28) [~~(30)~~] Healing arts--Any system, treatment, operation, diagnosis, prescription, or practice for the ascertainment, cure, relief, palliation, adjustment, or correction of any human disease, ailment, deformity, injury, or unhealthy or abnormal physical or mental condition.

(29) Healthcare provider--A doctor of medicine or osteopathy, podiatrist, dentist, chiropractor, clinical psychologist, optometrist, physician assistant, or nurse practitioner authorized to practice by the state of Texas and performing within the scope of their practice as defined by state law.

(30) [~~(31)~~] Image receptor--Any device that transforms incident x-ray photons either into a visible image or into another form that can be made into a visible image by further transformations.

(31) [~~(32)~~] Institutional review board (IRB)--Any board, committee, or other group created under 45 CFR Part 46 and 21 CFR Part 56, and formally designated by an institution to review, approve the initiation of, and conduct periodic review of biomedical research involving human subjects.

(32) [~~(33)~~] Interpreting physician (IP)--A licensed physician who interprets mammographic images and who meets the requirements of subsection (h)(1) [~~(r)(1)~~] of this section.

(33) [~~(34)~~] Interventional breast radiography--Imaging of a breast during invasive interventions for localization or biopsy procedures.

(34) [~~(35)~~] Investigational device exemption--An exemption allowing an [~~that allows the~~] investigational device to be used in a clinical study [~~in order~~] to collect safety and effectiveness data required to support a Premarket Approval application or a 510(k) Premarket Notification submission to FDA.

(35) [~~(36)~~] Kerma--The sum of the initial energies of all the charged particles liberated by uncharged ionizing particles in a material of given mass.

(36) [~~(37)~~] Laterality--The designation of either the right or left breast.

(37) [~~(38)~~] Lead interpreting physician (LIP)--The interpreting physician assigned the general responsibility for ensuring [~~that~~] a facility's QA [~~quality assurance~~] program meets all [~~of the~~] requirements of subsections (k), (l), and (m) [~~(u), (v), and (w)~~] of this section.

(38) [~~(39)~~] Mammogram--A radiographic image produced through mammography.

(39) [~~(40)~~] Mammographic modality--A technology, within the scope of 42 United States Code (U.S.C.) §263b, for radiography of the breast. Examples are screen-film mammography, [~~and~~] full-field digital mammography, and digital breast tomosynthesis (DBT).

(40) [~~(41)~~] Mammography--The use of x-rays [~~x-radiation~~] to produce an image of the breast that may be used to detect the presence of pathological conditions of the breast. Mammography [~~For the purposes of this section, mammography~~] does not include radiography of the breast performed [~~as follows~~]:

(A) during invasive interventions for localization or biopsy procedures, except as specified in subsection (w) [~~(gg)~~] of this section; or

(B) using [~~with~~] an investigational mammography device as part of a scientific study conducted under the [~~in accordance with~~] FDA's investigational device exemption regulations.

(41) [~~(42)~~] Mammography machine--An assemblage of components for mammography. This includes an x-ray high-voltage generator, x-ray control, tube housing assembly, beam-limiting device, and the necessary supporting structures. Additional components functioning with the machine are considered integral parts of the system. [~~machine(s)--A unit consisting of components assembled for the production of x-rays for use during mammography. These include, at a minimum, the following:~~]

[~~(A) an x-ray generator;~~]

[~~(B) an x-ray control;~~]

[~~(C) a tube housing assembly;~~]

[~~(D) a beam limiting device; and~~]

[~~(E) supporting structures.~~]

(42) [~~(43)~~] Mammography medical outcomes audit--A systematic collection of mammography results and the comparison of those results [~~compared~~] with outcomes data.

(43) [~~(44)~~] Mammography system--A system, including [~~that includes the following~~]:

(A) an x-ray machine used as a source of radiation in producing images of breast tissue;

(B) an imaging system used for the formation of a latent image of breast tissue;

(C) an imaging-processing device for changing a latent image of breast tissue to a visual image that can be used for diagnostic purposes;

(D) a [~~viewing~~] device used for viewing and evaluating [~~the visual evaluation of~~] an image of breast tissue [~~if the image is produced in interpreting visual data captured on an image receptor~~];

(E) an MRT who meets the qualifications specified in subsection (h)(2) of this section and [~~a medical radiologic technologist who~~] performs mammography; and

(F) a physician who interprets [~~engages in~~] mammography and [~~who~~] meets the requirements specified in subsection (h)(1) of this section [~~relating to the reading, evaluation, and interpretation of mammograms~~].

(44) [~~(45)~~] Mandatory training--Additional training required by the department [~~agency certifying body~~] or AB [~~FDA-approved accreditation body~~] for IPs [~~interpreting physicians~~], MRTs [~~medical radiologic technologists~~], or medical physicists as the result of a required corrective action.

[~~(46) Mean optical density--The average of the optical densities measured using uniform, defect-free absorber thicknesses of 2, 4, and 6 centimeters (cm) with values of kilovolt peak (kVp) clinically appropriate for those thicknesses.~~]

(45) [~~(47)~~] Medical physicist--An individual who performs surveys and evaluations of mammographic equipment and facility QA [~~quality assurance~~] programs as specified in [~~accordance with~~] this section and who meets the qualifications in subsection (h)(3) [~~(r)(3)~~] of this section.

(46) [~~(48)~~] Medical radiologic technologist (MRT [~~operator of equipment~~])--An individual specifically trained in the use of radiographic equipment and the positioning of patients for radiographic examinations, who performs mammography examinations as specified in [~~accordance with~~] this section and who meets the qualifications in subsection (h)(2) [~~(r)(2)~~] of this section.

(47) [(49)] Mobile service operation--The provision of mammography machines and personnel at temporary sites to perform mammography for limited time periods.

(48) [(50)] Multi-reading--Two or more physicians interpreting the same mammogram. At least one physician must [shall] be qualified as an IP [interpreting physician].

(49) Operator--An individual who performs interventional breast mammography examinations.

(50) [(51)] Optical density (OD)--A measure of the fraction of incident light transmitted through a developed film and defined by the equation:
Figure: 25 TAC §289.230(e)(50)
[Figure: 25 TAC §289.230(e)(51)]

(51) [(52)] Patient--Any individual who undergoes a mammography examination in a facility, regardless of whether the individual [person] is referred by a physician or is self-referred.

(52) [(53)] Phantom--A test object used to simulate radiographic characteristics of compressed breast tissue and containing components modeling [that radiographically model] aspects of breast disease and cancer in a radiograph.

(53) [(54)] Phantom image--A radiographic image of a phantom.

(54) [(55)] Physical science--This includes physics, chemistry, radiation science (including medical physics and health physics), and engineering.

(55) Physician--An individual licensed by the Texas Medical Board to practice medicine under Texas Occupations Code Chapter 155.

(56) Positive mammogram--A mammogram with [that has] an overall assessment of findings that are either "suspicious" or "highly suggestive of malignancy."

[(57) Practitioner of the healing arts (practitioner)--For the purposes of this section, a person licensed to practice healing arts by the Texas Medical Board as a physician.]

(57) [(58)] Provisional certification--A certification category enabling a facility to perform mammography and obtain the clinical images needed to complete the accreditation process [provisional authorization described in subsection (g) of this section].

(58) [(59)] Qualified instructor--An individual whose training and experience prepares the qualified instructor [him or her] to carry out specified training assignments. IPs [Interpreting physicians], MRTs [medical radiologic technologists], or medical physicists who meet the requirements of subsection (h)[(r)] of this section are [would be] considered qualified instructors in their respective areas of mammography. Other examples of an individual [individuals] who may be a qualified instructor [instructors] for the purpose of providing training to meet the requirements of this section include[, but are not limited to,] instructors in a post-high school training institution and manufacturers' representatives.

(59) [(60)] Quality control (QC) technologist--An individual meeting the requirements of subsection (h)(2)[(r)(2)] of this section who is responsible for those QA [quality assurance] responsibilities not assigned to the LIP [lead interpreting physician] or to the medical physicist.

(60) [(61)] Radiation machine--see definition for [For the purposes of this part, radiation machine also means] mammography machine.

(61) [(62)] Self-referral mammography--The use of x-ray [x-radiation] to test asymptomatic women for the detection of diseases of the breasts when such tests are not specifically and individually ordered by a licensed physician.

(62) [(63)] Serious adverse event--An adverse event that may significantly compromise clinical outcomes, or an adverse event for which a facility fails to take appropriate corrective action in a timely manner.

(63) [(64)] Serious complaint--A report of a serious adverse event.

(64) [(65)] Source-to-image receptor distance (SID)--The distance from the source to the center of the input surface of the image receptor.

(65) [(66)] Standard breast--A 4.2 cm thick compressed breast consisting of 50 percent [%] glandular tissue and 50 percent [%] adipose tissue.

(66) [(67)] Survey--An on-site physics consultation and evaluation of a facility QA [quality assurance] program performed as specified in subsection (l)(5) of this section by a medical physicist meeting the requirements of subsection (h)(3) of this section.

(67) [(68)] Technique chart--A chart providing [that provides] all necessary generator control settings and geometry needed to make clinical radiographs.

(68) [(69)] Traceable to a national standard--Calibrated at either the National Institute of Standards and Technology (NIST) or at a calibration laboratory participating [that participates] in a proficiency program with NIST at least once every two years. The results of the proficiency test conducted within 24 months of calibration must [shall] show agreement within plus or minus 3.0 percent [%] of the national standard in the mammography energy range.

[(d) Prohibitions.]

[(1) Radiographic equipment designed for general purpose or special nonmammography procedures shall not be used for mammography. This includes systems that have been modified or equipped with special attachments for mammography.]

[(2) The agency may prohibit use of mammography machines that pose a significant threat or endanger public health and safety, in accordance with §289.231 of this title and §289.205 of this title.]

[(3) Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed physician. This provision specifically prohibits intentional exposure for the following purposes:]

[(A) exposure of an individual for training, demonstration, or other non-healing arts purposes;]

[(B) exposure of an individual for the purpose of healing arts screening (self referral mammography) except as authorized by subsection (bb) of this section; and]

[(C) exposure of an individual for the purpose of research except as authorized by subsection (cc) of this section.]

[(e) Exemptions.]

[(1) Mammography machines or cabinet x-ray machines used exclusively for examination of breast biopsy specimens are exempt from the requirements of this section. These machines are required to meet applicable provisions of §289.226 of this title and

§289.228 of this title (relating to Radiation Safety Requirements for Analytical and Other Industrial Radiation Machines).]

[(2) Mammography machines used exclusively for interventional breast radiography are exempt from the requirements of this section except for those listed in subsection (gg) of this section. These machines are not required to be accredited by an FDA-approved accreditation body.]

[(3) Loaner machines as described in subsection (n)(5) of this section are exempt from the inspection requirements in subsection (ff) of this section. These machines are not required to be accredited by an FDA-approved accreditation body.]

[(4) Mammography machines with investigational device exemptions as described in subsection (cc) of this section and used in clinical studies are exempt from the requirements of this chapter. These machines are not required to be accredited by an FDA-approved accreditation body.]

[(5) All mammography registrants are exempt from the posting of radiation area requirements of §289.231(x) of this title provided that the operator has continuous surveillance and access control of the radiation area.]

(f) Mammography systems certification.

(1) [(f)] Requirements for [mammography systems] certification.

(A) [(1)] A facility must [To obtain a certification, facilities shall] meet the quality standards in subsections (h) - (q) [(r) - (aa)] of this section and be accredited by an AB. To [FDA-approved accreditation body. In order to] qualify for certification, a new facility [facilities] must apply to the department [agency certifying body in accordance with the following requirements and to an FDA-approved accreditation body] and receive acceptance of an [the] accreditation application by an AB. [If the facility chooses to be accredited by the agency accreditation body, the facility shall submit the information required in this subsection and §289.234(d) of this title.]

(B) [(2)] A person who receives, possesses, uses, owns, or acquires [Each person having] a mammography machine must apply for certification as specified [shall submit an application] in [accordance with] §289.226(e) of this subchapter, relating to general requirements for application for registration, [(1) - (3) and (5) - (7) and (f)(4) - (5) of this title,] and receive certification from the department [agency certifying body] before using a [beginning use of the] mammography machine on humans.

(C) [(3)] An application for certification must [shall] be signed by the:[lead interpreting physician. The signature of the applicant and the radiation safety officer (RSO) shall also be required.]

(i) LIP;

(ii) applicant; and

(iii) [(4)] radiation safety officer (RSO) [An application for certification may contain information on multiple mammography machines. Each mammography machine must be identified by referring to the machine's manufacturer, model name, and serial number on the control panel. If this is not a new certification, the registrant shall maintain and provide proof of current accreditation. If accreditation expires before the expiration of the certification, the registrant shall submit proof of renewed status to the agency.].

(D) [(5)] Each applicant must [shall] submit documentation of [the following]:

(i) [(A)] personnel qualifications, including dates of licensure or certification, as specified in [accordance with] subsection (h) [(r)] of this section;

(ii) [(B)] manufacturer, model name, and serial number of each mammography machine control panel;

(iii) [(C)] evidence that a medical physicist has:

(I) [(i)] [has] determined [that] each machine meets the equipment standards in subsection (i) [(s)] of this section;

(II) [(ii)] [has] performed a survey and a mammography equipment evaluation as specified in [accordance with] subsection (l)(5) and (6) [(v)(10) and (11)] of this section; and

(III) [(iii)] [has] determined [that] the average glandular dose for one craniocaudal [craniocaudal-caudal] view for each machine is less than [does not exceed] the value in subsection (i)(11)(D) [(v)(5)(F)] of this section;

(iv) [(D)] self-referral program information as specified in [accordance with] subsection (r) [(bb)] of this section, if the facility offers self-referral mammography;[and]

(v) [(E)] items required for authorization of a mobile service operation as specified in [accordance with] §289.226(g) of this subchapter, relating to application for registration of mobile service operations [title], if the facility provides a mobile service; and[.]

(vi) proof of current accreditation.

(2) [(g)] Issuance of certification [and provisional certification].

[(1)] [Certification.] A certification will be issued if the department [agency certifying body] determines the [that an] application meets the requirements of the Act and [the requirements of] this chapter. The certification authorizes the proposed operations and includes [activity in such form and contains such] conditions and limitations deemed necessary by [as] the department [agency certifying body deems appropriate or necessary].

(A) The certification may include [one of the following]:

(i) [(A)] mammography systems and facilities certification, following approval of accreditation by an AB [FDA-approved accreditation body]; or

(ii) [(B)] certification of interventional breast radiography machines.

(B) [(2)] Conditions [Requirements and conditions]. The department [agency certifying body] may incorporate in the certification at the time of issuance, or [thereafter] by amendment, [such] additional requirements and conditions [with respect to the registrant's possession, use, and transfer of radiation machines subject to this chapter as it deems appropriate or necessary in order] to:

(i) [(A)] minimize danger to occupational and public health and safety;

(ii) [(B)] require additional reporting and record keeping [reports and the keeping of additional records as may be appropriate or necessary]; and

(iii) [(C)] prevent loss or theft of radiation machines subject to this section.

(C) [(3)] Additional information. The department [agency certifying body] may request[, and the registrant shall provide,] additional information after the certification has been issued to

enable the department [~~agency certifying body~~] to determine whether the certification should be modified as specified in [~~accordance with~~] §289.226(r) of this subchapter, relating to renewal of certificates of registration [~~title~~].

(3) [~~(4)~~] Provisional certification [~~application. A new facility is eligible to apply for a provisional certification. The provisional certification will enable the facility to perform mammography and to obtain the clinical images needed to complete the accreditation process~~].

(A) To apply for and receive a provisional certification, a new facility must meet the requirements of this chapter and submit the necessary information to an AB [~~FDA-approved accreditation body. If the facility chooses to be accredited by the agency accreditation body, the facility shall submit the information required in subsection (f) of this section and §289.234(d) of this title to the agency accreditation body~~].

(B) [~~(5)~~] [~~Issuing provisional certifications.~~] Following the department's [~~agency certifying body's~~] receipt of the accreditation body's decision that a facility has submitted the required information, the department [~~agency certifying body~~] may issue a provisional certification to a facility if [~~upon determination that~~] the facility has satisfied the requirements of the Act and this chapter.

(i) A provisional certification is [~~shall be~~] effective for up to six months as noted on the certificate [~~from the date of issuance~~].

(ii) A provisional certification cannot be renewed, but a facility may apply for a 90-day extension of the provisional certification.[~~(6) Extension of provisional certification. Extension of provisional certifications shall be in accordance with the following.~~]

(C) [~~(A)~~] To apply for a 90-day extension to a provisional certification, a facility must [~~shall~~] submit to the AB [~~FDA-approved accreditation body~~] who issued the original certificate, a statement of actions taken [~~what the facility is doing~~] to obtain certification and evidence that there would be a significant adverse impact on access to mammography in the geographic area served if the [~~such~~] facility did not obtain an extension.

(i) [~~(B)~~] The department [~~agency certifying body~~] may issue a 90-day extension for a provisional certification if [~~upon determination that~~] the extension meets the criteria in paragraph (3) [~~(4)~~] of this subsection.

(ii) [~~(C)~~] Renewal [~~There can be no renewal~~] of a provisional certification beyond the 90-day extension is prohibited.

(4) [~~(7)~~] Reinstatement [~~policy~~].

(A) A previously certified facility that has allowed its certification to expire, [~~that has~~] been refused a renewal of its certification by the department [~~agency certifying body~~], or [~~that has~~] had its certification suspended or revoked by the department [~~agency certifying body~~], may reapply to have the certification reinstated so [~~that~~] the facility may be considered [~~to be~~] a new facility and thereby be eligible for a provisional certification.

(B) [~~(A)~~] Unless prohibited from reinstatement as specified in [~~under~~] subsection (f)(5)[~~(h)(5)~~] of this section, a facility applying for reinstatement must [~~shall~~]:

(i) contact an AB [~~FDA-approved accreditation body~~] for reapplication of [~~for~~] accreditation;

(ii) provide documentation of [~~fully document~~] its history as a previously provisionally certified or certified mammography facility, and include [~~including~~] the [~~following information~~]:

(I) name and address of the facility under which it was previously provisionally certified or certified;

(II) name of previous owner or lessor [~~owner/lessor~~];

(III) facility identification number assigned to the facility under its previous certification by the FDA or the department [~~agency certifying body~~]; and

(IV) expiration date of the most recent FDA or department [~~agency~~] provisional certification; and

(iii) justify application for reinstatement of accreditation by submitting to an AB [~~FDA-approved accreditation body~~] a corrective action plan detailing [~~that details~~] how the facility has corrected deficiencies contributing [~~that contributed~~] to the lapse [~~of~~], denial of renewal, or revocation of its certification.

(C) [~~(B)~~] The department [~~agency certifying body~~] may issue a provisional certification to the facility if the department [~~agency~~] determines [~~that~~] the facility has:

(i) [~~has~~] adequately corrected, or is in the process of correcting, pertinent deficiencies; and

(ii) [~~has~~] taken sufficient corrective action since the lapse [~~of~~], denial of renewal, or revocation of its previous certification.

(D) [~~(C)~~] After receiving the provisional certification, the facility may lawfully perform mammography while completing the requirements for accreditation and certification.

(5) [~~(h)~~] Suspension or revocation of certification.

(A) [~~(1)~~] Except as provided in subparagraph (B) of this paragraph [~~(2) of this subsection~~], the department [~~agency certifying body~~] may suspend or revoke a certification issued by the department [~~agency certification body~~] if it finds, after providing the owner or [~~operator of the~~] facility representative with notice and an opportunity for a hearing as specified in [~~accordance with~~] §289.205 of this chapter [~~title~~], that the owner, facility representative [~~operator~~], or any employee of the facility has:

(i) [~~(A)~~] misrepresented documentation to obtain [~~has been guilty of misrepresentation in obtaining~~] the certification;

(ii) [~~(B)~~] [~~has~~] failed to comply with the requirements of this chapter;

(iii) [~~(C)~~] [~~has~~] failed to comply with requests of the department [~~agency certifying body~~] or an AB [~~FDA-approved accreditation body~~] for records, information, reports, or materials [~~that are~~] necessary to determine the continued eligibility of the facility for a certification or continued compliance with the requirements of this chapter;

(iv) [~~(D)~~] [~~has~~] refused a request of a duly designated FDA inspector, state inspector, or an AB [~~FDA-approved accreditation body~~] representative for permission to inspect the facility or the operations and pertinent records of the facility;

(v) [~~(E)~~] [~~has~~] violated or aided and abetted in the violation of any provision of or regulation promulgated pursuant to the requirements of the Act and the requirements of this chapter; or

(vi) [~~(F)~~] [~~has~~] failed to comply with prior sanctions imposed by the department as specified in [~~agency certifying body under~~] §289.205 of this chapter [~~title~~].

(B) [~~(2)~~] The department [~~agency certifying body~~] may suspend a certification of a facility before holding a hearing if it makes a

finding described in subparagraph (A) [paragraph (1)] of this paragraph [subsection] and [also] determines that:

(i) [(A)] the failure to comply with requirements presents a serious risk to human health;

(ii) [(B)] the refusal to permit inspection makes immediate suspension necessary; or

(iii) [(C)] there is reason to believe [that] the violation or aiding and abetting of the violation was intentional or associated with fraud.

(C) [(3)] If the department [agency certifying body] suspends a certification as specified in subparagraph (B) of this [accordance with] paragraph [(2) of this subsection]:

(i) [(A)] the department will [agency certifying body shall] provide the facility with an opportunity to request [for] a hearing as specified in [under] §289.205 of this chapter [not later than 60 days from the effective date of this suspension]; and

(ii) [(B)] the suspension will [shall] remain in effect until it is determined by the department [agency certifying body determines] that the:

(I) [(i)] allegations of violations or misconduct were not substantiated;

(II) [(ii)] violations of requirements have been corrected to the department's [agency certifying body's] satisfaction; or

(III) [(iii) the] certification is revoked as specified in subparagraph (D) [accordance with paragraph (4)] of this paragraph [section].

(D) [(4)] After providing a hearing as specified in §289.205 of this chapter [accordance with paragraph (3)(A) of this subsection], the department [agency certifying body] may revoke the certification if it is determined by the department [agency determines] that the facility:

(i) [(A)] is unwilling or unable to correct violations that were the basis for suspension; or

(ii) [(B)] has engaged in fraudulent activity to obtain or continue certification.

(E) [(5)] If a facility's certification was revoked based on [on the basis of] an act described in §289.205 of this chapter, a [title, no] person who owned or operated that facility at the time the act occurred is prohibited from owning [may own or operate] a mammography facility for [within] two years following [of] the [date of] revocation date.

(6) [(i)] Appeal of adverse accreditation or reaccreditation decisions preventing [that preclude] certification or recertification.

(A) [(1)] The appeal process described in this paragraph [subsection] is only available [only] for adverse accreditation or reaccreditation decisions preventing [that preclude] certification by the department. If the department suspends or revokes a certificate [agency certifying body. Agency certifying body decisions to suspend or revoke certificates that are] already in effect, it will be handled as specified in [accordance with] subsection (f)(5) [(h)] of this section.

(B) [(2)] If [Upon learning that] a facility has failed to become accredited or reaccredited, the department [agency certifying body] will notify the facility that the department [agency certifying body] is unable to certify the [that] facility without proof of accreditation.

(C) [(3)] A facility that has been denied accreditation or reaccreditation and cannot achieve satisfactory resolution of an adverse accreditation decision through the AB's [FDA-approved accreditation body's] appeal process is entitled to further appeal to the FDA.

(D) [(4)] A facility cannot perform mammography services while an adverse accreditation decision is being appealed.

(7) [(j)] Denial of certification.

(A) [(1)] The department [agency certifying body] may deny the application if the department [agency certifying body] has reason to believe that:

(i) [(A)] the facility will not be operated as specified in [accordance with] the provisions of subsections (h) - (q) [(r) - (aa)] of this section;

(ii) [(B)] the facility will not permit inspections or provide access to records or information [in a] timely [fashion];

(iii) [(C)] made a materially [any material] false statement in the application or any statement of fact required under provision of the Act [was made];

(iv) [(D)] conditions revealed by such application or statement of fact or any report, record, inspection, or other means that would warrant the department [agency certification body] to refuse to grant a certification of mammography facility on an original application; or

(v) [(E)] the facility failed to observe any of the terms and conditions of the Act, this chapter, or order of the department [agency].

(B) [(2)] Before the department [agency certification body] denies an application for certification, the department must [agency shall] give notice of the denial, the facts warranting the denial, and [shall] afford the applicant an opportunity for a hearing in accordance with §289.205(h) of this chapter [title]. If no request for a hearing is received by the director of the Radiation Control Program within 30 days of date of receipt of the notice, the department [agency] may proceed to deny. The applicant must bear [shall have] the burden of proof showing cause why the application should not be denied.

(C) [(3)] If the department [agency certifying body] denies an application for certification from [by] a facility that has received accreditation from an AB [FDA-approved accreditation body], the department will [agency certifying body shall] provide the facility with a written statement of the grounds on which the denial is based.

(8) [(k)] Appeals of a certification denial [Appeals of denial of certification].

(A) [(1)] The appeals procedures described in this paragraph [subsection] are available only to facilities that are denied certification by the department [agency certifying body] after they have been accredited by an AB [FDA-approved accreditation body. Appeals for facilities that have failed to become accredited with the agency accreditation body shall be in accordance with §289.234(h) of this title].

(B) [(2)] A facility that has been denied certification may request reconsideration and appeal the department's [of the agency certifying body's] determination as specified in [accordance with] the applicable provisions of §289.205(h) of this chapter [title].

(9) [(l)] Modification of certification. Modification of a certification will follow the requirements in §289.226(s) of this subchapter, relating to modification, suspension, and revocation of certifi-

cates of registration [~~shall be in accordance with §289.226(r) of this title~~].

(10) [~~(m)~~] Specific terms and conditions of certification. Specific terms and conditions of certification will [~~shall~~] be as specified in [~~accordance with~~] §289.226(l) of this subchapter, relating to terms and conditions of certificates of registration [~~title~~].

(11) Renewal of certification.

(A) A certification for a mammography system is valid for three years from the date of issuance unless the certification of the facility is suspended or revoked before such deadlines.

(B) A mammography facility filing an application for renewal of their certification must meet the quality standards in subsections (h) - (q) of this section and be accredited by an AB. The renewal must include a list of all IPs, MRTs, and medical physicists practicing at the facility and must be filed as specified in:

(i) §289.226(r) of this subchapter, relating to renewal of certificates of registration;

(ii) §289.204(d) and (g) of this chapter, relating to payment of fees;

(iii) subsection (f)(1)(C) of this section; and

(iv) subsection (f)(1)(D)(i) of this section.

(C) A mammography facility filing an application for renewal before the existing certification expires may continue to perform mammography until the application status has been determined by the department.

(D) A facility with mammography machines used for interventional breast radiography must apply for renewal as specified in subsection (w)(5) of this section and pay the fee specified in §289.204(d) of this chapter.

(12) Expiration of certification.

(A) Each certification expires at the end of the day on the expiration date listed on the mammography certificate unless the certificate is suspended or revoked before the expiration date. Expiration of the certification does not relieve the facility of the requirements of this chapter.

(B) If a facility does not apply for renewal of the certification as specified in paragraph (11) of this subsection, as applicable, the facility must:

(i) terminate use of all mammography machines;

(ii) notify the department in writing of the storage location of mammography images and address how the requirements of subsection (j)(7)(E) of this section will be met;

(iii) pay any outstanding fees specified in §289.204 of this chapter; and

(iv) submit a record of the disposition of the mammography machine to the department.

(13) Termination of certification. When a facility decides to terminate all activities involving mammography machines authorized under the certification, the facility must:

(A) notify the department and the AB within 30 days;

(B) request termination of the certification in writing;

(C) pay any outstanding fees specified in §289.204 of this chapter;

(D) notify the department, in writing, of the storage location of mammography images and address how the requirements of subsection (j)(7)(E) of this section will be met; and

(E) submit a record of the disposition of the mammography machine to the department.

(g) [~~(n)~~] Responsibilities of the facility [~~registrant~~].

(1) In addition to the requirements of §289.226(m)(3) - (7) of this subchapter, relating to responsibilities of the registrant, the facility must [~~title, a registrant shall~~] notify the department [~~agency certifying body~~] in writing, within 30 days, of [~~prior to~~] any changes rendering [~~that would render~~] the information contained in the application or the certification inaccurate, including the[~~. These include but are not limited to the following~~]:

(A) name of the facility; [~~and~~]

(B) mailing address;

(C) [~~(B)~~] street address where the machine is [~~machine(s) will be~~] used; [~~and~~]

[~~(C) mammography machines.~~]

(D) addition or removal of any mammography machine; or

(E) name and qualifications of the RSO or LIP.

(2) Before [~~Prior to~~] employing an individual [~~the individuals~~] listed in subparagraphs (A) - (E) of this paragraph, the facility [~~registrant~~] is required to verify and maintain a copy [~~copies~~] of the [~~their~~] qualifications of the [~~. If a facility makes a change in the RSO, the qualifications of the RSO shall be submitted to the agency within 30 days of such change. Written notification of a change in any of the following in subparagraphs (B) - (E) of this paragraph is required within 30 days of such change~~]:

(A) RSO [~~radiation safety officer~~];

(B) LIP [~~lead interpreting physician~~];

(C) IP [~~interpreting physicians~~];

(D) MRT [~~medical radiologic technologists~~]; or

(E) medical physicist.

(3) A facility [~~Registrants~~] utilizing an IP [~~interpreting physicians~~] or MRT [~~technologists~~] from a temporary staffing service must [~~shall~~] verify and maintain copies of the qualifications of these individuals for inspection by the department [~~agency. The registrant does not need to notify the agency certifying body unless these personnel will be at the facility for a period exceeding four weeks~~].

(4) For accreditation, a facility adding or replacing a mammography machine must have a current accreditation or apply to the AB, unless exempted by subsection (d) of this section [~~All mammography facilities installing new or replacement mammography machines shall have either current accreditation or have submitted an application to an FDA-approved accreditation body for review unless exempted by subsection (e)(1) - (3) of this section. A mammography machine shall not be used to perform mammograms if an application for accreditation for that machine has been denied, or if the accreditation has been suspended or expired~~].

(5) For certification, a facility with an existing certificate may begin using a new or replacement machine before receiving an updated certificate if the facility submits to the department and AB an application with a medical physicist report as specified in subsection (l)(5) and (6) of this section [~~A facility with an existing certification~~

may begin using a new or replacement machine before receiving an updated certification if the registrant submits to the agency certifying body and to the FDA-approved accreditation body, documentation with a medical physicist's report in accordance with subsection (v)(10) and (11) of this section, verifying compliance of the new machine with this section. The medical physicist's report is required prior to using the machine on patients].

(6) Loaner mammography machines may be used on patients for 60 days without adding the mammography machine to the certification. A medical physicist's report verifying compliance of the loaner mammography machine with this section must [shall] be completed before [prior to] use on patients. The results of the survey must be submitted to the department [agency] with a cover letter indicating period of use. If the use period will exceed 60 days, the facility must [shall] add the mammography machine to its certification and a fee will be assessed.

(7) Records of training and experience and all other records required by this section must [shall] be maintained for review as specified in [accordance with] subsection (x) [(ee)] of this section.

[(o) Renewal of certification.]

[(1) A certification for a mammography system is valid for three years from the date of issuance unless the certification of the facility is suspended or revoked prior to such deadlines.]

[(2) A mammography facility filing an application for renewal of their certification shall meet the quality standards in subsections (r) - (aa) of this section and be accredited by an FDA-approved accreditation body. The renewal shall be filed in accordance with the following:]

[(A) §289.226(e)(1) - (3), (5) and (7) of this title and §289.226(f)(4) and (5) of this title;]

[(B) signatures of appropriate personnel in accordance with subsection (f)(3) of this section;]

[(C) machine information and medical physicist's survey in accordance with subsection (f)(5)(B) and (C) of this section;]

[(D) fees in accordance with §289.204 of this title; and]

[(E) a list of all interpreting physicians, medical radiologic technologists and medical physicists practicing at the facility.]

[(3) A mammography facility filing an application for renewal before the existing certification expires may continue to perform mammography until the application status has been determined by the agency.]

[(4) A facility with mammography machines used for interventional breast radiography shall file an application for renewal in accordance with subsection (gg)(8) of this section and pay the fee required by §289.204 of this title.]

[(p) Expiration of certification.]

[(1) Except as provided by subsection (o) of this section, each certification expires at the end of the day in the month and year stated on the mammography certificate. Expiration of the certification does not relieve the registrant of the requirements of this chapter.]

[(2) If a registrant does not submit an application for renewal of the certification under subsection (o) of this section, as applicable, the registrant shall on or before the expiration date specified in the certification:]

[(A) terminate use of all mammography machines;]

[(B) notify the agency certifying body in writing of the film storage location of mammography patients' films and address how the requirements of subsection (t)(4)(D) of this section will be met;]

[(C) pay any outstanding fees in accordance with §289.204 of this title; and]

[(D) submit a record of the disposition of the mammography machine(s) to the agency certifying body. If the machine(s) was transferred, include to whom it was transferred.]

[(q) Termination of certification. When a registrant decides to terminate all activities involving mammography machines authorized under the certification, the registrant shall:]

[(1) notify the agency certifying body and the FDA-approved accreditation body immediately;]

[(2) request termination of the certification in writing;]

[(3) pay any outstanding fees in accordance with §289.204 of this title;]

[(4) notify the agency certifying body, in writing, of the film storage location of mammography patients' films and address how the requirements of subsection (t)(4)(D) of this section will be met; and]

[(5) submit a record of the disposition of the mammography machine(s) to the agency certifying body. If the machine(s) was transferred, include to whom it was transferred.]

(h) [(r)] Personnel qualifications. The following requirements apply to all personnel involved in any aspect of mammography, including the production and interpretation of mammograms.

(1) Interpreting physician. Each physician interpreting mammograms must [shall] hold a current Texas license issued by the Texas Medical Board and meet the following qualifications.

(A) Initial qualifications. Before interpreting mammograms independently, the physician must [shall]:

(i) be certified by the American Board of Radiology, the American Osteopathic Board of Radiology, or one of the other bodies approved by the FDA to certify IPs [interpreting physicians] or have at least three months of documented formal training in the interpretation of mammograms and in topics related to mammography as specified in subparagraph (B) of this paragraph [accordance with subsection (hh)(2) of this section];

(ii) have completed [had] a minimum of 60 hours of documented category I CMEUs in mammography and at [. At] least 15 of the 60 hours must [shall] have been acquired within three years immediately before [prior to] the date [that] the physician became qualified as an IP (hours [interpreting physician. Hours] spent in residency specifically devoted to mammography will be equivalent to category I CMEUs and accepted if documented in writing by the appropriate representative of the training institution); and

(iii) have interpreted or multi-read, under the direct supervision of an IP [interpreting physician], at least 240 mammographic examinations within the six-month period immediately before [prior to] the date that the physician qualifies as an IP. The supervising interpreting physician's presence is not required when the physician being supervised makes the initial interpretation. However, the supervising physician must review and, if necessary, correct the final interpretation before it is given to the patient [interpreting physician].

(B) Subjects to be included in mammography training for interpreting physicians must include:

(i) radiation physics, including radiation physics specific to mammography;

(ii) radiation effects;

(iii) radiation protection; and

(iv) interpretation of mammograms. This must be under the direct supervision of a physician who meets the requirements of paragraph (1) of this subsection.

(C) [~~(B)~~] Exemptions.

(i) A physician [~~Physicians who~~] qualified as an IP as specified [~~interpreting physicians~~] in [~~accordance with~~] the requirements of §289.230 that were in effect before [~~prior to~~] April 28, 1999, or any other equivalent state or federal requirements in effect before [~~prior to~~] April 28, 1999, is [~~are~~] considered to have met the initial requirements of subparagraph (A) of this paragraph.

(ii) Physicians who have interpreted or multi-read at least 240 mammographic examinations under the direct supervision of an IP [~~interpreting physician~~] in any six-month [~~six month~~] period during the last two years of a diagnostic radiology residency and who became board certified at the first allowable time, are exempt from subparagraph (A)(iii) of this paragraph.

(D) [~~(C)~~] Continuing education. [~~and experience. The time period for completing continuing education is a 36-month period and the time period for completing continuing experience is a 24-month period. These periods begin when a physician completes the requirements to become an interpreting physician in subparagraph (A) of this paragraph. The facility shall choose one of the dates in clause (i) of this subparagraph to determine the 36-month continuing education period and one of the dates in clause (ii) of this subparagraph to determine the 24-month continuing experience period. Each interpreting physician shall maintain qualifications by meeting the following requirements:~~]

(i) Each IP must maintain continuing education by completing at least 15 category I mammography CMEUs, in a rolling 36-month period, by participating in or teaching mammography courses. CMEUs earned through teaching a specific course can only be counted once during the 36-month period. [~~participating in education programs by completing at least 15 category I CMEUs in mammography or by teaching mammography courses. CMEUs earned through teaching a specific course can be counted only once during the 36-month period. The continuing education must be completed in the 36 months immediately preceding:~~]

(I) The period for the initial continuing education begins when a physician completes the requirements in subparagraph (A) of this paragraph. [~~the date of the registrant's annual inspection;~~]

(II) The facility chooses one of the dates in subclause (III) of this clause to determine the start of the subsequent 36-month continuing education period. [~~the last day of the calendar quarter preceding the inspection; or~~]

(III) Continuing education must be completed in the 36 months immediately preceding: [~~any date in between the two;~~]

(-a-) the date of the facility's inspection;

(-b-) the last day of the calendar quarter preceding the inspection; or

(-c-) any date in between the two.

(ii) Each IP must complete at least eight hours of training in any mammography modality in which the IP has not been previously trained, before independently using the new modality. [~~interpreting or multi-reading at least 960 mammographic examinations that must be completed during the 24 months immediately preceding:~~]

~~*(I)* the date of the registrant's annual inspection;~~

~~*(II)* the last day of the calendar quarter preceding the inspection; or~~

~~*(III)* any date in between the two;~~

~~*(iii)* accumulating at least eight hours of CMEUs in any mammography modality in which the interpreting physician has not been previously trained, prior to independently using the new modality.~~

(E) Continuing experience.

(i) Each IP must maintain continuing experience by interpreting or multi-reading at least 960 mammographic examinations.

(ii) The period for the initial continuing experience begins when a physician completed the requirements in subparagraph (A) of this paragraph.

(iii) The facility chooses one of the dates in clause (iv) of this subparagraph to determine the start of the subsequent 24-month continuing experience period.

(iv) Continuing experience must be completed in the 24 months immediately preceding:

(I) the date of the facility's inspection;

(II) the last day of the calendar quarter preceding the inspection; or

(III) any date in between the two.

(F) [~~(D)~~] Re-establishing qualifications. Before resuming independent interpretation of mammograms, an IP failing [~~interpreting physicians who fail~~] to maintain the required continuing education or experience must [~~requirements shall~~] re-establish their qualifications by completing one or both of the following requirements, as applicable:

(i) obtain [~~a sufficient number of~~] additional category I CMEUs to bring the [~~their~~] total up to [~~the~~] 15 category I CMEU credits required in the previous 36 months; [~~and/or~~]

(ii) within the six months immediately before [~~prior to~~] resuming independent interpretation and under the direct supervision of a physician qualified as an IP [~~interpreting physician~~], interpret or multi-read one of the following, whichever is less:

(I) at least 240 mammographic examinations; or

(II) additional [~~a sufficient number of~~] mammographic examinations to bring the total up to 960 examinations for the prior 24 months.

(G) [~~(E)~~] Additional mandatory training. Additional mandatory training may be required by the department [~~agency~~] based on the recommendations of an AB, the department, [~~the American College of Radiology~~] or the FDA. Training is [~~Such training will be~~] developed on a case-by-case [~~case by case~~] basis.

(i) The department [~~agency~~] may require pre-approval of any additional mandatory training.

(ii) Documentation of the additional mandatory training must [~~shall~~] be submitted for review by the date specified by the department [~~agency~~].

(iii) Records of all additional mandatory training must [~~shall~~] be maintained by the facility [~~registrant~~] for inspection by the department as specified [~~agency~~] in [~~accordance with~~] subsection (x)(3)[~~(ee)(3)~~] of this section.

(2) Medical radiologic technologists (MRTs [~~operators of equipment~~]). Each individual [~~person~~] performing mammographic examinations must maintain current credentials as an ARRT(R) and MRT as specified in [~~shall have current certification as a medical radiologic technologist under~~] the Medical Radiologic Technologist Certification Act, Texas Occupations Code[~~,~~] Chapter 601, and must [~~shall~~] meet the following qualifications.

(A) Initial requirements. Before performing mammographic examinations, the MRT must [~~operator of equipment shall have~~]:

(i) complete [~~completed~~] a minimum of 40 contact hours of training as specified [~~outlined~~] in subparagraph (B) [~~subsection (hh)(1)~~] of this paragraph [~~section~~] by a qualified instructor; and

(ii) perform [~~performed~~] a minimum of 25 mammographic examinations under the direct supervision of an individual qualified as specified in [~~accordance with the requirements of~~] this paragraph. The 25 mammographic examinations may be obtained concurrently with the 40 contact hours of training specified in clause (i) of this subparagraph but must [~~shall~~] not exceed 16 hours of the 40 contact hours.

(B) Subjects to be included in mammography training for an MRT must include the following:

(i) breast anatomy and physiology;

(ii) positioning and compression;

(iii) QA/QC techniques;

(iv) imaging of patients with breast implants; and

(v) at least eight hours of training in each mammography modality to be used by the MRT in performing mammography examinations.

(C) [~~(B)~~] Exemptions. MRTs [~~Equipment operators who~~] qualified [~~as medical radiologic technologists~~] to perform mammography as specified in [~~accordance with~~] the requirements of §289.230 that were in effect before [~~prior to~~] April 28, 1999, and any other federal requirements in effect before [~~prior to~~] April 28, 1999, are considered to have met the initial requirements of subparagraph (A) of this paragraph.

(D) [~~(C)~~] Continuing education. [~~and experience. The time period for completing continuing education is a 36-month period and the time period for completing continuing experience is a 24-month period. The period for continuing education begins when a technologist completes the requirements in subparagraph (A) of this paragraph. The period for continuing experience begins when a technologist completes the requirements in subparagraph (A) of this paragraph, or April 28, 1999, whichever is later. The facility shall choose one of the dates in clause (i) of this subparagraph to determine the 36-month continuing education period and one of the dates in clause (ii) of this subparagraph to determine the 24-month continuing experience period. Each medical radiologic technologist shall maintain qualifications by meeting the following requirements:~~]

(i) Each MRT must maintain continuing education by completing at least 15 mammography CEUs, in a rolling 36-month period, by participating in or teaching mammography courses. CEUs earned through teaching a specific course can only be counted once during the 36-month period. [~~participating in education programs by completing at least 15 CEUs in mammography or by teaching mammography courses. CEUs earned through teaching a specific course can be counted only once during the 36-month period. The continuing education must be completed in the 36 months immediately preceding:~~]

(I) The period for the initial continuing education begins when an MRT completes the requirements in subparagraph (A) of this paragraph, or April 28, 1999, whichever is later. [~~the date of the registrant's annual inspection;~~]

(II) The facility chooses one of the dates in subclause (III) of this clause to determine the start of the subsequent 36-month continuing education period. [~~the last day of the calendar quarter preceding the inspection; or~~]

(III) Continuing education must be completed in the 36 months immediately preceding: [~~any date in between the two;~~]

(-a-) the date of the facility's inspection;

(-b-) the last day of the calendar quarter preceding the inspection; or

(-c-) any date in between the two.

(ii) Each MRT must complete at least eight hours of CEUs in any mammography modality in which the MRT has not been previously trained, before independently using the new modality. [~~performing a minimum of 200 mammographic examinations that must be completed during the 24 months immediately preceding:~~]

[(I) ~~the facility's annual inspection;~~]

[(II) ~~the last day of the calendar quarter preceding the inspection; or~~]

[(III) ~~any date in between the two; and~~]

[(iii) ~~accumulating at least eight hours of CEUs in any mammography modality in which the medical radiologic technologist has not been previously trained, prior to independently using the new modality.~~]

(E) Continuing experience.

(i) Each MRT must maintain continuing experience by completing 200 mammographic examinations.

(ii) The period for the initial continuing experience begins when an MRT completes the requirements in subparagraph (A) of this paragraph.

(iii) The facility chooses one of the dates in clause (iv) of this subparagraph to determine the start of the subsequent 24-month continuing experience period.

(iv) Continuing experience must be completed in the 24 months immediately preceding:

(I) the date of the facility's inspection;

(II) the last day of the calendar quarter preceding the inspection; or

(III) any date in between the two.

(F) [~~(D)~~] Requalification. Before resuming independent performance of mammograms, MRTs [~~medical radiologic technologists~~] who fail to maintain the continuing education or experience requirements must [~~shall~~] re-establish their qualifications by completing one or both of the following requirements, as applicable:

(i) obtain [~~obtaining a sufficient number of~~] additional CEUs to bring the [~~their~~] total up to [~~the~~] 15 CEU credits required

in the previous 36 months;[, at least six of which shall be related to each modality used by the technologist in mammography; and/or]

(ii) perform [performing] a minimum of 25 mammographic examinations under the direct supervision of a qualified MRT [medical radiologic technologist].

(G) [(E)] Additional mandatory training. Additional mandatory training may be required by the department [agency] based on the recommendations of an AB, the department, [the American College of Radiology] or the FDA. Training is [Such training will be] developed on a case-by-case [case by case] basis.

(i) The department [agency] may require pre-approval of any additional mandatory training.

(ii) Documentation of the additional mandatory training must [shall] be submitted for review by the date specified by the department [agency].

(iii) Records of all additional mandatory training must [shall] be maintained by the facility [registrant] for inspection by the department as specified in [agency in accordance with] subsection (x)(3) [(ee)(3)] of this section.

(3) Medical physicist. Each medical physicist performing mammographic surveys, evaluating mammographic equipment, or providing oversight of the facility QA [quality assurance] program as specified in [accordance with] subsection (k) [(u)] of this section must[, shall] hold a current Texas license under the Medical Physics Practice Act, Texas Occupations Code[,] Chapter 602, in diagnostic radiological physics. The medical physicist must [and] be registered with the department [agency] or employed by an entity registered with the department [agency], as specified in [accordance with] §289.226(j) of this subchapter [title] and the Act, unless exempted by §289.226(d)(7) [(6)] of this subchapter [title]. Each medical physicist must [shall] meet the following qualifications.

(A) Initial qualifications. Before performing surveys and evaluating mammographic equipment independently, the medical physicist must have [shall]:

(i) [have] a master's [masters] degree or higher in a physical science from an accredited institution, with no less than 20 semester hours, 30 quarter hours, or equivalent [(30 quarter hours)] of college undergraduate or graduate level physics;

(ii) [have] 20 contact hours of documented specialized training in conducting surveys of mammography facilities; and

(iii) [have] experience conducting surveys of at least one mammography facility and a total of at least 10 [ten] mammography machines. Experience [After April 28, 1999, experience] conducting surveys must be acquired under the direct supervision of a medical physicist who meets the requirements of subparagraphs (A), [and] (C), and (D) of this paragraph. No more than one survey of a specific machine within a period of 60 days can be counted towards the total mammography machine survey requirement.

(B) Alternative initial qualifications. Individuals who qualified as a medical physicist as specified in [accordance with] the requirements of this section that were in effect before [prior to] April 28, 1999, or any other equivalent state or federal requirements in effect before [prior to] April 28, 1999, and have met the following additional qualifications before [prior to] April 28, 1999, are determined to have met the initial qualifications of subparagraph (A) of this paragraph:

(i) a bachelor's degree or higher in a physical science from an accredited institution with no less than 10 [ten] semester hours or equivalent of college undergraduate or graduate level physics;

(ii) 40 contact hours of documented specialized training in conducting surveys of mammography facilities; and

(iii) experience conducting surveys of at least one mammography facility and a total of at least 20 mammography machines. No more than one survey of a specific machine within a period of 60 days can be counted towards the total mammography machine survey requirement. The training and experience requirements must be met after fulfilling the degree requirements.

(C) Continuing education. [and experience. The time period for completing continuing education is a 36-month period and the time period for completing continuing experience is a 24-month period. The period for continuing education will begin when a physicist completes the requirements in subparagraph (A) of this paragraph. The time period for continuing experience will begin when a physicist completes the requirements in subparagraph (A) of this paragraph, or April 28, 1999, whichever is later. The facility shall choose one of the dates in clause (i) of this subparagraph to determine the 36-month continuing education period and one of the dates in clause (ii) of this subparagraph to determine the 24-month continuing experience period. Each medical physicist shall maintain his/her qualifications by meeting the following requirements:]

(i) Each medical physicist must maintain continuing education by completing at least 15 mammography CEUs, in a rolling 36-month period, by participating in or teaching mammography courses. CEUs earned through teaching a specific course can only be counted once during the 36-month period. [participating in education programs, either by teaching or completing at least 15 CEUs in mammography that shall include hours of training appropriate to each mammographic modality evaluated by the medical physicist during his or her surveys. CEUs earned through teaching a specific course can be counted only once during the 36-month period. The continuing education must be completed in the 36 months immediately preceding:]

(I) The period for the initial continuing education begins when a medical physicist completes the requirements in subparagraph (A) of this paragraph, or April 28, 1999, whichever is later. [the date of the registrant's annual inspection;]

(II) The facility chooses one of the dates in subclause (III) of this clause to determine the start of the subsequent 36-month continuing education period. [by the last day of the calendar quarter preceding the inspection; or]

(III) Continuing education must be completed in the 36 months immediately preceding: [any date in between the two;]

(-a-) the date of the facility's inspection;

(-b-) the last day of the calendar quarter preceding the inspection; or

(-c-) any date in between the two.

(ii) Each medical physicist must also complete at least eight hours of training in any mammography modality in which the medical physicist has not been previously trained, before independently using the new modality. [performing surveys of two mammography facilities and a total of at least six mammography machines (no more than one survey of a specific facility within a ten-month period or a specific machine within a period of 60 days can be counted towards the total mammography machine survey requirement). The continuing experience must be completed during the 24 months immediately preceding:]

[(I) the date of the facility's annual inspection;]

[(II) by the last day of the calendar quarter preceding the inspection; or]

[(III) ~~any date in between the two; and~~]

[(iii) ~~accumulating at least eight hours of CEUs in any mammography modality in which the medical physicist has not been previously trained, prior to independently using the new modality.~~]

(D) Continuing experience.

(i) Each medical physicist must perform a survey of two mammography facilities and at least six mammography machines. No more than one survey of a specific facility within a 10-month period or a specific machine within 60 days can be counted toward the total mammography machine survey requirement.

(ii) The period for the initial continuing experience begins when a medical physicist completes the requirements in subparagraph (A) of this paragraph.

(iii) The facility chooses one of the dates in clause (iv) of this subparagraph to determine the start of the subsequent 24-month continuing experience period.

(iv) Continuing experience must be completed in the 24 months immediately preceding:

(I) the date of the facility's inspection;

(II) the last day of the calendar quarter preceding the inspection; or

(III) any date in between the two.

(E) [~~(D)~~] Re-establishing qualifications. Before resuming independent performance of surveys and equipment evaluations, medical physicists who fail to maintain the continuing education or experience requirements must [~~shall~~] reestablish their qualifications by completing one or both of the following requirements, as applicable:

(i) obtain [~~obtaining a sufficient number of~~] additional CEUs to bring the [~~their~~] total up to the 15 CEU credits required in the previous 36 months; [~~and/or~~]

(ii) perform [~~performing a sufficient number of~~] surveys, under the direct supervision of a qualified medical physicist, to bring their total up to two mammography facilities and a total of at least six mammography machines for the prior 24 months. No more than one survey of a specific machine within a period of 60 days may [~~shall~~] be counted towards the total mammography machine survey requirement.

(4) Retention of personnel records. [~~Records documenting the qualifications, continuing education, and experience of personnel in subsection (r)(1) - (3) shall be maintained for inspection by the agency in accordance with subsection (ee) of this section.~~]

(A) Facilities must maintain records of training and experience relevant to their qualifications, as specified in subsection (h)(1) - (3) of this section, for personnel who work or have worked at the facility as IPs, MRTs, or medical physicists for review by the department.

(B) Records of personnel no longer employed by the facility must be maintained for at least 24 months from the date of the departure of the employee, and these records must be available for review at the time of an annual inspection occurring during those 24 months. Personnel records must be maintained by the facility for inspection by the department as specified in subsection (x) of this section.

(i) The facility must provide copies of these personnel records to current IPs, MRTs, and medical physicists upon their request.

(ii) The facility must provide personnel records to a former employee if the former employee communicates their request within 24 months of the date of their departure.

(I) If it has been greater than 24 months and the facility has maintained those records, the facility must provide those records to former employees upon request.

(II) If a facility closes or stops providing mammography services, it must arrange for current and former personnel to access their personnel qualification records before closing. Access may be provided by a permanent transfer of records to the personnel or the transfer of the records to a facility or other entity that will provide access to these records for at least 24 months from the date of facility closure of mammography services.

(i) [~~(s)~~] Machine Requirements. Mammographic machines must meet the following requirements [~~Equipment standards. Only systems meeting the following standards shall be used~~].

(1) System design. The equipment must be [~~shall have been~~] specifically designed and manufactured for mammography and as required by [~~in accordance with Title~~] 21[~~,~~] CFR[~~,~~] §§1010.2, 1020.30, and 1020.31.

(2) A mammography machine converted from one mammographic modality to another is considered a new machine at the facility under this subsection.

(A) Before clinical use, the mammography machine must undergo a mammography equipment evaluation and demonstrate compliance with applicable requirements.

(B) The facility must also follow the accreditation body's procedures for applying for accreditation of the unit.

(3) Screen-film mammography systems must meet the requirements of 21 CFR Part 900.

(4) [~~(2)~~] Motion of tube-image receptor assembly. The x-ray tube must remain physically stable during exposures. In cases where tubes are designed to move during exposure, the facility must ensure proper and free movement of the unit [~~The assembly shall be capable of being fixed in any position where it is designed to operate. Once fixed in any such position, it shall not undergo unintended motion~~]. In the event of power interruption, this mechanism must [~~shall~~] not fail.

[~~(3) Image receptors. Systems using screen-film image receptors shall, at a minimum, provide for the following:~~]

[~~(A) operation with image receptors of 18 x 24 cm and 24 x 30 cm;~~]

[~~(B) operable moving grids matched to all image receptor sizes provided;~~]

[~~(C) operation with the grid removed from between the source and image receptor for systems used for magnification procedures; and~~]

[~~(D) image receptors to rest, post-loading, 15 minutes between exposures.~~]

(5) [~~(4)~~] Magnification. Systems used to perform diagnostic [~~noninterventional problem solving~~] procedures must [~~shall~~] have radiographic magnification capability available for use with[~~, at a minimum,~~] at least one magnification value within the range of 1.4 to 2.0.

(6) [~~(5)~~] Focal spot and target material selection. Selection of the focal spot or target material must [~~shall~~] be as follows.

(A) When more than one focal spot is provided, the system must [shall] indicate, before [prior to] exposure, which focal spot is selected.

(B) When more than one target material is provided, the system must [shall] indicate, before [prior to] exposure, the preselected target material.

(C) When the target material and [and/or] focal spot are [is] selected by a system algorithm [that is] based on the exposure [or on a test exposure], after the exposure, the system must [shall] display[, after the exposure,] the target material and [and/or] focal spot [actually] used during the exposure.

(7) [(6)] Compression. All mammography systems must [shall] incorporate a compression device.

(A) Application of compression. Each [Effective October 28, 2002, and thereafter, each] system must [shall] provide the following features operable from both sides of the patient:

(i) an initial power-driven compression activated by hands-free controls; and

(ii) fine adjustment compression controls.

(B) Compression paddle.

(i) Systems must [shall] be equipped with different sized compression paddles matching [that match] the sizes of all full-field image receptors provided for the system.

(ii) Compression paddles for special purposes, including those smaller than the full size of the image receptor (for example, spot compression) may be provided. Such paddles are not subject to the requirements of clauses (v) and (vi) of this subparagraph.

(iii) Except as provided in clause (iv) of this subparagraph, the compression paddle must [shall] be flat and parallel to the breast support table and must [shall] not deflect from parallel by more than 1.0 cm at any point on the surface of the compression paddle when compression is applied.

(iv) Equipment intended by the manufacturer's design to not be flat and parallel to the breast support table during compression must [shall] meet the manufacturer's design specifications and maintenance requirements.

(v) The chest wall edge of the compression paddle must [shall] be straight and parallel to the edge of the image receptor.

(vi) The chest wall edge may be bent upward to allow for patient comfort, but must [shall] not appear on the image.

(8) [(7)] Technique factor selection and display. Technique factor selection and display must [shall] be as follows.

(A) Manual selection of milliampere seconds (mAs) or at least one of its component parts, milliampere (mA) or [and/or] time, must [shall] be available.

(B) The technique factors (kVp [peak tube potential in kilovolts (kV)] and either tube current in mA and exposure time in seconds or the product of tube current and exposure time in mAs) [to be] used during an exposure must [shall] be indicated before the exposure begins, except when AEC [automatic exposure control (AEC)] is used, in which case the technique factors that are set before [prior to] the exposure must [shall] be indicated.

(C) When the AEC mode is used, the system must [shall] indicate the actual kVp and mAs used during the exposure. The mAs may be displayed as mA and time.

(9) [(8)] Automatic exposure control. Each [screen-film] system must [shall] provide an AEC mode [that is] operable in all combinations of equipment configuration provided, for example, [contact, magnification, and] various image receptor sizes.

(A) The positioning or selection of the detector must [shall] permit flexibility in the placement of the detector under the target tissue.

(i) The size and available positions of the detector must [shall] be clearly indicated at the x-ray input surface of the breast compression paddle.

(ii) The selected position of the detector must [shall] be clearly indicated.

(B) The system must [shall] provide means to vary the selected optical density from the normal, or zero, [(zero)] setting.[(9) X-ray film. The registrant shall use x-ray film for mammography that has been designated by the film manufacturer as appropriate for mammography.]

[(10) Intensifying screens. The registrant shall use intensifying screens for mammography that have been designated by the screen manufacturer as appropriate for mammography and shall use film that is matched to the screen's spectral output as specified by the manufacturer.]

[(11) Film processing solutions. For processing mammography films, the registrant shall use chemical solutions that are capable of developing the films used by the facility in a manner equivalent to the minimum requirements specified by the film manufacturer.]

[(12) Lighting. The registrant shall make available special lights for film illumination (hot lights) capable of producing light levels greater than that provided by the view box.]

[(13) Film masking devices. Registrants shall ensure that film masking devices that can limit the illuminated area to a region equal to or smaller than the exposed portion of the film are available to all interpreting physicians interpreting for the facility.]

(10) [(14)] Equipment variances. Facilities [Registrants] with mammography equipment with [that has been issued] variances issued by the FDA as specified in [to Title] 21[,] CFR[,] §§1020.2, 1020.30, 1020.31, or have [has had] an alternative to [for] a quality standard for equipment approved by the FDA as required by [under the provisions of Title] 21[,] CFR[,] §900.18, must [shall] maintain copies of those variances or alternative standards.

(11) Each mammography machine must meet the following technical specifications.

(A) Kilovoltage peak accuracy and reproducibility. At the most used clinical settings of kVp, the coefficient of variation of reproducibility of the kVp must be equal to or less than 0.02. The kVp must be accurate to within plus or minus 5.0 percent of the indicated or selected kVp at the following:

(i) the lowest clinical kVp that can be measured by a kVp test device;

(ii) the most used clinical kVp; and

(iii) the highest available clinical kVp.

(B) Beam quality and half-value layer (HVL). The HVL must meet the specifications of 21 CFR §1020.30(m)(1) for the minimum HVL. These values, extrapolated to the mammographic range, are shown as follows. This test is performed using the clinical kVp on the standard breast. Values not shown in Table I may be determined by linear interpolation or extrapolation.

Figure: 25 TAC §289.230(i)(11)(B)

(C) Breast entrance air kerma and AEC reproducibility. The coefficient of variation for both air kerma and mAs must not exceed 0.05.

(D) Dosimetry. The average glandular dose delivered during a single view or DBT exposure of an FDA-accepted phantom simulating a standard breast must not exceed 3.0 milligray (mGy) (0.3 rad) per exposure.

(E) X-ray field, light field, image receptor, and compression paddle alignment. All systems must meet the following.

(i) Beam-limiting devices that allow the entire chest wall edge of the x-ray field to extend to the chest wall edge of the image receptor must provide means to ensure the x-ray field does not extend beyond any edge of the image receptor by more than 2.0 percent of the SID.

(ii) The light field passing through the x-ray beam limitation device must be aligned with the x-ray field so the total of any misalignment of the edges, along the length or the width of the visually defined field at the plane of the breast support surface, does not exceed 2.0 percent of the SID.

(iii) When tested with the compression paddle placed above the breast support surface at a distance equivalent to standard breast thickness, the chest wall edge of the compression paddle does not extend beyond the edge of the image receptor by greater than 1.0 percent of the SID. The shadow of the vertical edge of the compression paddle must not be visible in the image.

(12) [~~(15)~~] Light fields. For any mammography system with a light beam that passes through the x-ray beam-limiting device, the light must [~~shall~~] provide an average illumination of not less than 160 lux (15 foot candles) at 100 cm or the maximum SID [~~source-image receptor distance (SID)~~], whichever is less.

(j) [~~(t)~~] Medical records and mammography reports.

(1) Contents and terminology. Each facility must [~~registrant shall~~] prepare a written report of the results of each mammographic examination performed. [~~mammography examination that shall include the following information:~~]

(2) The mammographic examination presented for interpretation must be in the original mammographic modality in which it was performed and must not consist of digital images produced through copying or digitizing hardcopy original images.

(3) The mammography report must include the:

(A) patient name [~~of the patient~~] and an additional patient identifier [~~date of birth~~];

(B) [~~date of the~~] examination date;

(C) facility name and location, including the city, state, zip code, and telephone number of the facility;

(D) [~~(C)~~] name and signature of the IP [~~interpreting physician~~] who interpreted the mammogram (electronic signatures are acceptable);

(E) [~~(D)~~] overall final assessment of findings using the final assessment categories as defined in clauses (i) - (vii) [~~subsection (c)~~] of this subparagraph, [~~section;~~] and classified in one of the following categories with the assessment statement, including only the word or phrase within the quotation marks:

(i) "Negative" indicates nothing to comment upon (if the IP is aware of clinical findings of symptoms, despite the negative assessment, these must be documented and addressed);

(ii) "Benign" indicates a normal result, with benign findings present, but no evidence of malignancy (if the IP is aware of clinical findings or symptoms, despite the benign assessment, these must be documented and addressed);

(iii) "Probably Benign" indicates a finding that has a high probability of being benign;

(iv) "Suspicious" indicates a finding without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant;

(v) "Highly suggestive of malignancy" indicates a finding that has a high probability of being malignant;

(vi) "Known biopsy proven malignancy" is reserved for known malignancies being mammographically evaluated for definitive therapy; or

(vii) "Post procedure mammogram for marker placement" indicates a mammogram to confirm the deployment and position of a breast tissue marker; or

(F) in cases where the final assessment category cannot be assigned due to incomplete work-up, the IP must assign one of the following classification statements and reasons why the final assessment cannot be made:

(i) "Incomplete: Need additional imaging evaluation" is reserved for examinations where additional imaging needs to be performed before an assessment category identified in subparagraph (E)(i) - (vii) of this paragraph can be given; or

(ii) "Incomplete: Need prior mammograms for comparison" is reserved for examinations where comparison with prior mammograms should be performed before an assessment category identified in subparagraph (E) of this paragraph can be given; if this assessment category is used, a follow-up report with an assessment category identified in subparagraph (E)(i) - (v) of this paragraph must be issued within 30 calendar days of the initial report whether or not comparison views can be obtained;

(G) overall assessment of breast density, classified in one of the following categories:

(i) "The breasts are almost entirely fatty";

(ii) "There are scattered areas of fibroglandular density";

(iii) "The breasts are heterogeneously dense, which may obscure small masses"; or

(iv) "The breasts are extremely dense, which lowers the sensitivity of mammography"; and

(H) [~~(E)~~] recommendations made to the healthcare provider [~~physician~~] about what additional actions, if any, should be taken. All clinical questions raised by the referring healthcare provider must [~~physician shall~~] be addressed in the report to the extent possible, even if the assessment is negative or benign.

(4) [~~(2)~~] Communication of mammography results to the patient and healthcare [~~health care~~] providers [~~or physicians~~], as applicable. [~~Each registrant shall send reports as soon as possible, but no later than 30 days from the date of the mammography examination, to:~~]

(A) Each facility must send a mammography report to referring healthcare providers, or patients who do not name a health-

care provider to receive the mammography report, the report described in subsection (j)(3) of this section within 30 days of the mammography examination. If the assessment of the mammography report is "Suspicious" or "Highly suggestive of malignancy," the facility must send this report within seven calendar days of the mammography examination. [~~patients advising them of the results of the mammography examination and any further medical needs indicated. The report shall include a summary written in language easily understood by a lay person; and~~]

(B) Each facility must send a mammography report summary, written in plain language, to patients advising them of the results of the mammography examination and any further medical needs within 30 days of the mammography examination. If the assessment of the mammography report is "Suspicious" or "Highly suggestive of malignancy," the facility must send this report summary within seven calendar days of the final interpretation of the mammogram [~~referring physicians, or in the case of self-referral, to the physician indicated by the patient, advising them of the results of the mammography examination, containing the information specified in paragraph (1) of this subsection, and any further medical needs indicated~~].

(5) A summary of the report written in plain language must be provided within 30 days of interpretation and include:

(A) patient name;

(B) name, address, and telephone number of the facility performing the mammographic examination; and

(C) assessment of breast density as described in subsection (j)(3)(G) of this section, as applicable.

(i) If the mammography report identifies the patient's breast density as "The breasts are almost entirely fatty" or "There are scattered areas of fibroglandular density," the summary must include the statement, "Breast tissue can be either dense or not dense. Dense tissue makes it harder to find breast cancer on a mammogram and also raises the risk of developing breast cancer. Your breast tissue is not dense. Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation."

(ii) If the mammography report identifies the breast density as "The breasts are heterogeneously dense, which may obscure small masses" or "The breasts are extremely dense, which lowers the sensitivity of mammography," the summary must include the statement, "Breast tissue can be either dense or not dense. Dense tissue makes it harder to find breast cancer on a mammogram and also raises the risk of developing breast cancer. Your breast tissue is dense. In some people with dense tissue, other imaging tests in addition to a mammogram may help find cancers. Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation."

(6) [~~(3)~~] Follow-up with patients and healthcare provider [~~physicians~~]. Each facility must [~~registrant shall~~] follow-up to confirm if [~~the following~~]:

(A) [~~that~~] patients with positive findings and patients needing repeat examinations [~~exams~~] have received proper notification; and

(B) healthcare providers [~~that physicians~~] have received proper notification of patients with positive findings or needing repeat examinations [~~exams~~].

(7) [~~(4)~~] Retention of clinical images for a current, closed, or terminated facility [~~registrants~~].

(A) A facility must implement policies and procedures to minimize the possibility of loss of these records. The original mammograms must be retained, in retrievable form in the mammographic modality in which they were produced, for a minimum of five years. Original mammograms cannot be produced by copying or digitizing hardcopy originals [~~Each registrant that performs mammograms shall maintain mammography films and reports in a permanent medical record for a minimum of five years~~]. If [~~no~~] additional mammograms of the patient are not performed at the facility, the images [~~films~~] and reports must [~~shall~~] be maintained for a minimum of 10 [~~ten~~] years as specified in subsection (x) of this section.

(B) Each facility performing [~~registrant that performs~~] mammograms must [~~shall~~], within 15 calendar [~~30~~] days of request by or on behalf of the patient, permanently or temporarily transfer the original mammograms and copies of the patient's reports to a medical institution, a physician, or to the patient directly.

(i) Transferred mammograms must be in the mammographic modality in which they were produced and cannot be produced by copying or digitizing hardcopy originals.

(ii) For digital mammograms or DBT, if the examination is being transferred for final interpretation purposes, the facility must be able to provide the recipient with original digital images electronically.

(C) If the medical records are permanently forwarded, the receiving institution or physician must [~~shall~~] maintain and become responsible for the original images [~~film~~] until the fifth or tenth anniversary, as specified in subparagraph (A) of this paragraph.

(D) Any fee charged to a patient for providing the services in subparagraphs (B) - (C) of this paragraph must not exceed the documented costs associated with this service.

(E) [~~(D)~~] Closure [~~Upon closure~~] or termination.[~~,~~]

(i) The facility must [~~the registrant shall~~] maintain the mammography images [~~films~~] for five [~~5~~] years. [~~If the facility complies with the following:~~]

(ii) [~~(i)~~] Within [~~within~~] 180 days of closing, the facility must [~~registrant shall directly~~] notify each patient or patient's representative with instructions on how to access [~~retrieve~~] or authorize disposal of the patient's records.[~~; and~~]

(I) Access may be provided by the permanent transfer of mammographic records to the patient, the patient's healthcare provider, or a facility or other entity that will provide access to patients and healthcare providers. Access to the records must be provided by the facility or other entity for the remainder of the time periods specified in subparagraph (A) of this paragraph.

(II) If a facility ceases to perform mammography but continues to operate as a medical entity and is able to satisfy the record keeping requirements of subparagraph (A) of this paragraph, it may choose to continue to retain the medical records rather than transfer them to another facility, unless a transfer is requested by, or on behalf of, the patient. The facility must notify the AB and department in writing of the arrangements it has made and must make reasonable efforts to notify all affected patients.

(iii) [~~(ii)~~] Within [~~within~~] 60 days of closing, the facility must [~~registrant shall~~] publish a notice in at least one newspaper, or publicly available media, [~~or more newspapers~~] covering the geographical area served by the closing facility. The notice must [~~shall~~] include:

(I) contact information for [~~on~~] retrieving patient records; and

(II) information that the records will be destroyed if not retrieved by the patient or the patient's representative within five [5] years.[; and]

(iv) [(iii)] If [if] records have not been retrieved by the patient or the patient's representative during [following] the five-year [5-year] period after closing, the registrant may destroy the records.

(8) [(5)] Mammographic image identification. Each mammographic image must include [shall have] the following information indicated on it in a permanent, legible manner and placed so it does [as] not [to] obscure anatomic structures:

(A) patient name [name of patient] and date of birth;

(B) date of examination;

(C) view and laterality, [(this information shall be] placed on the image in a position near the axilla[)];

(D) facility name and location, including [(at a minimum the location shall include] city, state, and zip code[)];

(E) MRT [technologist] identification;

(F) cassette [cassette/screen] identification, if applicable; [and]

(G) mammography machine identification, if there is more than one machine in the facility;[.]

(H) compressed breast thickness or degree of compression; and

(I) kVp.

[(6) Information shall also be maintained for each clinical image by utilizing a label on each film, recording on the film jacket, or maintaining a log or other means. The information shall include, but is not limited to, compressed breast thickness or degree of compression, and kVp.]

(k) [(u)] Quality assurance - general. Each facility must [registrant shall] establish and maintain a written quality assurance program to ensure the safety, reliability, clarity, and accuracy of mammography services performed at the mammography facility, including corrective actions [to be] taken if images are of poor quality.

(1) Responsible individuals. Responsibility for the QA [quality assurance] program and [for] each of its elements must [shall] be assigned to individuals who are qualified for their assignments and [who shall be] allowed adequate time to perform these duties.

(A) Lead interpreting physician. The facility must [registrant shall] identify a LIP [lead interpreting physician] who is responsible for [shall have the general responsibility of]:

(i) ensuring [that] the QA [quality assurance] program meets all requirements of this subsection and subsections (l) and (m) [(v) and (w)] of this section;

(ii) reviewing and documenting, with date and signature, the MRTs' QC [technologists' quality control] test results at least every three months or more frequently if consistency has not yet been achieved;

(iii) reviewing and documenting, with date and signature, the physicists' results within 60 days of the receipt of the results or more frequently when needed; and

(iv) assigning the individual and evaluating their [determining the individual's] qualifications to perform the QA [quality assurance] tasks in subparagraphs (B) - (D) of this paragraph.

(B) Interpreting physicians. All [interpreting] physicians interpreting mammograms for a facility must [the registrant shall]:

(i) follow the facility's [registrant's] procedures for corrective action when the images they are asked to interpret are of poor quality; these [. These] procedures must [shall] be included in the facility's operating and safety procedures (OSP); and

(ii) participate in the medical outcomes audit program.

(C) Medical physicist. Each facility must [registrant shall] use the services of a licensed medical physicist to survey mammography equipment and oversee the equipment-related QA [quality assurance] practices of the facility. At a minimum, the medical physicist is [shall be] responsible for performing the surveys, performing [and the] mammography equipment evaluations, and providing the facility with the reports described in subsection (l)(5) and (6) [(v)(10) and (11)] of this section.

(D) Quality control technologist. The QC [quality control] technologist, designated by the LIP [lead interpreting physician], must [shall] ensure performance of the items designated in subsection (l)(1) - (4), (7), and (9) [(v)(1) - (4), (7) - (9), (12), and (14)] of this section. If other personnel are assigned the QA [quality assurance] tasks in accordance with subparagraph (A)(iv) of this paragraph, the QC [quality control] technologist must ensure [shall insure that] the requirements of subsection (l)(1) - (4), (7), and (9) [(v)(1) - (4), (7) - (9), (12), and (14)] of this section are met.

(2) Quality assurance records.

(A) The LIP [lead interpreting physician], QC [quality control] technologist, and medical physicist must [shall] ensure [that] records concerning mammography technique and procedures, QC [quality control] (include monitoring data, corrective actions, and the effectiveness of the corrective actions), safety, protection, and employee qualifications related to [meet] assigned QA [quality assurance] tasks are properly maintained and updated.

(B) The QC [These quality control] records must [shall] be kept for each test specified in subsections (l) and (m) [(v) and (w)] of this section, as specified in [accordance with] subsection (x) [(ee)] of this section.

(l) [(v)] Quality assurance - equipment. [Registrants with screen-film systems shall perform the following quality control tests at the intervals specified. In addition to the intervals specified in paragraphs (4)(B) and (5)(H) of this subsection, the tests shall be performed prior to initial use.]

(1) Facilities with screen-film systems must perform QC tests as specified in 21 CFR Part 900 [Daily quality control tests. Film processors used to develop mammograms shall be adjusted and maintained to meet the technical development specifications for the mammography film in use. A processor performance test shall be completed and the results charted on each day that clinical films are processed before any clinical films are processed that day].

[(A) Processor performance test. Using mammography film used clinically at the facility, sensitometer tests shall include assessment of the following:]

[(i) base plus fog density that shall be within plus 0.03 of the established operating level;]

[(ii) mid-density that shall be within plus or minus 0.15 of the established operating level; and]

[(iii) density difference that shall be within plus or minus 0.15 of the established operating level].

[(B) Film processors being used for mammography at multiple locations, such as a mobile service operation, shall be subject to the requirements of this paragraph.]

[(C) Film processors utilized for mammography shall be adjusted to and operated at the specifications recommended by the mammographic film manufacturer, or at other settings such that the sensitometric performance is at least equivalent.]

[(D) Each registrant shall utilize the same film processor for clinical and phantom images. Clinical images shall be processed within an interval not to exceed 24 hours from the time the first clinical image is taken. Facilities utilizing batch processing shall do the following:]

[(i) use a container to transport clinical images that will protect the film from exposure to light and radiation; and]

[(ii) maintain a log to include each patient name and unique identification number, date, and time of the first exam of each batch, and date and time of batch development.]

(2) Systems with image receptor modalities, other than screen-film, must follow a QA program that is substantially the same as the one recommended by the image receptor manufacturer [Weekly quality control tests. These tests shall be performed at an interval no greater than seven days. If mammography is not being performed on the date the test is due and more than seven days have past since the last test, the tests shall be performed prior to resuming mammography. An image quality evaluation test, using an FDA-accepted phantom, shall meet the following parameters].

[(A) The optical density of the film at the center of an image of a standard FDA-accepted phantom shall be at least 1.20 when exposed under a typical clinical condition and shall not change by more than plus or minus 0.20 from the established operating level.]

[(B) The density difference between the background of the phantom and an added test object, used to assess image contrast, shall be measured and shall not vary by more than plus or minus 0.05 from the established operating level.]

[(C) The phantom image shall be made on the standard mammographic film in use at the facility with techniques used for clinical images of a standard breast. The phantom image shall meet the requirements in subparagraphs (A) and (B) of this paragraph and clause (i) of this subparagraph. No mammograms shall be taken on patients if any of these minimums are not met.]

[(i) The mammographic machine shall be capable of producing images of the mammographic phantom in accordance with the phantom image scoring protocol in subsection (hh)(4) of this section or paragraph (7) of this subsection.]

[(ii) Each phantom image and a record of the evaluation of that image shall be maintained at the location where the mammography image was produced or with the radiographic equipment for mobile service operations.]

[(3) Quarterly quality control tests. These tests shall be performed within the calender quarter at an interval not to exceed 90 days.]

[(A) Fixer retention in film. The residual fixer shall be no more than 5 micrograms per square cm.]

[(B) Repeat analysis. A repeat analysis on clinical images repeated or rejected shall be performed, analyzed, and documented. The total repeat or reject rate shall not exceed 5.0%. If the total repeat or reject rate changes from the previously determined rate by more than 2.0% of the total films included in the analysis, the reason(s) for the change shall be determined. Corrective action shall be taken and documented if the total repeat or reject rate for the facility exceeds 5.0% or changes from the previously determined rate by more than 2.0% of the total films included in the analysis. Test films, cleared films, or film processed as a result of exposure of a film bin are not to be included in the count for repeat analysis. Films included in the repeat analysis are not required to be kept after completion of the analysis.]

[(4) Semiannual quality control tests. These tests shall be performed at an interval not to exceed six months.]

[(A) Darkroom fog. The optical density attributable to darkroom fog shall not exceed 0.05 when a mammography film of the type used in the facility, which has a mid-density of no less than 1.2 OD, is exposed to typical darkroom conditions for two minutes while such film is placed on the counter top, emulsion side up. If the darkroom has a safelight used for mammography film, it shall be on during this test.]

[(B) Screen-film contact. Testing for screen-film contact shall be conducted using 40 mesh copper screen. The entire area of the cassette that may be clinically exposed shall be tested. This shall include all cassettes used for mammography in the facility.]

[(C) Compression device performance. The maximum compression force for the initial power drive shall be between 25 pounds and 45 pounds. The system shall be capable of compressing the breast with a force of at least 25 pounds and shall be capable of maintaining this compression for at least 15 seconds.]

[(5) Annual quality control tests. These tests shall be performed at an interval not to exceed (14) months.]

[(A) Automatic exposure control performance. The AEC shall be capable of maintaining film optical density within plus or minus 0.15 of the mean optical density when thickness of a homogeneous material is varied over a range of 2 to 6 cm and the kVp is varied appropriately for such thicknesses over the kVp range and in the AEC mode used clinically in the facility.]

[(B) Kilovoltage peak accuracy and reproducibility. At the most commonly used clinical settings of kVp, the coefficient of variation of reproducibility of the kVp shall be equal to or less than 0.02. The kVp shall be accurate to within plus or minus 5.0% of the indicated or selected kVp at the following:]

[(i) the lowest clinical kVp that can be measured by a kVp test device;]

[(ii) the most commonly used clinical kVp; and]

[(iii) the highest available clinical kVp.]

[(C) Focal spot condition. Facilities shall evaluate focal spot condition by determining the system resolution as follows.]

[(i) Each system used for mammography, in combination with the mammography screen-film combination used in the facility, shall provide a minimum resolution of 11 cycles/millimeter (mm) (line-pairs/mm) when a high contrast resolution bar test pattern is oriented with the bars perpendicular to the anode-cathode axis, and a minimum resolution of 13 line-pairs/mm when the bars are parallel to that axis.]

[(ii) The bar pattern shall be placed 4.5 cm above the breast support surface, centered with respect to the chest wall edge of the image receptor, and with the edge of the pattern within 1 cm of the chest wall edge of the image receptor.]

[(iii) When more than one target material is provided, the measurement in clause (i) of this subparagraph shall be made using the appropriate focal spot for each target material.]

[(iv) When more than one SID is provided, the test shall be performed at the SID most commonly used clinically.]

[(v) Test kVp shall be set at the value used clinically by the facility for a standard breast and shall be performed in the AEC mode, if available. If necessary, a suitable absorber may be placed in the beam to increase exposure times. The screen-film cassette combination used by the facility shall be used to test for this requirement and shall be placed in the normal location used for clinical procedures.]

[(D) Beam quality and half-value layer (HVL). The HVL shall meet the specifications of Title 21, CFR, §1020.30(m)(1) for the minimum HVL. These values, extrapolated to the mammographic range, are shown as follows. This test is performed using the clinical kVp on the standard breast. Values not shown in Table I may be determined by linear interpolation or extrapolation.]
[Figure: 25 TAC §289.230(v)(5)(D)]

[(E) Breast entrance air kerma and AEC reproducibility. The coefficient of variation for both air kerma and mAs shall not exceed 0.05.]

[(F) Dosimetry. The average glandular dose delivered during a single craniocaudal view of an FDA accepted phantom simulating a standard breast shall not exceed 3.0 milligray (mGy) (0.3 rad) per exposure.]

[(G) X-ray field/light field/image receptor/compression paddle alignment. All systems shall meet the following.]

[(i) All systems shall have beam-limiting devices that allow the entire chest wall edge of the x-ray field to extend to the chest wall edge of the image receptor and provide means to assure that the x-ray field does not extend beyond any edge of the image receptor by more than 2.0% of the SID.]

[(ii) If a light field that passes through the x-ray beam limitation device is provided, it shall be aligned with the x-ray field so that the total of any misalignment of the edges of the light field and the x-ray field along either the length or the width of the visually defined field at the plane of the breast support surface shall not exceed 2.0% of the SID.]

[(iii) The chest wall edge of the compression paddle shall not extend beyond the chest wall edge of the image receptor by more than 1.0% of the SID when tested with the compression paddle placed above the breast support surface at a distance equivalent to standard breast thickness. The shadow of the vertical edge of the compression paddle shall not be visible on the image.]

[(H) Uniformity of screen speed. Uniformity of screen speed of all the cassettes in the facility shall be tested and the difference between the maximum and minimum optical densities shall not exceed 0.30. Screen artifacts shall also be evaluated during this test.]

[(I) System artifacts. System artifacts shall be evaluated with a high-grade, defect-free sheet of homogeneous material large enough to cover the mammography cassette and shall be performed for all cassette sizes used in the facility using a grid appropriate for the cassette size being tested. System artifacts shall also be evaluated for all available focal spot sizes and target filter combinations used clinically.]

[(J) Radiation output. The system shall be capable of producing a minimum output of 7.0 mGy air kerma per second (800 milliroentgen (mR) per second) when operating at 28 kVp in the standard mammography mode at any SID where the system is designed to operate. The system shall be capable of maintaining the required minimum radiation output averaged over a 3.0 second period.]

[(K) Decompression. If the system is equipped with a provision for automatic decompression after completion of an exposure or interruption of power to the system, the system shall be tested to confirm that it provides the following:]

[(i) an override capability to allow maintenance of compression;]

[(ii) a continuous display of the override status; and]

[(iii) a manual emergency compression release that can be activated in the event of power or automatic release failure.]

[(L) The technique settings used for subparagraph (F) of this paragraph and paragraph (2) of this subsection shall be those used by the facility for its clinical images of a standard breast.]

[(6) Densitometer and sensitometer. The calibration of the densitometer and sensitometer must be in accordance with the manufacturer's specifications.]

[(7) Quality control tests - other modalities. For systems with image receptor modalities other than screen-film, the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems in paragraph (5)(F) of this subsection.]

(3) [(8)] Mobile service operation.

(A) The mobile facility must [registrant shall] verify [that] mammography machines used to produce mammograms at more than one location meet the requirements in paragraphs (1) and (2) [(1) - (7)] of this subsection.

(B) At [In addition, at] each examination location, before any examinations are conducted, the facility must [registrant shall] verify satisfactory performance of the mammography machines by using a testing [test] method, as required by the manufacturer, establishing [that establishes] the adequacy of the image quality produced by the machine.

(C) Processor performance testing must be completed as required by 21 CFR Part 900 [shall be in accordance with paragraph (1) of this subsection].

(4) [(9)] Use of test results. After completion of the tests specified in paragraphs (1) and (2) [(1) - (8)] of this subsection, the following must [shall] occur.

(A) The facility must [registrant shall] compare the test results to the [corresponding specified action limits; or, for nonscreen-film modalities, to the] manufacturer's recommended action limits[; or for post-move, pre-examination testing of mobile mammography machines, to the limits established in the test method used by the facility].

(B) If components [Components] of the mammography system [that] fail QA [quality assurance] tests, the facility must follow [shall have] corrective actions required by 21 CFR Part 900, or the QA program recommended by the image receptor manufacturer [as indicated in the following].

[(i) If components in subclause (I) and (II) of this clause fail, corrective action shall be taken before any mammography films are processed:]

[(I) paragraph (1) of this subsection describing processor quality control; and]

[(II) paragraph (4)(A) of this subsection describing darkroom fog;]

[(ii) If components in subclause (I) - (VI) of this clause fail, corrective action shall be taken before any mammography examinations are performed:]

[(I) paragraph (2) of this subsection describing phantom image quality;]

[(II) paragraph (4)(B) of this subsection describing screen-film contact;]

[(III) paragraph (4)(C) of this subsection describing compression device performance;]

[(IV) paragraph (5)(F) of this subsection describing dosimetry;]

[(V) paragraph (7) of this subsection describing quality control tests of other modalities; and]

[(VI) paragraph (8) of this subsection describing quality control tests for mobile mammography machines.]

[(iii) If components in the remaining quality assurance tests in subsection (v) of this section fail, corrective action shall be taken within 30 days of the test date.]

(C) Documentation of the tests and the corrective actions described in subparagraph (B) of this paragraph must [shall] be maintained as specified in [accordance with] subsection (x) [(ee)] of this section.

(5) [(10)] Surveys. Annually, not to exceed 14 months from the date of the previous survey [At least once a year], each mammography system must [facility shall] undergo a survey by a medical physicist, or [by] an individual under the direct supervision of a medical physicist, as specified in paragraphs (1) - (3) of this subsection.

[(A) At a minimum, this survey shall include the following:]

[(i) performance of tests to ensure that the facility meets the quality assurance requirements of the weekly phantom image quality test described in paragraph (2) of this subsection, the annual tests described in paragraph (5) of this subsection, and if applicable, quality control tests as described for other modalities in paragraph (7) and for mobile service operations as described in paragraph (8) of this subsection; and]

[(ii) evaluation of the adequacy of the results of all tests conducted by the facility as well as written documentation of any corrective actions taken and their results in accordance with paragraphs (1) - (4) of this subsection, and, if applicable, paragraphs (7) and (8) of this subsection.]

(A) [(B)] The medical physicist must [shall] provide a written survey report to the facility within 30 days of the date of the survey. The report must [shall] include a summary of the test performed, all test conditions, specifications, results, and recommendations for corrective actions[, in accordance with subparagraph (A)(i) and (ii) of this paragraph].

(B) [(C)] If any deficiencies require immediate corrective action as specified in paragraphs (1) - (3) of this subsection [the following tests indicate deficiencies], the physicist must [shall] give a preliminary [oral or] written report to the facility within 72 hours of the survey.[:]

[(i) processor quality control in accordance with paragraph (9)(B)(i)(I) of this subsection;]

[(ii) phantom images, screen-film contact, compression device performance, or dosimetry in accordance with paragraph (9)(B)(ii)(I) - (IV) of this subsection;]

[(iii) quality control tests for other modalities, if applicable, in accordance with paragraph (9)(B)(ii)(V) of this subsection; or]

[(iv) quality control tests for mobile mammography machines, if applicable, in accordance with paragraph (9)(B)(ii)(VI) of this subsection.]

(C) [(D)] The survey report must include the: [shall be dated and signed by the medical physicist performing or supervising the survey. If the survey was performed entirely or in part by another individual under the direct supervision of the medical physicist, that individual and the part of the survey that individual performed shall also be identified in the survey.]

(i) date, name, and signature of the medical physicist performing or supervising the survey;

(ii) name and signature of each individual under the direct supervision of the medical physicist performing any part of the survey, as applicable;

(iii) name of the facility;

(iv) address of facility;

(v) registration number of the facility;

(vi) make, model, and serial number from the machine control panel;

(vii) registration number of the service provider performing the survey;

(viii) service provider email address;

(ix) business mailing address of the service provider performing the survey; and

(x) date of the last calibration of testing equipment.

(D) [(E)] The facility must maintain the survey report as specified [shall be maintained by the registrant] in [accordance with] subsection (x) [(ee)] of this section.

(6) [(11)] Mammography equipment evaluations. Additional evaluations of mammography machines must follow manufacturer specifications. Screen-film mammography machines must follow applicable requirements in 21 CFR Part 900. The mammography equipment evaluation and dosimetry must be performed by a medical physicist or an individual under the direct supervision of a medical physicist [or image processors shall be conducted whenever a new mammography machine or processor is installed, a mammography machine or processor is disassembled and reassembled at the same or a new location, major components of mammography machine are changed or repaired, or a processor is overhauled or reconditioned. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in this subsection and subsection (s) of this section].

[(A) All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing.]

[(B) The mammography equipment evaluation and dosimetry shall be performed by a medical physicist or by an individual under the direct supervision of a medical physicist.]

(7) Each diagnostic review workstation (RWS) used to interpret images must follow manufacturer specifications for display conditions and quality control. If the RWS manufacturer does not specify QC procedures, then a QA program that is substantially the same as the QA program recommended by the image receptor manufacturer must be established and followed.

[(12) Facility cleanliness. The registrant shall establish and implement adequate protocols for maintaining darkroom, screen, and view box cleanliness and shall document that all cleaning procedures are performed at the frequencies specified in the protocols.]

(8) [(13)] Calibration of air kerma measuring instruments. Instruments used by medical physicists in their annual survey and mammography equipment evaluation to measure the air kerma or air kerma rate from a mammography machine must [shall] be calibrated at least once every two years and each time the instrument is repaired. The instrument calibration must be traceable to a national standard and calibrated with an accuracy of plus or minus six percent, or 95 percent confidence level, [6.0% (95% confidence level)] in the mammography energy range.

(9) [(14)] Infection control. Facilities must [shall] establish and comply with a system specifying procedures [to be followed by the facility] for cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials. This system must [shall] specify the methods for documenting facility compliance with the infection control procedures established and must [shall]:

(A) comply with all applicable federal, state, and local regulations pertaining to infection control; and

(B) comply with the manufacturer's recommended procedures for the cleaning and disinfection of the mammography equipment used in the facility; or

(C) if adequate manufacturer's recommendations are not available, comply with generally accepted guidance on infection control, until such recommendations become available.

(m) [(w)] Quality assurance - mammography medical outcomes audit. Each registrant must [shall] establish and maintain a mammography medical outcomes audit program to followup [follow-up] positive mammographic assessments and to correlate pathology results with the IP's [interpreting physician's] findings. The [This] program must [shall] be designed to ensure the reliability, clarity, and accuracy of the interpretation of mammograms.

(1) General requirements.

(A) Each facility must [registrant shall] establish a system to collect and review outcome data for all mammograms performed, including follow-up on the disposition of all positive mammograms and correlation of pathology results with the IP's [interpreting physician's] mammography report.

(B) For cases of breast cancer among patients imaged at the facility that become known to the facility, the facility must initiate a follow-up on surgical and pathology results and a review of the mammographic examinations taken before the diagnosis of a malignancy.

(C) The [Analysis of these] outcome data must [shall] be made individually and collectively for all IPs [interpreting physicians] at the facility and include determinations of the following. [In addition, any cases of breast cancer among women imaged at the facility that subsequently become known to the facility shall prompt the facility to initiate follow-up on surgical and/or pathology results and review of the mammograms taken prior to the diagnosis of a malignancy.]

(i) Positive predictive value. The percent of patients with positive mammograms who are diagnosed with breast cancer within one year of the date of the mammographic examination.

(ii) Cancer detection rate. Of the patients initially examined with screening mammograms who receive an assessment of "Incomplete: Need additional imaging evaluation," "Suspicious," or "Highly Suggestive of Malignancy" on the screening mammogram or on a subsequent diagnostic mammogram, the number of patients who are diagnosed with breast cancer within one year of the date of the initial screening mammogram, expressed as a ratio per 1,000 patients.

(iii) Recall rate. The percentage of screening mammograms given an assessment of "Incomplete: Need additional imaging evaluation."

(2) Frequency of audit analysis. The facility's first audit analysis must begin within [shall be initiated no later than] 12 months of the facility becoming certified, and completed within the following 12 months [after the date the facility becomes certified or 12 months after April 28, 1999, whichever date is the latest. This audit analysis shall be complete within an additional 12 months] to permit completion of diagnostic procedures and data collection.

(A) Subsequent audit analyses will be conducted at least once every 12 months.

(B) The facility must maintain the audit analysis as specified in [These shall be maintained in accordance with] subsection (x)[(ee)] of this section.

(3) Reviewing interpreting physician. Each LIP [lead interpreting physician] or an interpreting physician designated by the LIP must [lead interpreting physician shall] review the medical outcomes audit data at least annually, not to exceed [once every] 12 months following the data collection period. This individual must [shall] analyze the results of the audit and is [shall be] responsible for the following:

(A) recording the dates of the audit period [period(s)];

(B) documenting the results;

(C) notifying other IPs [interpreting physicians] of their results and the facility's collective [registrant's aggregate] results; [and]

(D) documenting any follow up actions and the nature of the follow up; and[.]

(E) recording the audit completion by providing a signature and date on the audit.

(n) [(x)] Mammographic procedure and techniques for mammography of patients with breast implants. Each registrant must [shall] have a procedure to inquire if [whether or not] the patient has breast implants before [prior to] the mammographic exam. Except where contraindicated, or unless modified by a physician's directions, patients with breast implants must [shall] have mammographic views to maximize the visualization of breast tissue.

(o) [(y)] Complaints. Each accredited facility must [shall] do the following:

(1) establish a written procedure for collecting and resolving consumer complaints;

(2) maintain a record of each serious complaint received by the facility as specified in [~~accordance with~~] subsection (x) [~~(ee)~~] of this section; [~~and~~]

(3) provide the consumer with adequate directions for filing serious complaints with the facility's AB if the facility is unable to resolve a serious complaint to the consumer's satisfaction; and

(4) [~~(3)~~] report unresolved serious complaints to the facility's AB [~~FDA-approved accreditation body~~] within 30 days of receiving the complaint.

(p) [~~(z)~~] Clinical image quality. Clinical images produced by any certified facility must continue to comply with the standards for clinical image quality established by the [~~that~~] facility's AB [~~accreditation body~~].

(q) [~~(aa)~~] Additional mammography review, targeted clinical reviews, and patient notification.

(1) If the department [~~agency certifying body~~] believes the [~~that~~] mammography quality at a facility is [~~may have been~~] compromised and presents a serious risk to human health, the facility must [~~shall~~] provide clinical images and other relevant information, as specified by the department [~~agency certifying body~~], for review by the AB [~~FDA-approved accreditation body~~]. The additional mammography review will assist the department with determining:

(A) the facility's compliance with this section; and

(B) if there is a need to notify affected patients, their healthcare provider, or the public that the reliability, clarity, and accuracy of the interpretation of mammograms has been compromised.

(2) If the department [~~agency certifying body~~] determines the [~~that~~] mammography quality at a facility has been compromised and presents a serious risk to human health, the facility must [~~shall~~] provide clinical images and other relevant information, as specified by the department [~~agency certifying body~~], for review by the AB [~~FDA-approved accreditation body~~]. The department [~~agency certifying body~~] may require such facility to notify patients who received mammograms[~~,~~] and their referring healthcare provider [~~physicians~~]. The notification must occur within a time frame and in a manner specified by the department. The notification must: [~~shall include the deficiencies presenting such risk, the potential consequences to the patient, appropriate remedial measures, and such other relevant information as the agency certifying body may require. Such notification shall occur within a time frame and in a manner specified by the agency.~~]

(A) inform the patient the mammography system failed to satisfy the department and AB's standards;

(B) recommend the patient consult with the patient's healthcare provider regarding the need for another mammogram;

(C) list three non-affiliated facilities closest to the original testing facility that have a certified mammography system; and

(D) include the deficiencies presenting such risk, the potential consequences to the patient, appropriate remedial measures, and other relevant information required by the department.

(3) If the facility is unable or unwilling to perform such notification, the department may notify patients and their referring physicians or other healthcare providers individually or through the mass media.

(4) [~~(3)~~] The department, the AB [~~agency certifying body, the agency accreditation body or another FDA-approved accreditation body~~], or the FDA may request a targeted clinical image review [~~due to, but not limited to, serious complaints or severe items of non-compliance~~].

(r) [~~(bb)~~] Self-referral mammography. Any person proposing to conduct a self-referral mammography program must [~~shall~~] not initiate such a program without prior approval from [~~of~~] the department [~~agency~~]. When requesting such approval, the [~~that~~] person must [~~shall~~] submit the following information:

(1) the number and type of views (or projections);

(2) the age of the population to be examined and the frequency of the exam following established, nationally recognized criteria, such as those of the American Cancer Society, American College of Radiology (ACR), or the National Council on Radiation Protection and Measurements;

(3) written procedures to include methods of:

(A) advising a patient [~~patients~~] and healthcare provider [~~private physicians~~] of the results of the mammography examination as specified in [~~accordance with~~] subsection (j)(4) [~~(t)(2)~~] of this section;

(B) follow-up with patients and healthcare provider as specified [~~physicians~~] in [~~accordance with~~] subsection (j)(6) [~~(t)(3)~~] of this section; and

(C) recommending a healthcare provider to patients who do not have a healthcare provider when clinically indicated, to include when a patient's mammogram assessment is probably benign, suspicious, or highly suggestive of malignancy [~~physician means of selecting a physician~~]; and

(4) methods for educating mammography patients in breast self-examination techniques and on the necessity for follow-up by a physician.

(s) [~~(cc)~~] Medical research and investigational devices.

(1) Any research using radiation producing devices on humans must be approved by an IRB as required by [~~Title~~] 45[~~,~~] CFR[~~,~~] Part 46 and [~~Title~~] 21[~~,~~] CFR[~~,~~] Part 56. The IRB must include at least one licensed physician to direct any use of radiation as specified in [~~accordance with~~] §289.231(b) of this subchapter [~~title~~].

(2) Facilities with mammography machines with investigational device exemptions [~~that are~~] involved in clinical studies must comply with primary regulations governing [~~that govern~~] the conduct of clinical studies and that apply to the manufacturers, sponsors, clinical investigators, institutional review boards, and the medical device. These regulations include [~~the following~~]:

[~~(A) 21 CFR, Part 812, Investigational Device Exemptions;~~]

(A) [~~(B)~~] 21 CFR[~~,~~] Part 50, Protection of Human Subjects;

[~~(C) 21 CFR, Part 56, Institutional Review Boards;~~]

(B) [~~(D)~~] 21 CFR[~~,~~] Part 54, Financial Disclosure by Clinical Investigators;

(C) 21 CFR Part 56, Institutional Review Boards;

(D) 21 CFR Part 812, Investigational Device Exemptions; and

(E) 21 CFR[~~,~~] Part 820 [~~821~~], Subpart C, Design Controls [~~of the Quality System Regulation~~].

(t) [~~(dd)~~] Operating and safety [~~Other operating~~] procedures (OSP).

(1) Each facility must implement and maintain written OSP [~~Operating and safety procedures. Each registrant shall have and implement written operating and safety procedures that shall be made available to each individual operating x-ray equipment, including any restrictions of the operating technique required for the safe operation of the particular system. These procedures shall include, but are not limited to, the items in subsection (hh)(3) of this section~~].

(2) The OSP must be available to each individual operating x-ray equipment, including any restrictions of the operating technique required for the safe operation of the particular system.

(3) The facility's OSP must address the following requirements, as applicable:

(A) §289.203(b) of this chapter, related to posting notices to workers;

(B) §289.203(c) of this chapter, related to instructions to workers;

(C) §289.203(d) of this chapter, related to notifications and reports to individuals;

(D) §289.231(b) of this subchapter, related to ordering x-ray examinations;

(E) §289.231(m) of this subchapter, related to occupational dose requirements;

(F) §289.231(n) and (q) of this subchapter, related to personnel monitoring requirements;

(G) §289.231(x) and (y) of this subchapter, related to posting of a radiation area;

(H) subsection (h) of this section, related to credentialing requirements for LIPs, IPs, MRTs, and medical physicists;

(I) subsection (j)(7) of this section, related to retention of clinical images;

(J) subsections (k) - (m) of this section, related to quality assurance program;

(K) subsection (k)(1)(B)(i) of this section, related to image quality and corrective action for images of poor quality;

(L) subsection (l)(1) - (3) of this section, related to repeat analysis;

(M) subsection (n) of this section, related to procedures and techniques for mammography patients with breast implants;

(N) subsection (o) of this section, related to the procedure to handle complaints;

(O) subsection (r) of this section, related to self-referral mammography;

(P) subsection (u)(2) of this section, related to the use of a technique chart;

(Q) subsection (u)(5) of this section, related to exposure of individuals other than the patient;

(R) subsection (u)(6) of this section, related to use of protective devices; and

(S) subsection (u)(7) of this section, related to holding of patients or image receptors.

(u) Other operating procedures.

(1) Phantom image scoring protocol must be performed as specified in (l)(1) - (3) of this section.

(2) Technique chart. A technique chart or manual must [~~shall~~] be provided and followed. It must be [~~or electronically~~] displayed in the vicinity of the control panel of each machine that specifies technique factors used for a [~~to be utilized versus~~] patient's anatomical size. [~~The technique chart shall be used by all operators.~~]

(3) Receipt, transfer, and disposal of mammography machines. Each registrant must [~~shall~~] maintain records showing the receipt, transfer, and disposal of mammographic machines. These records must [~~shall~~] include the date of receipt, transfer, and [~~or~~] disposal; the name and signature of the person [~~individual~~] making the record; and the manufacturer's model name and serial number from the control panel of the mammographic machine. Records must [~~shall~~] be maintained as specified in [~~accordance with~~] subsection (x)[~~(ee)~~] of this section for inspection by the department [~~agency~~].

(4) Viewing system. Windows, mirrors, closed circuit television, or an equivalent system must [~~shall~~] be provided to permit the operator to continuously observe the patient during irradiation. The operator must [~~shall~~] be able to maintain verbal, visual, and aural contact with the patient.

(5) Exposure of an individual [~~individuals~~] other than the patient. Only the staff and ancillary personnel required for the medical procedure or training may [~~shall~~] be in the room during the radiation exposure unless such individual's assistance is required.

(6) Protective devices. Protective devices must [~~shall~~] be utilized when required, as in paragraph (7) of this subsection.

(A) Protective devices must [~~shall~~] be of no less than 0.25 millimeter (mm) lead equivalent material.

(B) Protective devices, including aprons, gloves, and shields must [~~shall~~] be checked annually for defects such as holes, cracks, and tears. These checks may be performed by the registrant by visual or tactile means, or x-ray imaging. If a defect is found, protective devices must [~~shall~~] be replaced or removed from service until repaired. A record of this test must [~~shall~~] be made and maintained by the registrant as specified in [~~accordance with~~] subsection (x) [~~(ee)~~] of this section for inspection by the department [~~agency~~].

(7) Holding of patient or image receptor.

(A) When a patient or image receptor must be held in position during radiography, mechanical supporting or restraining devices must [~~shall~~] be used when the exam permits.

(B) If a patient or image receptor must be held by an individual during an exposure, the [~~that~~] individual must [~~shall~~] be protected with appropriate shielding devices described in paragraph (6) of this subsection.

(C) The facility's [~~registrant's~~] written OSP specified in subsection (t) [~~operating and safety procedures required by paragraph (1)~~] of this section must [~~subsection shall~~] include the following:

(i) a list of circumstances in which mechanical holding devices cannot be routinely utilized; and

(ii) a procedure used for selecting an individual to hold or support the patient or image receptor.

(D) In those cases where the patient must hold the image receptor, any portion of the body other than the area of clinical interest struck by the useful beam must [~~shall~~] be protected by not less than 0.25 mm lead equivalent material.

(8) Calibration, maintenance, and modifications. Each registrant must [~~shall~~] maintain records showing calibrations, maintenance, and modifications performed on each mammographic machine.

These records must [shall] include the date of the calibration, maintenance, or modification performed; the name of the individual making the record; and the manufacture's model name and serial number of the control panel of the mammographic machine. These records must [shall] be maintained as specified in [accordance with] subsection (x) [(ee)] of this section.

[(ee) Record requirements. Records required by this section shall be maintained for inspection by the agency in accordance with paragraph (3) of this subsection. Records may be maintained electronically in accordance with §289.231(ff)(3) of this title.]

[(1) Records for mammography machines authorized for mobile service operations.]

[(A) Copies of the following shall be kept with mammography machines authorized for mobile services:]

[(i) operating and safety procedures in accordance with subsection (dd)(1) of this section;]

[(ii) medical radiologic technologists' credentials;]

[(iii) current quality control records for at least the last 90 calendar days for on-board processors in accordance with subsection (v)(1) of this section;]

[(iv) current §289.203 of this title, §289.226 of this title, §289.230 of this title, §289.231 of this title, and §289.234 of this title if accredited by the agency accreditation body;]

[(v) copy of certification;]

[(vi) certification of inspection in accordance with subsection (ff)(5) of this section;]

[(vii) notice of failure from last inspection in accordance with subsection (ff)(6) of this section, if applicable; and]

[(viii) copy of mammography accreditation.]

[(B) Copies of all other records required by this section shall be maintained at a specified location.]

[(2) Records required at separate authorized use locations. Copies of the following shall be kept at each separate authorized use location:]

[(A) credentials for interpreting physicians operating at that location in accordance with subsection (r)(1) of this section;]

[(B) credentials for medical radiologic technologists operating at that location in accordance with subsection (r)(2) of this section;]

[(C) credentials for medical physicists operating at that location in accordance with subsection (r)(3) of this section;]

[(D) continuing education and experience records for interpreting physicians, medical radiologic technologists, and medical physicists operating at that location in accordance with subsection (r)(1)(C), (2)(C), and (3)(C) of this section;]

[(E) mandatory training records for interpreting physicians and medical physicists operating at that location in accordance with subsection (r)(1)(E) and (2)(E) of this section, if applicable;]

[(F) current physicist annual survey of the mammography system;]

[(G) current §289.203 of this title, §289.226 of this title, §289.230 of this title, §289.231 of this title, and §289.234 of this title if accredited by the agency accreditation body;]

[(H) copy of certification;]

[(I) quality assurance program in accordance with subsections (u), (v), and (w) of this section;]

[(J) quality control records in accordance with subsection (u)(2) of this section;]

[(K) operating and safety procedures in accordance with subsection (dd)(1) of this section;]

[(L) records of receipts, transfers, and disposal in accordance with subsection (dd)(3) of this section;]

[(M) calibration, maintenance, and modification records in accordance with subsection (dd)(8) of this section;]

[(N) certification of inspection in accordance with subsection (ff)(5) of this section;]

[(O) notification of failure in accordance with subsection (ff)(6), if applicable;]

[(P) records of notification of patients in accordance with subsection (ff)(10) this section; and]

[(Q) copy of mammography accreditation.]

[(3) Time requirements for record keeping. Time requirements for record keeping shall be according to the following chart.] [Figure: 25 TAC §289.230(ee)(3)]

(v) [(ff)] Inspections. In addition to the requirements of §289.231(kk) of this subchapter [title], the following applies to inspections of mammography systems.

(1) The department [agency] may inspect each mammography system that receives a certification as specified in [accordance with] this chapter no [not] later than the 60th day after the date the certification is issued.

(2) The department [agency] may inspect, at least once annually, each mammography system that receives a certification.

(3) To protect the public health, the department [agency] may conduct more frequent inspections than required by this subsection.

(4) The department [agency] may make reasonable attempts to coordinate inspections in this section with other inspections required as specified in [accordance with] this chapter for the facility where the mammography system is used.

(5) After each satisfactory inspection, the department issues [agency shall issue] a certificate of inspection for each mammography system inspected. The certificate of inspection must [shall] be posted at a conspicuous place on or near the place where the mammography system is used. The certificate of inspection includes [may include] the [following]:

(A) specific identification of the mammography system inspected;

(B) [the] name and address of the facility where the mammography system was used at the time of the inspection; and

(C) [the] date of the inspection.

(6) Any severity level I violation involving a mammography system, determined [found] by the department [agency], as specified in [accordance with] §289.205 of this chapter [title], constitutes grounds for posting notice of failure of the mammography system to satisfy department [agency] requirements.

(A) Notification of such failure must [shall] be posted:

(i) on the mammography machine at a conspicuous place if the violation is machine-related; or

(ii) near the place where the mammography system practices if the violation is personnel-related; and

(iii) in a sufficient number of places to permit the patient to observe the notice.

(B) The notice of failure must [~~shall~~] remain posted until the facility is authorized to remove it by the department [~~agency~~]. A facility may post documentation of corrections of the violations submitted to the department [~~agency~~] along with the notice of failure until approval to remove the notice of failure is received from the department [~~agency~~].

(7) Facilities that receive a severity level I violation and are deemed a serious risk to human health must [~~shall~~] notify patients as specified in (q)(2) of this section. [~~on whom the facility performed a mammogram during the period in which the system failed to meet the agency's certification standards. The facility shall:~~]

[~~(A) inform the patient that the mammography system failed to satisfy the agency certifying body's standards;~~]

[~~(B) recommend that the patient consult with the patient's physician regarding the need for another mammogram; and~~]

[~~(C) list the three facilities closest to the original testing facility that have a certified mammography system.~~]

(8) In addition to the requirements of paragraph (7) of this subsection, the department [~~agency~~] may require a facility to notify a patient of any other failure of the facility's mammography system to meet the department's [~~agency's~~] certification standards.

(9) The patient notification must [~~shall~~] include the following:

(A) an explanation of the mammography system failure to the patient; and

(B) the potential consequences to the mammography patient.

(10) The facility must [~~registrant shall~~] make a record of the mammography patients notified as specified in [~~accordance with~~] paragraphs (7) and (8) of this subsection for inspection by the department [~~agency~~].

(A) The record must [~~records shall~~] include the name and address of each mammography patient notified, date of notification, and a copy of the text sent to the individual.

(B) The record must [~~records shall~~] be maintained as specified in [~~accordance with~~] subsection (x) [~~(ee)~~] of this section.

(w) [~~(gg)~~] Requirements for interventional breast radiography machines.

[~~(1) Prohibitions.~~]

[~~(A) The agency may prohibit use of interventional breast radiography machines that pose a significant threat or endanger public health and safety, in accordance with §289.231 and §289.205 of this title.~~]

[~~(B) Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed physician. The provision specifically prohibits intentional exposure of an individual for training, demonstration, or other non-healing arts purposes.~~]

[~~(2) Exemptions.~~]

[~~(A) Machines used exclusively for interventional breast radiography are not required to be accredited by an FDA-approved accreditation body.~~]

[~~(B) Loaner machines as described in subsection (n)(6) of this section are exempt for the inspection requirements in subsection (ff) of this section.~~]

[~~(C) All interventional breast radiography registrants are exempt from the posting of radiation area requirements of §289.231(x) of this title provided that the operator has continuous surveillance and access control of the radiation area.~~]

(1) [~~(3)~~] Interventional [~~Requirements for interventional~~] breast radiography machine certificate of registration (COR) [~~certification~~].

(A) A person who receives, possesses, uses, owns, or acquires [~~Each person having~~] an interventional breast radiography machine must apply for a certificate of registration as specified [~~shall submit an application~~] in [~~accordance with~~] §289.226(e) [~~(1) - (3), (5), and (7)~~] of this subchapter, relating to general requirements for application and registration [~~title~~], and must [~~shall~~] receive a COR [~~certification~~] from the department before using an interventional breast radiography machine on humans [~~agency within 30 days of beginning use~~].

(B) An application for a COR must [~~certification shall~~] be signed by:

(i) a licensed physician, and

(ii) the RSO [~~applicant and the RSO~~].

(C) An application for a COR [~~certification~~] may contain information on multiple interventional breast radiography machines. Each machine must be identified by referring to the machine's manufacturer, model name, and serial number located on the control panel.

(D) Each applicant must [~~shall~~] submit documentation of [~~evidence that~~] a [~~medical physicist's~~] survey [~~has been~~] performed by a medical physicist, as specified in [~~accordance with~~] paragraph (11)[~~(13)~~] of this subsection.

(2) [~~(4)~~] Issuance of a certificate of registration [~~certification~~].

(A) [~~Certification.~~] A COR [~~certification~~] for interventional breast radiography machines will be issued if the department [~~agency~~] determines the [~~that an~~] application meets the requirements of the Act and [~~the requirements of~~] this chapter. The COR [~~certification~~] authorizes the proposed operations and includes [~~activity in such form and contains such~~] conditions and limitations [~~as~~] the department [~~agency~~] deems [~~appropriate or~~] necessary.

(B) Conditions [~~Requirements and conditions~~]. The department [~~agency~~] may incorporate in the COR [~~certification~~] at the time of issuance, or [~~thereafter~~] by amendment, [~~such~~] additional requirements and conditions for [~~with respect to~~] the facility's [~~registrant's~~] possession, use, and transfer of radiation machines [~~subject to this chapter as it deems appropriate or~~] necessary [~~in order~~] to:

(i) minimize danger to occupational and public health and safety;

(ii) require additional reports and maintain [~~the keeping of~~] additional records as [~~may be appropriate or~~] necessary; and

(iii) prevent loss or theft of radiation machines subject to this section.

(C) Additional information. The department [agency] may request[, and the registrant shall provide,] additional information after the certification has been issued to enable the department [agency] to determine whether the certification should be modified as specified in [accordance with] §289.226(r) of this subchapter relating to renewal of a certificate of registration [title].

(3) [(5)] Modification, suspension, or revocation of the certificate of registration [certification]. Modification, suspension, or revocation of the COR must occur as specified [certification shall be] in [accordance with] §289.226(s) [(r)] of this subchapter [title].

(4) [(6)] Specific terms and conditions of the certificate of registration [certification]. Specific terms and conditions of the COR, as specified [certification shall be] in [accordance with] §289.226[(l)] of this subchapter, must be followed [title].

(5) Renewal of certification. The registrant must file an application for renewal of the COR as follows.

(A) A person who receives, possesses, uses, owns, or acquires an interventional breast radiography machine must apply for renewal as specified in §289.226(e)(1) - (3), (5), and (7) of this subchapter.

(B) An application for renewal must be signed by a licensed physician and the RSO.

(C) An application for renewal must include a medical physicist's survey as specified in paragraph (11) of this subsection.

(D) If a registrant files an application for renewal in proper form at least 30 days before the existing certification expires, the existing certification does not expire until the application status has been determined by the department.

(6) Expiration of the certificate of registration.

(A) COR of an interventional breast radiography machine expires at the end of the day in the month and year stated on the certificate. Expiration of the COR does not relieve the registrant of the requirements of this chapter.

(B) If a registrant does not apply for renewal of the certification under paragraph (8) of this subsection, as applicable, the registrant must:

(i) terminate use of all interventional breast radiography machines;

(ii) pay any outstanding fees as specified in §289.204 of this chapter; and

(iii) submit a record of the disposition of the interventional breast radiography machine to the department. If the machine was transferred, include to whom it was transferred.

(7) Termination of certification. When a registrant decides to terminate all activities involving an interventional breast radiography machine authorized under the COR, the registrant must notify the department immediately and:

(A) request termination of the COR in writing signed by the RSO, owner, or a person authorized to act on behalf of the registrant;

(B) pay any outstanding fees as specified in §289.204 of this chapter; and

(C) submit a record of the disposition of the interventional breast radiography machine to the department. If the machine was transferred, include to whom it was transferred.

(8) [(7)] Responsibilities of registrant.

[(A) The registrant shall comply with the following:]

[(i) purpose and scope in accordance with subsections (a) and (b) of this section; and]

[(ii) applicable definitions in subsection (c) of this section.]

(A) [(B)] In addition to the requirements of §289.226(m)(3) - (7) of this subchapter [title], a facility must [registrant shall] notify the department [agency] in writing before [prior to] any changes rendering [that would render] the information [contained] in the application or the COR [certification] inaccurate, including the[. These include but are not limited to the following]:

(i) name and mailing address;

(ii) street address where the interventional breast radiography machine [machine(s)] will be used; and

(iii) addition or removal of any interventional breast radiography machine [machine(s)].

(B) [(C)] If a facility makes a change in the RSO, the qualifications of the RSO must [shall] be submitted to the department [agency] within 30 days of such change.

(C) [(D)] A facility with an existing certification may begin using a new or replacement interventional breast radiography machine before receiving an updated certification if the registrant submits to the department the required [agency (required/prescribed)] documentation with a medical physicist's report as specified in [accordance with] paragraph (11) [(13)] of this subsection, verifying compliance of the new interventional breast radiography machine with this section. The medical physicist's report is required before [prior to] using the interventional breast radiography machine on patients.

(D) [(E)] Loaner interventional breast radiography machines may be used on patients for 60 days without adding the interventional breast radiography machine to the COR [certification]. A medical physicist's report verifying compliance of the loaner interventional breast radiography machine with this section must [shall] be completed before [prior to] use on patients. If the use period exceeds [will exceed] 60 days, the facility must [shall] add the interventional breast radiography machine to its certification and a fee will be assessed.

[(8) Renewal of certification. The registrant shall file an application for renewal of certification as follows.]

[(A) Each person having an interventional breast radiography machine shall submit an application for renewal in accordance with §289.226(e)(1) - (3), (5), and (7) of this title.]

[(B) An application for renewal shall be signed by the RSO, licensed physician, and the applicant.]

[(C) An applicant for renewal shall submit a medical physicist's survey in accordance with paragraph (13) of this subsection.]

[(D) If a registrant files an application for renewal in proper form at least 30 days before the existing certification expires, such existing certification shall not expire until the application status has been determined by the agency.]

[(9) Expiration of certification.]

[(A) Each certification of interventional breast radiography machine expires at the end of the day in the month and year stated on the certificate. Expiration of the certification does not relieve the registrant of the requirements of this chapter.]

[(B) If a registrant does not submit an application for renewal of the certification under paragraph (8) of this subsection, as applicable, the registrant shall on or before the expiration date specified in the certification:]

[(i) terminate use of all interventional breast radiography machines;]

[(ii) pay any outstanding fees in accordance with §289.204 of this title; and]

[(iii) submit a record of the disposition of the interventional breast radiography machine(s) to the agency. If the machine(s) was transferred, include to whom it was transferred.]

[(10) Termination of certification. When a registrant decides to terminate all activities involving interventional breast radiography machine(s) authorized under the certification, the registrant shall notify the agency immediately and do the following:]

[(A) request termination of the certification in writing signed by the RSO, owner, or an individual authorized to act on behalf of the registrant;]

[(B) pay any outstanding fees in accordance with §289.204 of this title; and]

[(C) submit a record of the disposition of the interventional breast radiography machine(s) to the agency certifying body. If the machine(s) was transferred, include to whom it was transferred.]

(9) [(11)] Personnel requirements.

(A) An operator must maintain [A medical radiologic technologist (operators of equipment) shall hold] a current general certificate as required by [in accordance with] the Medical Radiologic Technologist Certification Act, Texas Occupations Code[,] Chapter 601.

(B) A medical physicist must maintain [shall hold] a current Texas license as required by [under] the Medical Physics Practice Act, Texas Occupations Code[,] Chapter 602, in diagnostic radiological physics and be registered with the department [agency] or employed by an entity registered with the department [agency], as specified in [accordance with] §289.226(j) of this subchapter, relating to application for registration or radiation machine services, [title] and the Act, unless exempted by §289.226(d)(7)[(6)] of this subchapter, relating to exemptions [title].

(10) [(12)] Requirements to have a written quality assurance program. Requirements to have a written QA [quality assurance] program as described by the manufacturer or [and/or] the medical physicist to ensure the safety, reliability, clarity, and accuracy of services performed at the facility must [shall] comply with the following.

(A) If any failures are noted, corrective actions must [shall] be taken within the time frame established [indicated/established] by the manufacturer or medical physicist. If a time frame is not [In the event, that no time frames are] indicated, corrective action must [shall] be completed within 30 days of the failure.

(B) If any component tested fails the dosimetry test, the corrective action must [will] be taken before any further interventional breast radiography examinations are performed.

(11) [(13)] Interventional breast radiography machine evaluations and annual survey.

(A) Interventional breast radiography machines are required to have a medical physicist perform a survey:

(i) whenever a new interventional breast radiography machine is installed, or disassembled[,] and reassembled, at the same or a new location;

(ii) whenever major components of an interventional breast radiography machine are changed or repaired; and

(iii) annually or at intervals not to exceed 14 months from the date of the previous survey [on an annual basis].

(B) Annual survey. Annual surveys for interventional mammography machines must be conducted as specified, or substantially the same as specified, in the machine's QA program recommended by the manufacturer [The following quality assurance tests shall be performed: AEC, kVp, focal spot condition, HVL, collimation, alignments, and dosimetry tests in accordance with subsection (v)(5)(A) - (G) of this section].

(C) The medical physicist must [shall] provide the facility with a preliminary [oral or] written report of deficiencies within 72 hours of the survey if it involves dosimetry.

(D) The medical physicist must [shall] prepare a written report for the facility within 30 days of the date of the survey. The survey report must include a summary of the tests performed, all test conditions, specifications, results, and recommendations for corrective actions and [to include the following]:

(i) date, name, and signature of the medical physicist performing or supervising the survey; [a written survey report that includes a summary of the tests performed, all test conditions, specifications, results, and recommendations for corrective actions; and]

(ii) name and signature of each individual under the direct supervision of the medical physicist performing any part of the survey, as applicable; [date and signature of the medical physicist performing or supervising the survey. If the survey was performed entirely or in part by another individual under the direct supervision of the medical physicist, that individual and the part of the survey that individual performed shall also be identified in the survey.]

(iii) name of the facility;

(iv) address of facility;

(v) registration number of the facility;

(vi) make, model, and serial number from the machine control panel;

(vii) registration number of physicist and service company performing the survey;

(viii) service provider email address;

(ix) mailing or business address of the service provider performing the survey; and

(x) date of the last calibration of testing equipment.

(12) [(14)] Operating and safety procedures (OSP). Each facility must [registrant shall] have and implement written OSP [operating and safety procedures] that must [shall] be made available to each individual operating the x-ray equipment, including any restrictions of the operating technique required for the safe operation of the particular system. These procedures must address the following requirements [shall include, but are not limited to]:

(A) [posting notices to workers in accordance with] §289.203(b) of this chapter, related to posting notices to workers [title];

(B) [~~instructions to workers in accordance with~~] §289.203(c) of this chapter, related to instruction to workers [~~title~~];

(C) §289.203(d) of this chapter, related to notifications and reports to individuals [~~in accordance with §289.203(d) of this title~~];

(D) [~~ordering x-ray exams in accordance with~~] §289.231(b) of this subchapter, related to ordering x-ray examinations [~~title~~];

(E) §289.231(m) of this subchapter, related to occupational dose requirements [~~in accordance with §289.231(m) of this title~~];

(F) [~~personnel monitoring requirements in accordance with~~] §289.231(n) and (q) of this subchapter, related to personnel monitoring requirements [~~title~~];

(G) paragraph (9) of this subsection, related to credentialing requirements for operators [~~medical radiologic technologists,~~] and medical physicists [~~in accordance with paragraph (11) of this subsection~~];

(H) [~~use of a technique chart in accordance with~~] paragraph (19) [~~(22)~~] of this subsection, related to use of a technique chart;

(I) paragraph (16) of this subsection, related to exposure of individuals other than the patient [~~in accordance with paragraph (18) of this subsection~~]; and

(J) subsection (u)(7) of this section, related to holding of patients or image receptors [~~in accordance with subsection (dd)(7) of this section~~].

(13) [~~(15)~~] Receipt, transfer, and disposal of interventional breast radiography machines. Each facility must [~~registrant shall~~] maintain records showing the receipt, transfer, and disposal of interventional breast radiography machines. These records must be maintained in subsection (x) of this section for inspection by the department and [~~shall~~] include the:

(A) date of receipt, transfer, or disposal;

(B) [~~the~~] name and signature of the individual making the record; and

(C) [~~the~~] manufacturer's model name and serial number on the control panel. [~~These records shall be maintained in accordance with subsection (ee) of this section for inspection by the agency.~~]

(14) [~~(16)~~] Calibration, maintenance, and modifications. Each facility must [~~registrant shall~~] maintain records showing calibrations, maintenance, and modifications performed on each interventional breast radiography machine. These records must be maintained as specified in subsection (x) of this section for inspection by the department and [~~shall~~] include the:

(A) date of the calibration, maintenance, or modification performed;

(B) [~~the~~] name of the individual making the record; and

(C) [~~the~~] manufacturer's model name and serial number on the control panel. [~~These records shall be maintained in accordance with subsection (ee) of this section for inspection by the agency.~~]

(15) [~~(17)~~] Viewing system. Windows, mirrors, closed circuit television, or an equivalent system must [~~shall~~] be provided to permit the operator to continuously observe the patient during irradiation. The operator must [~~shall be able to~~] maintain verbal, visual, and aural contact with the patient.

(16) [~~(18)~~] Exposure of individuals other than the patient. Only the staff and ancillary personnel required for the medical procedure or training are allowed [~~shall be~~] in the room during the radiation exposure unless such individual's assistance is required.

~~[(19) Maintenance of records. Maintenance of applicable records in subsection (ee) of this section.]~~

(17) [~~(20)~~] Inspection requirements. Inspections of interventional breast radiography machines are specified [~~Inspection requirements~~] in [~~accordance with~~] subsection (v)(2) - (4) [~~(ff)(2) - (4)~~] of this section.

(18) [~~(21)~~] Equipment requirements. Interventional breast radiography machines must meet the equipment [~~Equipment~~] requirements specified in [~~accordance with~~] §289.227(h) of this subchapter, [~~title (~~] relating to certified x-ray systems [~~Use of Radiation Machines in the Healing Arts)~~].

(19) [~~(22)~~] Technique chart. A chart or manual must [~~shall~~] be provided or electronically displayed in the vicinity of the control panel of each interventional breast radiography machine that specifies technique factors used for a [~~to be utilized versus~~] patient's anatomical size. The technique chart must [~~shall~~] be used by all operators.

(x) Record requirements. Records specified in this section must be maintained for inspection by the department as specified in paragraph (3) of this subsection. Records may be maintained electronically as specified in §289.231(ff)(3) of this subchapter.

(1) Records for mammography machines authorized for mobile service operations.

(A) Copies of the following must be kept with mammography machines authorized for mobile services:

(i) OSP as specified in subsection (t)(1) of this section;

(ii) operator's credentials;

(iii) current quality control records for at least the last 90 calendar days for on-board processors as specified in subsection (l)(1) of this section;

(iv) current copies of §289.203, §289.226, §289.230, and §289.231 of this chapter;

(v) copy of certification;

(vi) certification of inspection as specified in subsection (v)(5) of this section;

(vii) notice of failure from last inspection as specified in subsection (v)(6) of this section, if applicable; and

(viii) copy of mammography accreditation.

(B) Copies of all other records specified in this section must be maintained at a specified location.

(2) Records required at separate authorized use locations. Copies of the following must be kept at each separate authorized use location:

(A) credentialing, continuing education, and continuing experience records for IPs, MRTs, and medical physicists operating at the location specified in subsection (h) of this section;

(B) mandatory training records for IPs and medical physicists operating at the location specified in subsection (h) of this section, if applicable;

(C) current physicist annual survey of the mammography system;

(D) current copies of §289.203, §289.226, §289.230, and §289.231 of this chapter;

(E) copy of certification;

(F) QA program as specified in subsections (k), (l), and (m) of this section;

(G) quality control records as specified in subsection (k)(2) of this section;

(H) OSP as specified in subsection (t)(1) of this section;

(I) records of receipts, transfers, and disposal as specified in subsection (u)(3) of this section;

(J) calibration, maintenance, and modification records as specified in subsection (t)(8) of this section;

(K) certification of inspection as specified in subsection (v)(5) of this section;

(L) notification of failure as specified in subsection (v)(6), if applicable;

(M) records of notification of patients as specified in subsection (v)(10) this section; and

(N) copy of mammography accreditation.

(3) Retention requirements for record keeping. Time requirements for record keeping must be according to the following chart. Figure: 25 TAC §289.230(x)(3)

[(hh) Appendices.]

[(1) Subjects to be included in mammography training for medical radiologic technologists shall include, but not be limited to, the following:]

[(A) breast anatomy and physiology;]

[(B) positioning and compression;]

[(C) quality assurance/quality control techniques;]

[(D) imaging of patients with breast implants; and]

[(E) at least eight hours of training in each mammography modality to be used by the technologist in performing mammography exams.]

[(2) Subjects to be included in mammography training for interpreting physicians shall include, but not be limited to, the following:]

[(A) radiation physics, including radiation physics specific to mammography;]

[(B) radiation effects;]

[(C) radiation protection; and]

[(D) interpretation of mammograms. This shall be under the direct supervision of a physician who meets the requirements of subsection (r)(1) of this section.]

[(3) Operating and safety procedures. The registrant's operating and safety procedures shall include, but are not limited to, the following procedures as applicable:]

[(A) posting notices to workers in accordance with §289.203(b) of this title;]

[(B) instructions to workers in accordance with §289.203(c) of this title;]

[(C) notifications and reports to individuals in accordance with §289.203(d) of this title;]

[(D) ordering x-ray exams in accordance with §289.231(b) of this title;]

[(E) occupational dose requirements in accordance with §289.231(m) of this title;]

[(F) personnel monitoring requirements in accordance with §289.231(n) and (q) of this title;]

[(G) posting of a radiation area in accordance with §289.231(x) and (y) of this title;]

[(H) credentialing requirements for lead interpreting physicians, interpreting physicians, medical radiologic technologists, and medical physicists in accordance with subsection (r) of this section;]

[(I) retention of clinical images in accordance with subsection (t)(4) of this section;]

[(J) quality assurance program in accordance with subsections (u) - (w) of this section;]

[(K) image quality and corrective action for images of poor quality in accordance with subsection (u)(1)(B)(i) of this section;]

[(L) repeat analysis in accordance with subsection (v)(3)(B) of this section;]

[(M) procedures and techniques for mammography patients with breast implants in accordance with subsection (x) of this section;]

[(N) procedure to handle complaints in accordance with subsection (y) of this section;]

[(O) self-referral mammography in accordance with subsection (bb) of this section;]

[(P) use of a technique chart in accordance with subsection (dd)(2) of this section;]

[(Q) exposure of individuals other than the patient in accordance with subsection (dd)(5) of this section;]

[(R) use of protective devices in accordance with subsection (dd)(6) of this section; and]

[(S) holding of patients or image receptors in accordance with subsection (dd)(7) of this section.]

[(4) Phantom image scoring protocol for film-screen modality. Each of the following object groups are to be scored separately. In order to receive a passing score on the phantom image, all three test object groups must pass. A failure in any one of the areas results in a phantom failure.]

[(A) Fibers. A score of 4.0 for fibers is required to meet the evaluation criteria. The diameter size of fibers are 1.56 mm, 1.12 mm, 0.89 mm, 0.75 mm, 0.54 mm, and 0.40 mm. Score the fibers as follows.]

[(i) Begin with the largest fiber and move down in size, adding one point for each full fiber until a score of zero or one half is given. Stop counting at the first point where you lose visibility of objects.]

[(ii) If the entire length of the fiber can be seen and its location and orientation are correct, that fiber receives a score of one.]

[(iii) ~~If at least half, but not all, of the fiber can be seen and its location and orientation are correct, that fiber receives a score of one half.~~]

[(iv) ~~If less than one half of a fiber can be seen or if the location or orientation are incorrect, that fiber receives a score of zero.~~]

[(v) ~~After determining the last fiber to be counted, look at the overall background for artifacts. If there are background objects that are fiber-like in appearance and are of equal or greater brightness than the last visible half or full fiber counted, subtract the last half or full fiber scored.~~]

[~~(B) Speck groups. A score of 3.0 for speck groups is required to meet the evaluation criteria. Diameter sizes of speck groups are 0.54 mm, 0.40 mm, 0.32 mm, 0.24 mm, and 0.16 mm. There are six specks per group. Score the speck groups as follows.~~]

[(i) ~~Begin with the largest speck group and move down in size adding one point for each full speck group until a score of one half or zero is given, then stop.~~]

[(ii) ~~If at least four of the specks in any group are visualized, the speck group is scored as one.~~]

[(iii) ~~If two or three specks in a group are visualized, the score for the group is one half.~~]

[(iv) ~~If one speck or no specks from a group are visualized, the score is zero.~~]

[(v) ~~After determining the last speck group to receive a full or one-half point, look at the overall background for artifacts. If there are speck-like artifacts within the insert region of the phantom that are of equal or greater brightness than individual specks counted in the last visible half or full speck group counted, subtract the artifact speck from the observed specks in the last group scored, one by one. Note that the highest number of speck-like artifacts that can potentially be subtracted is the number of visible specks that were scored in the last group. Repeat the scoring of the last visible speck group after these deductions.~~]

[~~(C) Masses. A score of 3.0 is required to meet the evaluation criteria. Diameter sizes of masses are 2.00 mm, 1.00 mm, 0.75 mm, 0.50 mm, and 0.25 mm. Score the masses as follows.~~]

[(i) ~~Begin with the largest mass and add one point for each full mass observed until a score of one half or zero is assigned.~~]

[(ii) ~~Score one for each mass that appears as a minus density object in the correct location that can be seen clearly enough to observe round, circumscribed borders.~~]

[(iii) ~~Score one half if the mass is clearly present in the correct location, but the borders are not visualized as circular.~~]

[(iv) ~~After determining the last full or half mass to be counted, look at the overall background for artifacts. If there are background objects that are mass-like in appearance and are of equal or greater visibility than the last visible mass, subtract the last full or half point assigned from the original score.~~]

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

Filed with the Office of the Secretary of State on February 5, 2025.

TRD-202500401
Cynthia Hernandez
General Counsel
Department of State Health Services
Earliest possible date of adoption: April 6, 2025
For further information, please call: (512) 834-6655

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25 TAC §289.234

STATUTORY AUTHORITY

The repeal is authorized by Texas Health and Safety Code Chapter 401 (the Texas Radiation Control Act), which provides for DSHS radiation control rules and regulatory program to be compatible with federal standards and regulations; §401.051, which provides the required authority to adopt rules and guidelines relating to the control of sources of radiation; §401.064, which provides for the authority to adopt rules relating to inspection of x-ray equipment; Chapter 401, Subchapter J, which authorizes enforcement of the Act; Chapter 401, Subchapter L, which provides for the Certification of Mammography Systems; and Texas Government Code §531.0055 and Texas Health and Safety Code §1001.075, which authorize the Executive Commissioner of HHSC to adopt rules and policies for the operation and provision of health and human services by DSHS and the administration of Texas Health and Safety Code Chapter 1001.

§289.234. Mammography Accreditation.

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

Filed with the Office of the Secretary of State on February 5, 2025.

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Cynthia Hernandez
General Counsel
Department of State Health Services
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For further information, please call: (512) 834-6655

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TITLE 37. PUBLIC SAFETY AND CORRECTIONS

PART 6. TEXAS DEPARTMENT OF CRIMINAL JUSTICE

CHAPTER 152. CORRECTIONAL INSTITUTIONS DIVISION

SUBCHAPTER D. OTHER RULES

37 TAC §152.71

The Texas Board of Criminal Justice (board) proposes amendments to §152.71, concerning Acceptance of Gifts Related to Buildings for Religious and Secular Programs. The proposed amendments revise "offender" to "inmate" and "rule" to "section" throughout; revise the policy statement for clarity; remove language specifying a building related to the provision of religious and secular programs; add language to state the TDCJ shall meet with donor groups to evaluate a prospective donated

building or enhancement; revise language to state a donor or designee will be qualified; remove language requiring the building to be used for religious and secular programs; and add language to specify building enhancements.

Ron Steffa, Chief Financial Officer for the Texas Department of Criminal Justice, has determined that for each year of the first five years the proposed amendments will be in effect, enforcing or administering the proposed amendments will not have foreseeable implications related to costs or revenues for state or local government because the proposed amendments merely clarify existing procedures.

Mr. Steffa has also determined that for each year of the first five-year period, there will not be an economic impact on persons required to comply with the rules because the proposed amendments merely clarify existing procedures. There will not be an adverse economic impact on small or micro businesses or on rural communities. Therefore, no regulatory flexibility analysis is required.

The anticipated public benefit, as a result of enforcing the proposed amendments, will be to enhance clarity and public understanding. No cost will be imposed on regulated persons.

The proposed amendments will have no impact on government growth; no impact on local employment; no creation or elimination of a government program; no creation or elimination of employee positions; no increase or decrease in future legislative appropriations to the TDCJ; no increase or decrease in fees paid to the TDCJ; no new regulation and no effect on an existing regulation; no increase or decrease in the number of individuals subject to the rule; and no effect upon the economy. The proposed amendments will not constitute a taking.

Comments should be directed to the Office of the General Counsel, Texas Department of Criminal Justice, P.O. Box 4004, Huntsville, Texas 77342, ogccomments@tdcj.texas.gov. Written comments from the general public must be received within 30 days of the publication of this rule in the *Texas Register*.

The amendments are proposed under Texas Government Code §492.001, which authorizes the board to govern the department; §492.013, which authorizes the board to adopt rules; and §501.009, which requires the agency to adopt a policy requiring each warden to identify and encourage volunteer and faith-based organizations that provide programs for inmates.

Cross Reference to Statutes: None.

§152.71. Acceptance of Gifts Related to Buildings for Religious and Secular Programs.

(a) Policy. The Texas Board of Criminal Justice (TBCJ) and Texas Department of Criminal Justice (TDCJ) encourage public or private donations of buildings and building enhancements for the purpose of assisting the reintegration of inmates into society through religious and secular programs. The TBCJ is the only entity authorized to accept such gifts on behalf of the TDCJ. [~~Only the Texas Board of Criminal Justice (TBCJ) is authorized to accept gifts on behalf of the Texas Department of Criminal Justice (TDCJ) from any public or private source, for use in maintaining and improving correctional programs and services. The TBCJ also specifically and earnestly encourages the involvement of volunteers and volunteer organizations for the purpose of assisting the reintegration of offenders into society through religious and secular programs. Correctional facilities of the TDCJ benefit from donated additional space or enhancements to existing space for religious and secular programs. The TBCJ and the TDCJ actively encourage the donation of buildings and enhancements for buildings that are related to the provision of religious and secular programs.~~]

(b) Procedures.

(1) The TDCJ shall meet with donor groups for the purpose of evaluating a prospective donated [~~accepting a~~] building or building enhancement [~~for a building related to the provision of religious and secular programs~~]. The TBCJ respects the right of contributors to designate a specific project at a specific TDCJ unit for [~~at~~] which the donated building or building enhancement will be used.

(2) A donor or designee will [~~shall~~] be qualified to design and construct the donated building or enhancement in accordance with the TDCJ Administrative Plan for Capital Improvements by Donor Groups. Subject to final project approval by the executive director or designee, all plans for the building or enhancement must be approved by the Facilities Division. All design and construction activities by the donor or designee will be coordinated through the Facilities Division. The Capital Improvement Review Committee shall review and coordinate all steps pertaining to the project, ensuring all requirements of the TDCJ Administrative Plan for Capital Improvements by Donor Groups are followed. The donor or designee will design and construct the donated building or enhancement at no cost to the TDCJ.

(3) The TDCJ shall be the owner of the donated building or building enhancement and shall be responsible for the operation, control, and maintenance of the building or building enhancement[~~, which shall be used for religious and secular programs~~]. The naming of buildings obtained under this section [~~rule~~] shall be in accordance with 37 Texas Administrative Code §155.21.

(4) Buildings that serve as chapels provided by or enhanced by donations under this section [~~rule~~] shall be used to provide a place for all inmates [~~offenders~~] to practice their religion as guaranteed by the First Amendment to the United States Constitution, in accordance with TDCJ policy and procedures for facilitating the religious practices of inmates [~~offenders~~]. Furthermore, the buildings shall be used by inmates [~~offenders~~] to participate in religious and secular programs with volunteers, TDCJ chaplaincy staff, and other program personnel.

(5) These donations, including donations at privately-operated, state-owned facilities, shall be presented at a regularly scheduled meeting of the TBCJ for discussion, consideration, and possible action.

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

Filed with the Office of the Secretary of State on February 21, 2025.

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Stephanie Greger
General Counsel
Texas Department of Criminal Justice
Earliest possible date of adoption: April 6, 2025
For further information, please call: (936) 437-6700

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CHAPTER 163. COMMUNITY JUSTICE ASSISTANCE DIVISION STANDARDS

37 TAC §163.33

The Texas Board of Criminal Justice (board) proposes amendments to §163.33, concerning Community Supervision Staff.

The proposed amendments revise "rule" to "section" throughout; revise the definition of "direct supervision"; and make grammatical and formatting updates.

Ron Steffa, Chief Financial Officer for the Texas Department of Criminal Justice, has determined that for each year of the first five years the proposed amendments will be in effect, enforcing or administering the proposed amendments will not have foreseeable implications related to costs or revenues for state or local government because the proposed amendments merely clarify existing procedures.

Mr. Steffa has also determined that for each year of the first five-year period, there will not be an economic impact on persons required to comply with the rules because the proposed amendments merely clarify existing procedures. There will not be an adverse economic impact on small or micro businesses or on rural communities. Therefore, no regulatory flexibility analysis is required. The anticipated public benefit, as a result of enforcing the proposed amendments, will be to enhance clarity and public understanding. No cost will be imposed on regulated persons.

The proposed amendments will have no impact on government growth; no impact on local employment; no creation or elimination of a government program; no creation or elimination of employee positions; no increase or decrease in future legislative appropriations to the TDCJ; no increase or decrease in fees paid to the TDCJ; no new regulation and no effect on an existing regulation; no increase or decrease in the number of individuals subject to the rule; and no effect upon the economy. The proposed amendments will not constitute a taking.

Comments should be directed to the Office of the General Counsel, Texas Department of Criminal Justice, P.O. Box 4004, Huntsville, Texas 77342, ogccomments@tdcj.texas.gov. Written comments from the general public must be received within 30 days of the publication of this rule in the *Texas Register*.

The amendments are proposed under Texas Government Code §492.013, which authorizes the board to adopt rules; and §509.003, which authorizes the board to adopt reasonable rules establishing standards and procedures for the TDCJ Community Justice Assistance Division.

Cross Reference to Statutes: None.

§163.33. Community Supervision Staff.

(a) Purpose.

(1) The purpose of this section [~~Community Justice Assistance Division (CJAD) rule~~] is to establish [~~set forth~~] the eligibility, professional training, certification, and record-keeping requirements for Community Supervision and Corrections Departments' (CSCDs) professional staff, direct care staff, and contract staff.

(2) Once the Community Justice Assistance Division (CJAD) [~~CJAD~~] has certified a community supervision officer (CSO) or residential CSO in accordance with this section [~~rule~~], the CSO or residential CSO will maintain certification and eligibility for certification provided they are in compliance with training hour requirements and are employed by a CSCD.

(3) CSCDs, CSOs, residential CSOs, direct care staff, and contract staff members who work at CSCDs, Substance Abuse Felony Punishment Facilities (SAFPFs), CSCD residential facilities, or Community Correction Facilities (CCFs) must comply with this section [~~rule~~].

(4) This section [~~rule~~] specifies the certification and training requirements for professional staff and direct care staff based on their status as a new employee, an employee with less than four years of experience, an employee with more than four years of experience, a returning employee, or an employee who is exempt from certain certification requirements based upon their years of on-the-job experience.

(b) Definitions.

(1) "Contract staff" are staff working at a CSCD or one of its facilities pursuant to a contract rather than as permanent, full-time employees of the CSCD.

(2) "CSOs" [~~are community supervision officers who~~] provide direct supervision to offenders on community supervision.

(3) "Direct care staff" provide [~~are staff providing~~] direct care within a residential facility operated by a CSCD.

(4) "Direct supervision" refers to a type of supervision described in Section 163.35(b)(1) [~~offenders who are legally on community supervision and who work or reside in the jurisdiction in which they are being supervised and receive a minimum of one face-to-face contact with a CSO every three months. Direct supervision begins at the time of initial face-to-face contact with an eligible CSO. Local CSCDs may maintain direct supervision of offenders living or working in adjoining jurisdictions if the CSCD has documented approval from the adjoining jurisdictions~~].

(5) "Professional staff," in [~~for purposes of~~] this section [~~rule~~], includes CSCD directors and assistant directors, CCF directors and assistant directors, CSO supervisory staff, CSOs, and residential CSOs.

(6) "Professional training" includes a formal presentation of specific behavioral learning objectives and skills or specific knowledge in actual day-to-day community supervision work [~~and~~] approved by the CSCD director, in writing, as professional training.

(7) "Residential CSOs" [~~are community supervision officers who~~] provide direct supervision to offenders sentenced to community supervision within a residential facility managed by a CSCD.

(c) Eligibility for Employment [~~employment~~] as a CSO or Residential [~~residential~~] CSO. To be eligible for employment as a CSO or residential CSO serving in a position of direct supervision of offenders, a person must:

(1) have [~~Have~~] a bachelor's degree conferred by an institution of higher education accredited by an accrediting organization recognized by the Texas Higher Education Coordinating Board;

(2) not [~~Not~~] be [~~a person~~] employed or volunteering as a peace officer or working [~~work~~] as a reserve or volunteer peace officer;

(3) be [~~Be~~] eligible to supervise offenders in accordance with Texas Criminal Justice Information Services (CJIS) Access Policy; and

(4) become [~~Become~~] certified and attend professional training in accordance with this section [~~rule~~].

(d) Newly Hired [~~hired~~] CSO or Residential [~~residential~~] CSO Certification [~~certification~~]. A newly hired CSO or residential CSO shall complete the certification course and achieve a passing grade on the applicable CJAD certification examination within one year of the date of employment as a CSO or residential CSO. A CSO or residential CSO may complete course work and take examinations to achieve dual certification.

(1) A CSO or residential CSO who fails to achieve certification within the first year of employment shall not serve in a position

of direct supervision over offenders until certification is achieved unless the CJAD grants an extension for the completion of course work and re-examination.

(2) A CSO or residential CSO who completes the certification course work but fails to pass the certification examination may take the examination a second time. A CSO or residential CSO who fails the examination a second time shall complete the certification course again before taking the examination for the third and final time.

(3) A CSO or residential CSO who has failed the certification examination three times is eligible to pursue certification no sooner than two years after the last failed examination in accordance with this section [~~rule~~] and shall not serve in a position of direct supervision over offenders until certification is achieved.

(e) Exempt CSO and Residential [~~residential~~] CSO Certification [~~certification~~]. A CSO or residential CSO who has been continuously employed by any CSCD in Texas from on or before September 1, 1989, is exempt from the certification requirements. Certification courses and the certification examination, however, shall be available to exempt CSOs and residential CSOs. Exempt CSOs or residential CSOs who complete the certification course work but fail to pass the certification examination may take the examination a second time. An exempt CSO or residential CSO who fails the examination a second time may complete the certification course again before taking the examination for the third and final time. Although exempt from certification, exempt CSOs and residential CSOs are required to complete professional training each biennium in accordance with this section [~~rule~~].

(f) Recertification of Professional Staff Upon Re-employment [~~professional staff upon re-employment~~]. Professional staff subject to the certification provisions of this section [~~rule~~] who have left the employment of a Texas CSCD for more than one year are required to become recertified in accordance with this section [~~rule~~]. All professional staff [~~employees~~] who had less than one year of experience before leaving the employment of a CSCD must become certified or recertified in accordance with this section [~~rule~~].

(g) Professional Training of Professional Staff [~~training of professional staff~~].

(1) Professional staff with less than four years of experience shall complete at least 80 documented hours of professional training each biennium.

(A) Up to 40 hours in excess of the 80 required professional training hours may be carried over to the next biennium.

(B) Professional staff who fail to complete the required 80 hours of professional training within a biennium shall not serve in a position of direct supervision of offenders until the required professional training hours are completed.

(2) Professional staff with at least four years of experience shall complete at least 40 documented hours of professional training each biennium, beginning the biennium after which four years of experience is achieved.

(A) At least two of the required four years of experience shall have been earned as a full-time, wage-earning officer in Texas community supervision. Up to two of the four years of required experience may have been earned through work in juvenile probation or parole, adult parole, or similar work in other states. The required four years of experience is not required to be continuous.

(B) Up to 20 hours in excess of the 40 required professional training hours may be carried over to the next biennium.

(C) Professional staff who fail to complete the required 40 hours of professional training within a biennium shall not serve in a position of direct supervision over offenders until the required professional training hours are completed. Professional staff who are exempt from certification as defined in this section [~~rule~~] and fail to complete the required 40 hours of professional training within a biennium shall not serve in a position of direct supervision over offenders until the required professional training hours are completed.

(h) Training of CSOs Who Supervise SAFPF Program Participants [~~who supervise SAFPF program participants~~].

(1) CSOs who supervise participants in a SAFPF program shall complete the CJAD approved training designed for officers who supervise SAFPF program participants in [~~during the course of~~] treatment in a SAFPF and in the continuum of care component of the SAFPF program.

(2) The training shall be completed within one year of being assigned supervision of SAFPF program participants~~,~~ unless the CJAD grants an extension for completion of the course work.

(3) CSOs who supervise SAFPF program participants and who fail to complete the CJAD approved SAFPF training shall not serve in a position of direct supervision over SAFPF program participants until the required CJAD approved SAFPF training is completed~~,~~ unless the CJAD grants an extension.

(i) Direct Care Staff Certifications and Professional Training [~~care staff certifications and professional training~~].

(1) Newly Hired Direct Care Staff Certifications [~~hired direct care staff certifications~~]. Direct care staff working in a residential facility shall be required to complete the following types of training and obtain the required certifications within one year of their initial hire date as follows:

(A) training [~~Training~~] in ethics, discrimination, and sexual harassment;

(B) certification [~~Certification~~] in first aid procedures, cardiopulmonary resuscitation (CPR) procedures, and HIV/AIDS education. Direct care staff shall maintain certification in first aid procedures, CPR procedures, and HIV/AIDS education in accordance with the training authority's guidelines for frequency of training and certification in first aid procedures, CPR procedures, and HIV/AIDS education;

(C) residential [~~Residential~~] staff certification training offered by the CJAD; and

(D) a [~~A~~] defensive driving course. Direct care staff shall [~~and~~] provide certification of completion with a passing grade from the course provider to the CSCD director or designee. Direct care staff shall take defensive driving courses in accordance with the training authority's guidelines for frequency of training and certification in defensive driving.

(2) Direct care staff working in a residential facility shall be required to complete professional training as follows:

(A) All residential direct care staff, including contract staff, with less than four years of experience at the close of business on August 31st of any biennium, shall be required to complete a minimum of 40 hours of documented professional training per biennium.

(B) A minimum of 20 professional training hours per biennium shall be specific to the needs of the offender population served by the facility.

(C) Up to 20 hours in excess of the 40 required professional training hours may be carried over to the next biennium.

(3) Direct care residential staff with four or more years of experience at the close of business on August 31st of any biennium, regardless of when the four years of experience is achieved, shall complete at least 20 documented hours of professional training each biennium.

(A) In [~~For purposes of~~] this section, experience may include up to two years of prior employment as a correctional officer or direct care staff in a juvenile facility, jail, parole facility, state jail facility, prison, private vendor residential facility, or similar work in another state. At least two of the required four years of experience shall have been as a full-time, wage-earning direct care staff member in a CCF funded by the TDCJ CJAD in Texas. The required four years of experience is not required to be continuous.

(B) The reduced number of hours of required professional training for the direct care residential staff who have at least four years of experience shall not affect or reduce the training requirements regarding CPR, first aid, or defensive driving. A maximum of 10 hours earned in excess of the 20 required professional training hours may be carried over to the next biennium. Direct care residential staff who fail to complete the required 20 hours of training within a biennium shall not serve as direct care residential staff until the required hours are completed.

(j) Maintenance of Records [~~records~~]. Each CSCD director shall have a written policy that requires the maintenance of training records for all [~~each~~] professional staff, [~~or~~] direct care staff, [~~employee~~] and contract staff [~~member~~]. The CSCD director or designee shall ensure that training records for staff identified in this section [~~rule~~] are maintained and available for CJAD auditors. Those records shall include the:

(1) [~~The~~] number of professional training hours completed and the dates of the training;

(2) [~~The~~] specific training programs attended with supporting documentation;

(3) [~~The~~] specific certifications obtained with supporting documentation;

(4) [~~The~~] number of completed professional training hours certified in writing by the CSCD director or designee as professional training; and

(5) [~~The~~] number of professional training hours carried over from one biennium to the next biennium in accordance with this section [~~these rules~~].

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

Filed with the Office of the Secretary of State on February 24, 2025.

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Stephanie Greger
General Counsel
Texas Department of Criminal Justice
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For further information, please call: (936) 437-6700

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37 TAC §163.42

The Texas Board of Criminal Justice (board) proposes amendments to §163.42, concerning Substantial Noncompliance. The proposed amendments reflect the Office of Internal Audit as independent of the TDCJ.

Ron Steffa, Chief Financial Officer for the Texas Department of Criminal Justice, has determined that for each year of the first five years the proposed amendments will be in effect, enforcing or administering the proposed amendments will not have foreseeable implications related to costs or revenues for state or local government because the proposed amendments merely clarify existing procedures.

Mr. Steffa has also determined that for each year of the first five-year period, there will not be an economic impact on persons required to comply with the rules because the proposed amendments merely clarify existing procedures. There will not be an adverse economic impact on small or micro businesses or on rural communities. Therefore, no regulatory flexibility analysis is required. The anticipated public benefit, as a result of enforcing the proposed amendments, will be to enhance clarity and public understanding. No cost will be imposed on regulated persons.

The proposed amendments will have no impact on government growth; no impact on local employment; no creation or elimination of a government program; no creation or elimination of employee positions; no increase or decrease in future legislative appropriations to the TDCJ; no increase or decrease in fees paid to the TDCJ; no new regulation and no effect on an existing regulation; no increase or decrease in the number of individuals subject to the rule; and no effect upon the economy. The proposed amendments will not constitute a taking.

Comments should be directed to the Office of the General Counsel, Texas Department of Criminal Justice, P.O. Box 4004, Huntsville, Texas 77342, ogccomments@tdcj.texas.gov. Written comments from the general public must be received within 30 days of the publication of this rule in the *Texas Register*.

The amendments are proposed under Texas Government Code §492.013, which authorizes the board to adopt rules; and §509.003, which authorizes the board to adopt reasonable rules establishing standards and procedures for the TDCJ Community Justice Assistance Division.

Cross Reference to Statutes: None.

§163.42. Substantial Noncompliance.

(a) Definition. Substantial noncompliance with the Texas Department of Criminal Justice Community Justice Assistance Division (TDCJ CJAD) standards, for purposes of Texas Government Code §509.012, is defined as:

(1) intentional diversion, theft, or misapplication of TDCJ CJAD funding or grants for purposes other than the state funding award or allocation;

(2) violations of laws, regulations, or official manuals specific to the operations of the community supervision and corrections departments (CSCDs);

(3) intentional refusal to implement a TDCJ CJAD approved action plan that is a result of audits, reviews, or inspections;

(4) for purposes of qualifying for state aid under 37 Texas Administrative Code §163.43(a)(1)(F), relating to Funding and Financial Management, failure to hold the meeting to finalize the CSCD budget as required by Texas Local Government Code §140.004; and

(5) interference, obstruction, or hindrance with any efforts by the Texas Comptroller of Public Accounts, county auditor of the county that manages the CSCD's funds, TDCJ CJAD, Texas Board of Criminal Justice Office of the Independent Auditor [~~TDCJ Internal Audit Division~~], Legislative Budget Board, Texas State Auditor's Office, or Texas Sunset Advisory Commission to examine or audit the records, transactions, and performance of the CSCD or facilities.

(b) Imposing Sanctions. Sanctions imposed for substantial noncompliance shall be in accordance with the provisions outlined in 37 Texas Administrative Code §163.47, relating to Contested Matters.

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

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