25 TEXAS ADMINISTRATIVE CODE (TAC)

§289.230

Certification of Mammography Systems and X-ray Machines Used for Interventional Breast Radiography

Texas Regulations for Control of Radiation

(revisions effective June 9, 2025 are shown as shaded text)

25 TAC 289.230

Certification of Mammography Systems and X-ray Machines Used for Interventional Breast Radiography (continued)

TITLE 25 HEALTH SERVICES
PART 1 DEPARTMENT OF STATE HEALTH SERVICES
CHAPTER 289 RADIATION CONTROL
SUBCHAPTER E REGISTRATION REGULATIONS

§289.230. Certification of Mammography Systems and X-Ray 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.

(2) Mammography machines certified under this section must be used 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) In addition to the requirements of this section, all facilities are subject to the requirements of:

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

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

(C) §289.205 of this chapter (relating to Hearing and Enforcement Procedures);

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

(E) §289.231 of this subchapter (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.

(3) The procedures as specified in §289.205 of this chapter relating to modifications, suspensions, revocations, denials, and hearings regarding certificates of registration are applicable to certifications issued by the department.

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

(5) An entity, defined in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) as a "covered entity" under 45 CFR Parts 160 and 164, may be subject to privacy standards governing how information identifying a patient can be used and disclosed. Failure to follow HIPAA requirements may result in the department referring 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) Definitions. The following words and terms, when used in this section, have the following meanings unless the context indicates otherwise.

(1) Accreditation--The approved use of a mammography machine by an AB.

(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 corrective action must be taken by the facility.

(4) Additional mammography review (AMR)--A review of clinical images and other relevant facility information necessary to assess compliance with accreditation standards.

(5) Adverse event--An undesirable experience associated with mammography activities. Adverse events include:

(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) 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).

(7) American Registry of Radiologic Technologists - Radiography (ARRT(R))--the credential issued by the American Registry of Radiologic Technologists in radiography.

(8) Automatic exposure control (AEC)--A device automatically controlling one or more technique factors to obtain the required quantity of radiation at preselected locations.

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

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

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

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

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

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

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

(19) Control panel--The part of the radiation machine control upon which are mounted the hardware necessary for setting the technique factors.

(20) Direct instruction--Instruction, including:

(A) interaction between an instructor and student, such as when the instructor provides a lecture, conducts demonstrations, or reviews student performance; or

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

(21) Direct supervision--Oversight of operations, including the following.

(A) During joint interpretation of mammograms, the supervising interpreting physician reviews, discusses, and confirms the interpretation of the physician being supervised and signs the 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 performing the examination.

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

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

(A) operating equipment to produce a mammogram;

(B) processing film or digital images;

(C) interpreting the mammogram; or

(D) maintaining the viewing conditions for interpretation.

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

(24) Final assessment categories--The overall final assessment of findings in a report of a mammography examination classified in (j)(3)(E) of this section.

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

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

(27) Half-value layer (HVL)--The thickness of a specified material attenuating the beam of radiation to the extent the exposure rate is reduced to one-half of its original value.

(28) 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) 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) 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) Interpreting physician (IP)--A licensed physician who interprets mammographic images and who meets the requirements of subsection (h)(1) of this section.

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

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

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

(36) Laterality--The designation of either the right or left breast.

(37) Lead interpreting physician (LIP)--The interpreting physician assigned the general responsibility for ensuring a facility's QA program meets all requirements of subsections (k), (l), and (m) of this section.

(38) Mammogram--A radiographic image produced through mammography.

(39) 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, full-field digital mammography, and digital breast tomosynthesis (DBT).

(40) Mammography--The use of x-rays to produce an image of the breast that may be used to detect the presence of pathological conditions of the breast. Mammography does not include radiography of the breast performed:

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

(B) using an investigational mammography device as part of a scientific study conducted under the FDA's investigational device exemption regulations.

(41) 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.

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

(43) Mammography system--A system, including:

(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 device used for viewing and evaluating an image of breast tissue;

(E) an MRT who meets the qualifications specified in subsection (h)(2) of this section and performs mammography; and

(F) a physician who interprets mammography and meets the requirements specified in subsection (h)(1) of this section.

(44) Mandatory training--Additional training required by the department or AB for IPs, MRTs, or medical physicists as the result of a required corrective action.

(45) Medical physicist--An individual who performs surveys and evaluations of mammographic equipment and facility QA programs as specified in this section and who meets the qualifications in subsection (h)(3) of this section.

(46) Medical radiologic technologist (MRT)--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 this section and who meets the qualifications in subsection (h)(2) of this section.

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

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

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

(50) 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)

$$OD = \log_{10} \frac{I_o}{I_t}$$

where I_o = light intensity incident on the film and
I_t = light transmitted through the film.

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

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

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

(54) 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 an overall assessment of findings that are either "suspicious" or "highly suggestive of malignancy."

(57) Provisional certification--A certification category enabling a facility to perform mammography and obtain the clinical images needed to complete the accreditation process.

(58) Qualified instructor--An individual whose training and experience prepares the qualified instructor to carry out specified training assignments. IPs, MRTs, or medical physicists who meet the requirements of subsection (h) of this section are considered qualified instructors in their respective areas of mammography. Other examples of an individual who may be a qualified instructor for the purpose of providing training to meet the requirements of this section include instructors in a post-high school training institution and manufacturers' representatives.

(59) Quality control (QC) technologist--An individual meeting the requirements of subsection (h)(2) of this section who is responsible for those QA responsibilities not assigned to the LIP or to the medical physicist.

(60) Radiation machine--see definition for mammography machine.

(61) Self-referral mammography--The use of x-ray 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) 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) Serious complaint--A report of a serious adverse event.

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

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

(66) Survey--An on-site physics consultation and evaluation of a facility QA 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) Technique chart--A chart providing all necessary generator control settings and geometry needed to make clinical radiographs.

(68) Traceable to a national standard--Calibrated at either the National Institute of Standards and Technology (NIST) or at a calibration laboratory participating 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 show agreement within plus or minus 3.0 percent of the national standard in the mammography energy range.

(f) Mammography systems certification.

(1) Requirements for certification.

(A) A facility must meet the quality standards in subsections (h) - (q) of this section and be accredited by an AB. To qualify for certification, a new facility must apply to the department and receive acceptance of an accreditation application by an AB.

(B) A person who receives, possesses, uses, owns, or acquires a mammography machine must apply for certification as specified in §289.226(e) of this subchapter, relating to general requirements for application for registration, and receive certification from the department before using a mammography machine on humans.

(C) An application for certification must be signed by the:

(i) LIP;

(ii) applicant; and

(iii) radiation safety officer (RSO).

(D) Each applicant must submit documentation of:

(i) personnel qualifications, including dates of licensure or certification, as specified in subsection (h) of this section;

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

(iii) evidence that a medical physicist has:

(I) determined each machine meets the equipment standards in subsection (i) of this section;

(II) performed a survey and a mammography equipment evaluation as specified in subsection (l)(5) and (6) of this section; and

(III) determined the average glandular dose for one craniocaudal view for each machine is less than the value in subsection (i)(11)(D) of this section;

(iv) self-referral program information as specified in subsection (r) of this section, if the facility offers self-referral mammography;

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

(vi) proof of current accreditation.

(2) Issuance of certification. A certification will be issued if the department determines the application meets the requirements of the Act and this chapter. The certification authorizes the proposed operations and includes conditions and limitations deemed necessary by the department.

(A) The certification may include:

(i) mammography systems and facilities certification, following approval of accreditation by an AB; or

(ii) certification of interventional breast radiography machines.

(B) Conditions. The department may incorporate in the certification at the time of issuance, or by amendment, additional requirements and conditions to:

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

(ii) require additional reporting and record keeping; and

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

(C) Additional information. The department may request additional information after the certification has been issued to enable the department to determine whether the certification should be modified as specified in §289.226(r) of this subchapter, relating to renewal of certificates of registration.

(3) Provisional certification.

(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.

(B) Following the department's receipt of the accreditation body's decision that a facility has submitted the required information, the department may issue a provisional certification to a facility if the facility has satisfied the requirements of the Act and this chapter.

(i) A provisional certification is effective for up to six months as noted on the certificate.

(ii) A provisional certification cannot be renewed, but a facility may apply for a 90-day extension of the provisional certification.

(C) To apply for a 90-day extension to a provisional certification, a facility must submit to the AB who issued the original certificate, a statement of actions taken to obtain certification and evidence that there would be a significant adverse impact on access to mammography in the geographic area served if the facility did not obtain an extension.

(i) The department may issue a 90-day extension for a provisional certification if the extension meets the criteria in paragraph (3) of this subsection.

(ii) Renewal of a provisional certification beyond the 90-day extension is prohibited.

(4) Reinstatement.

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

(B) Unless prohibited from reinstatement as specified in subsection (f)(5) of this section, a facility applying for reinstatement must:

(i) contact an AB for reapplication of accreditation;

(ii) provide documentation of its history as a previously provisionally certified or certified mammography facility, and include the:

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

(II) name of previous owner or lessor;

(III) facility identification number assigned to the facility under its previous certification by the FDA or the department; and

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

(iii) justify application for reinstatement of accreditation by submitting to an AB a corrective action plan detailing how the facility has corrected deficiencies contributing to the lapse, denial of renewal, or revocation of its certification.

(C) The department may issue a provisional certification to the facility if the department determines the facility has:

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

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

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

(5) Suspension or revocation of certification.

(A) Except as provided in subparagraph (B) of this paragraph, the department may suspend or revoke a certification issued by the department if it finds, after providing the owner or facility representative with notice and an opportunity for a hearing as specified in §289.205 of this chapter, that the owner, facility representative, or any employee of the facility has:

(i) misrepresented documentation to obtain the certification;

(ii) failed to comply with the requirements of this chapter;

(iii) failed to comply with requests of the department or an AB or records, information, reports, or materials necessary to determine the continued eligibility of the facility for a certification or continued compliance with the requirements of this chapter;

(iv) refused a request of a duly designated FDA inspector, state inspector, or an AB representative for permission to inspect the facility or the operations and pertinent records of the facility;

(v) 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) failed to comply with prior sanctions imposed by the department as specified in §289.205 of this chapter.

(B) The department may suspend a certification of a facility before holding a hearing if it makes a finding described in subparagraph (A) of this paragraph and determines that:

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

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

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

(C) If the department suspends a certification as specified in subparagraph (B) of this paragraph:

(i) the department will provide the facility with an opportunity to request a hearing as specified in §289.205 of this chapter; and

(ii) the suspension will remain in effect until it is determined by the department that the:

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

(II) violations of requirements have been corrected to the department's satisfaction; or

(III) certification is revoked as specified in subparagraph (D) of this paragraph.

(D) After providing a hearing as specified in §289.205 of this chapter, the department may revoke the certification if it is determined by the department that the facility:

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

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

(E) If a facility's certification was revoked based on an act described in §289.205 of this chapter, a person who owned or operated that facility at the time the act occurred is prohibited from owning a mammography facility for two years following the revocation date.

(6) Appeal of adverse accreditation or reaccreditation decisions preventing certification or recertification.

(A) The appeal process described in this paragraph is only available for adverse accreditation or reaccreditation decisions preventing certification by the department. If the department suspends or revokes a certificate already in effect, it will be handled as specified in subsection (f)(5) of this section.

(B) If a facility has failed to become accredited or reaccredited, the department will notify the facility that the department is unable to certify the facility without proof of accreditation.

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

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

(7) Denial of certification.

(A) The department may deny the application if the department has reason to believe that:

(i) the facility will not be operated as specified in the provisions of subsections (h) - (q) of this section;

(ii) the facility will not permit inspections or provide access to records or information timely;

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

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

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

(B) Before the department denies an application for certification, the department must give notice of the denial, the facts warranting the denial, and afford the applicant an opportunity for a hearing in accordance with §289.205(h) of this chapter. 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 may proceed to deny. The applicant must bear the burden of proof showing cause why the application should not be denied.

(C) If the department denies an application for certification from a facility that has received accreditation from an AB, the department will provide the facility with a written statement of the grounds on which the denial is based.

(8) Appeals of a certification denial.

(A) The appeals procedures described in this paragraph are available only to facilities that are denied certification by the department after they have been accredited by an AB.

(B) A facility that has been denied certification may request reconsideration and appeal the department's determination as specified in the applicable provisions of §289.205(h) of this chapter.

(9) 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 certificates of registration.

(10) Specific terms and conditions of certification. Specific terms and conditions of certification will be as specified in §289.226(l) of this subchapter, relating to terms and conditions of certificates of registration.

(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.

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(g) Responsibilities of the facility.

(1) In addition to the requirements of §289.226(m)(3) - (7) of this subchapter, relating to responsibilities of the registrant, the facility must notify the department in writing, within 30 days, of any changes rendering the information contained in the application or the certification inaccurate, including the:

(A) name of the facility;

(B) mailing address;

(C) street address where the machine is used;

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

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

(2) Before employing an individual listed in subparagraphs (A) - (E) of this paragraph, the facility is required to verify and maintain a copy of qualifications of the:

(A) RSO;

(B) LIP;

(C) IP;

(D) MRT; or

(E) medical physicist.

(3) A facility utilizing an IP or MRT from a temporary staffing service must verify and maintain copies of the qualifications of these individuals for inspection by the department.

(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.

(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.

(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 be completed before use on patients. The results of the survey must be submitted to the department with a cover letter indicating period of use. If the use period will exceed 60 days, the facility must 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 be maintained for review as specified in subsection (x) of this section.

(h) 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 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:

(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 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;

(ii) have completed a minimum of 60 hours of documented category I CMEUs in mammography and at least 15 of the 60 hours must have been acquired within three years immediately before the date the physician became qualified as an IP (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, at least 240 mammographic examinations within the six-month period immediately before 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.

(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) Exemptions.

(i) A physician qualified as an IP as specified in the requirements of §289.230 that were in effect before April 28, 1999, or any other equivalent state or federal requirements in effect before April 28, 1999, is 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 in any 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) Continuing education.

(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.

(I) The period for the initial continuing education begins when a physician completes the requirements in subparagraph (A) of this paragraph.

(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.

(III) Continuing education must be completed in the 36 months immediately preceding:

(-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.

(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) Re-establishing qualifications. Before resuming independent interpretation of mammograms, an IP failing to maintain the required continuing education or experience must re-establish their qualifications by completing one or both of the following requirements, as applicable:

(i) obtain additional category I CMEUs to bring the total up to 15 category I CMEU credits required in the previous 36 months;

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

(I) at least 240 mammographic examinations; or

(II) additional mammographic examinations to bring the total up to 960 examinations for the prior 24 months.

(G) Additional mandatory training. Additional mandatory training may be required by the department based on the recommendations of an AB, the department, or the FDA. Training is developed on a case-by-case basis.

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

(ii) Documentation of the additional mandatory training must be submitted for review by the date specified by the department.

(iii) Records of all additional mandatory training must be maintained by the facility for inspection by the department as specified in subsection (x)(3) of this section.

(2) Medical radiologic technologists (MRTs). Each individual performing mammographic examinations must maintain current credentials as an ARRT(R) and MRT as specified in the Medical Radiologic Technologist Certification Act, Texas Occupations Code Chapter 601, and must meet the following qualifications.

(A) Initial requirements. Before performing mammographic examinations, the MRT must:

(i) complete a minimum of 40 contact hours of training as specified in subparagraph (B) of this paragraph by a qualified instructor; and

(ii) perform a minimum of 25 mammographic examinations under the direct supervision of an individual qualified as specified in 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 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) Exemptions. MRTs qualified to perform mammography as specified in the requirements of §289.230 that were in effect before April 28, 1999, and any other federal requirements in effect before April 28, 1999, are considered to have met the initial requirements of subparagraph (A) of this paragraph.

(D) Continuing education.

(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.

(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.

(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.

(III) Continuing education must be completed in the 36 months immediately preceding:

(-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.

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

(i) obtain additional CEUs to bring the total up to 15 CEU credits required in the previous 36 months;

(ii) perform a minimum of 25 mammographic examinations under the direct supervision of a qualified MRT.

(G) Additional mandatory training. Additional mandatory training may be required by the department based on the recommendations of an AB, the department, or the FDA. Training is developed on a case-by-case basis.

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

(ii) Documentation of the additional mandatory training must be submitted for review by the date specified by the department.

(iii) Records of all additional mandatory training must be maintained by the facility for inspection by the department as specified in subsection (x)(3) of this section.

(3) Medical physicist. Each medical physicist performing mammographic surveys, evaluating mammographic equipment, or providing oversight of the facility QA program as specified in subsection (k) of this section must hold a current Texas license under the Medical Physics Practice Act, Texas Occupations Code Chapter 602, in diagnostic radiological physics. The medical physicist must be registered with the department or employed by an entity registered with the department, as specified in §289.226(j) of this subchapter and the Act, unless exempted by §289.226(d)(7) of this subchapter. Each medical physicist must meet the following qualifications.

(A) Initial qualifications. Before performing surveys and evaluating mammographic equipment independently, the medical physicist must have:

(i) a master's degree or higher in a physical science from an accredited institution, with no less than 20 semester hours, 30 quarter hours, or equivalent of college undergraduate or graduate level physics;

(ii) 20 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 10 mammography machines. Experience conducting surveys must be acquired under the direct supervision of a medical physicist who meets the requirements of subparagraphs (A), (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 the requirements of this section that were in effect before April 28, 1999, or any other equivalent state or federal requirements in effect before April 28, 1999, and have met the following additional qualifications before 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 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.

(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.

(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.

(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.

(III) Continuing education must be completed in the 36 months immediately preceding:

(-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.

(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) 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 reestablish their qualifications by completing one or both of the following requirements, as applicable:

(i) obtain additional CEUs to bring the total up to the 15 CEU credits required in the previous 36 months;

(ii) perform 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 be counted towards the total mammography machine survey requirement.

(4) Retention of personnel records.

(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 any 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) Machine Requirements. Mammographic machines must meet the following requirements.

(1) System design. The equipment must be specifically designed and manufactured for mammography and as required by 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) 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. In the event of power interruption, this mechanism must not fail.

(5) Magnification. Systems used to perform diagnostic procedures must have radiographic magnification capability available for use with at least one magnification value within the range of 1.4 to 2.0.

(6) Focal spot and target material selection. Selection of the focal spot or target material must be as follows.

(A) When more than one focal spot is provided, the system must indicate, before exposure, which focal spot is selected.

(B) When more than one target material is provided, the system must indicate, before exposure, the preselected target material.

(C) When the target material and focal spot are selected by a system algorithm based on the exposure, after the exposure, the system must display the target material and focal spot used during the exposure.

(7) Compression. All mammography systems must incorporate a compression device.

(A) Application of compression. Each system must 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 be equipped with different sized compression paddles matching 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 be flat and parallel to the breast support table and must 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 meet the manufacturer's design specifications and maintenance requirements.

(v) The chest wall edge of the compression paddle must 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 not appear on the image.

(8) Technique factor selection and display. Technique factor selection and display must be as follows.

(A) Manual selection of milliampere seconds (mAs) or at least one of its component parts, milliampere (mA) or time, must be available.

(B) The technique factors (kVp and either tube current in mA and exposure time in seconds or the product of tube current and exposure time in mAs) used during an exposure must be indicated before the exposure begins, except when AEC is used, in which case the technique factors that are set before the exposure must be indicated.

(C) When the AEC mode is used, the system must indicate the actual kVp and mAs used during the exposure. The mAs may be displayed as mA and time.

(9) Automatic exposure control. Each system must provide an AEC mode operable in all combinations of equipment configuration provided, for example, various image receptor sizes.

(A) The positioning or selection of the detector must permit flexibility in the placement of the detector under the target tissue.

(i) The size and available positions of the detector must be clearly indicated at the x-ray input surface of the breast compression paddle.

(ii) The selected position of the detector must be clearly indicated.

(B) The system must provide means to vary the selected optical density from the normal, or zero, setting.

(10) Equipment variances. Facilities with mammography equipment with variances issued by the FDA as specified in 21 CFR §§1020.2, 1020.30, 1020.31, or have an alternative to a quality standard for equipment approved by the FDA as required by 21 CFR §900.18, must 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.

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(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)

Table I

X-ray Tube Voltage in kV (kilovolt peak) and Minimum HVL

Designed Operating Range (kV)	Measured Operating Voltage (kV)	Minimum HVL (millimeter of aluminum)
Below 50	20	0.20
Below 50	25	0.25
Below 50	30	0.30

(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) Light fields. For any mammography system with a light beam that passes through the x-ray beam-limiting device, the light must provide an average illumination of not less than 160 lux (15 foot candles) at 100 cm or the maximum SID, whichever is less.

(j) Medical records and mammography reports.

(1) Contents and terminology. Each facility must prepare a written report of the results of each mammographic examination performed.

(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 and an additional patient identifier;

(B) examination date;

(C) facility name and location, including the city, state, zip code, and telephone number of the facility;

(D) name and signature of the IP who interpreted the mammogram (electronic signatures are acceptable);

(E) overall final assessment of findings using the final assessment categories as defined in clauses (i) - (vii) of this subparagraph, 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) recommendations made to the healthcare provider about what additional actions, if any, should be taken. All clinical questions raised by the referring healthcare provider must be addressed in the report to the extent possible, even if the assessment is negative or benign.

(4) Communication of mammography results to the patient and healthcare providers, as applicable.

(A) Each facility must send a mammography report to referring healthcare providers, or patients who do not name a healthcare 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.

(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.

(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) Follow-up with patients and healthcare provider. Each facility must follow-up to confirm if:

(A) patients with positive findings and patients needing repeat examinations have received proper notification; and

(B) healthcare providers have received proper notification of patients with positive findings or needing repeat examinations.

(7) Retention of clinical images for a current, closed, or terminated facility.

(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. If additional mammograms of the patient are not performed at the facility, the images and reports must be maintained for a minimum of 10 years as specified in subsection (x) of this section.

(B) Each facility performing mammograms must, within 15 calendar 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 maintain and become responsible for the original images 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) Closure or termination.

(i) The facility must maintain the mammography images for five years.

(ii) Within 180 days of closing, the facility must notify each patient or patient's representative with instructions on how to access or authorize disposal of the patient's records.

(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) Within 60 days of closing, the facility must publish a notice in at least one newspaper, or publicly available media, covering the geographical area served by the closing facility. The notice must include:

(I) contact information for 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 years.

(iv) If records have not been retrieved by the patient or the patient's representative during the five-year period after closing, the registrant may destroy the records.

(8) Mammographic image identification. Each mammographic image must include the following information indicated on it in a permanent, legible manner and placed so it does not obscure anatomic structures:

(A) patient name and date of birth;

(B) date of examination;

(C) view and laterality, placed on the image in a position near the axilla;

(D) facility name and location, including city, state, and zip code;

(E) MRT identification;

(F) cassette identification, if applicable;

(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.

(k) Quality assurance - general. Each facility must 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 taken if images are of poor quality.

(1) Responsible individuals. Responsibility for the QA program and each of its elements must be assigned to individuals who are qualified for their assignments and allowed adequate time to perform these duties.

(A) Lead interpreting physician. The facility must identify a LIP who is responsible for:

(i) ensuring the QA program meets all requirements of this subsection and subsections (l) and (m) of this section;

(ii) reviewing and documenting, with date and signature, the MRTs' QC 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 qualifications to perform the QA tasks in subparagraphs (B) - (D) of this paragraph.

(B) Interpreting physicians. All physicians interpreting mammograms for a facility must:

(i) follow the facility's procedures for corrective action when the images they are asked to interpret are of poor quality; these procedures must 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 use the services of a licensed medical physicist to survey mammography equipment and oversee the equipment-related QA practices of the facility. At a minimum, the medical physicist is responsible for performing the surveys, performing mammography equipment evaluations, and providing the facility with the reports described in subsection (l)(5) and (6) of this section.

(D) Quality control technologist. The QC technologist, designated by the LIP, must ensure performance of the items designated in subsection (l)(1) - (4), (7), and (9) of this section. If other personnel are assigned the QA tasks in accordance with subparagraph (A)(iv) of this paragraph, the QC technologist must ensure the requirements of subsection (l)(1) - (4), (7), and (9) of this section are met.

(2) Quality assurance records.

(A) The LIP, QC technologist, and medical physicist must ensure records concerning mammography technique and procedures, QC (include monitoring data, corrective actions, and the effectiveness of the corrective actions), safety, protection, and employee qualifications related to assigned QA tasks are properly maintained and updated.

(B) The QC records must be kept for each test specified in subsections (l) and (m) of this section, as specified in subsection (x) of this section.

(l) Quality assurance - equipment.

(1) Facilities with screen-film systems must perform QC tests as specified in 21 CFR Part 900.

(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.

(3) Mobile service operation.

(A) The mobile facility must verify mammography machines used to produce mammograms at more than one location meet the requirements in paragraphs (1) and (2) of this subsection.

(B) At each examination location, before any examinations are conducted, the facility must verify satisfactory performance of the mammography machines by using a testing method, as required by the manufacturer, establishing the adequacy of the image quality produced by the machine.

(C) Processor performance testing must be completed as required by 21 CFR Part 900.

(4) Use of test results. After completion of the tests specified in paragraphs (1) and (2) of this subsection, the following must occur.

(A) The facility must compare the test results to the manufacturer's recommended action limits.

(B) If components of the mammography system fail QA tests, the facility must follow corrective actions required by 21 CFR Part 900, or the QA program recommended by the image receptor manufacturer.

(C) Documentation of the tests and the corrective actions described in subparagraph (B) of this paragraph must be maintained as specified in subsection (x) of this section.

(5) Surveys. Annually, not to exceed 14 months from the date of the previous survey, each mammography system must undergo a survey by a medical physicist, or an individual under the direct supervision of a medical physicist, as specified in paragraphs (1) - (3) of this subsection.

(A) The medical physicist must provide a written survey report to the facility within 30 days of the date of the survey. The report must include a summary of the test performed, all test conditions, specifications, results, and recommendations for corrective actions.

(B) If any deficiencies require immediate corrective action as specified in paragraphs (1) - (3) of this subsection, the physicist must give a preliminary written report to the facility within 72 hours of the survey.

(C) The survey report must include the:

(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) The facility must maintain the survey report as specified in subsection (x) of this section.

(6) 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.

(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.

(8) 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 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, in the mammography energy range.

(9) Infection control. Facilities must establish and comply with a system specifying procedures for cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials. This system must specify the methods for documenting facility compliance with the infection control procedures established and must:

(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) Quality assurance - mammography medical outcomes audit. Each registrant must establish and maintain a mammography medical outcomes audit program to followup positive mammographic assessments and to correlate pathology results with the IP's findings. The program must be designed to ensure the reliability, clarity, and accuracy of the interpretation of mammograms.

(1) General requirements.

(A) Each facility must 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 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 outcome data must be made individually and collectively for all IPs at the facility and include determinations of the following.

(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 12 months of the facility becoming certified, and completed within the following 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 subsection (x) of this section.

(3) Reviewing interpreting physician. Each LIP or an interpreting physician designated by the LIP must review the medical outcomes audit data at least annually, not to exceed 12 months following the data collection period. This individual must analyze the results of the audit and is responsible for the following:

(A) recording the dates of the audit period;

(B) documenting the results;

(C) notifying other IPs of their results and the facility's collective results;

(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) Mammographic procedure and techniques for mammography of patients with breast implants. Each registrant must have a procedure to inquire if the patient has breast implants before the mammographic exam. Except where contraindicated, or unless modified by a physician's directions, patients with breast implants must have mammographic views to maximize the visualization of breast tissue.

(o) Complaints. Each accredited facility must 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 subsection (x) of this section;

(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) report unresolved serious complaints to the facility's AB within 30 days of receiving the complaint.

(p) Clinical image quality. Clinical images produced by any certified facility must continue to comply with the standards for clinical image quality established by the facility's AB.

(q) Additional mammography review, targeted clinical reviews, and patient notification.

(1) If the department believes the mammography quality at a facility is compromised and presents a serious risk to human health, the facility must provide clinical images and other relevant information, as specified by the department, for review by the AB. 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 determines the mammography quality at a facility has been compromised and presents a serious risk to human health, the facility must provide clinical images and other relevant information, as specified by the department, for review by the AB. The department may require such facility to notify patients who received mammograms and their referring healthcare provider. The notification must occur within a time frame and in a manner specified by the department. The notification must:

(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)The department, the AB or the FDA may request a targeted clinical image review.

(r) Self-referral mammography. Any person proposing to conduct a self-referral mammography program must not initiate such a program without prior approval from the department. When requesting such approval, the person must 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 and healthcare provider of the results of the mammography examination as specified in subsection (j)(4) of this section;

(B) follow-up with patients and healthcare provider as specified in subsection (j)(6) 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; and

(4) methods for educating mammography patients in breast self-examination techniques and on the necessity for follow-up by a physician.

(s) Medical research and investigational devices.

(1) Any research using radiation producing devices on humans must be approved by an IRB as required by 45 CFR Part 46 and 21 CFR Part 56. The IRB must include at least one licensed physician to direct any use of radiation as specified in §289.231(b) of this subchapter.

(2) Facilities with mammography machines with investigational device exemptions involved in clinical studies must comply with primary regulations governing the conduct of clinical studies and that apply to the manufacturers, sponsors, clinical investigators, institutional review boards, and the medical device. These regulations include:

(A) 21 CFR Part 50, Protection of Human Subjects;

(B) 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, Subpart C, Design Controls.

(t) Operating and safety procedures (OSP).

(1) Each facility must implement and maintain written OSP.

(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).

(2) Technique chart. A technique chart or manual must be provided and followed. It must be displayed in the vicinity of the control panel of each machine that specifies technique factors used for a patient's anatomical size.

(3) Receipt, transfer, and disposal of mammography machines. Each registrant must maintain records showing the receipt, transfer, and disposal of mammographic machines. These records must include the date of receipt, transfer, and disposal; the name and signature of the person making the record; and the manufacturer's model name and serial number from the control panel of the mammographic machine. Records must be maintained as specified in subsection (x) of this section for inspection by the department.

(4) Viewing system. Windows, mirrors, closed circuit television, or an equivalent system must be provided to permit the operator to continuously observe the patient during irradiation. The operator must be able to maintain verbal, visual, and aural contact with the patient.

(5) Exposure of an individual other than the patient. Only the staff and ancillary personnel required for the medical procedure or training may be in the room during the radiation exposure unless such individual's assistance is required.

(6) Protective devices. Protective devices must be utilized when required, as in paragraph (7) of this subsection.

(A) Protective devices must be of no less than 0.25 millimeter (mm) lead equivalent material.

(B) Protective devices, including aprons, gloves, and shields must 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 be replaced or removed from service until repaired. A record of this test must be made and maintained by the registrant as specified in subsection (x) of this section for inspection by the department.

(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 be used when the exam permits.

(B) If a patient or image receptor must be held by an individual during an exposure, the individual must be protected with appropriate shielding devices described in paragraph (6) of this subsection.

(C) The facility's written OSP specified in subsection (t) of this section must 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 be protected by not less than 0.25 mm lead equivalent material.

(8) Calibration, maintenance, and modifications. Each registrant must maintain records showing calibrations, maintenance, and modifications performed on each mammographic machine. These records must 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 be maintained as specified in subsection (x) of this section.

(v) Inspections. In addition to the requirements of §289.231(kk) of this subchapter, the following applies to inspections of mammography systems.

(1) The department may inspect each mammography system that receives a certification as specified in this chapter no later than the 60th day after the date the certification is issued.

(2) The department may inspect, at least once annually, each mammography system that receives a certification.

(3) To protect the public health, the department may conduct more frequent inspections than required by this subsection.

(4) The department may make reasonable attempts to coordinate inspections in this section with other inspections required as specified in this chapter for the facility where the mammography system is used.

(5) After each satisfactory inspection, the department issues a certificate of inspection for each mammography system inspected. The certificate of inspection must be posted at a conspicuous place on or near the place where the mammography system is used. The certificate of inspection includes the:

(A) specific identification of the mammography system inspected;

(B) name and address of the facility where the mammography system was used at the time of the inspection; and

(C) date of the inspection.

(6) Any severity level I violation involving a mammography system, determined by the department, as specified in §289.205 of this chapter, constitutes grounds for posting notice of failure of the mammography system to satisfy department requirements.

(A) Notification of such failure must 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 remain posted until the facility is authorized to remove it by the department. A facility may post documentation of corrections of the violations submitted to the department along with the notice of failure until approval to remove the notice of failure is received from the department.

(7) Facilities that receive a severity level I violation and are deemed a serious risk to human health must notify patients as specified in (q)(2) of this section.

(8) In addition to the requirements of paragraph (7) of this subsection, the department may require a facility to notify a patient of any other failure of the facility's mammography system to meet the department's certification standards.

(9) The patient notification must 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 make a record of the mammography patients notified as specified in paragraphs (7) and (8) of this subsection for inspection by the department.

(A) The record must 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 be maintained as specified in subsection (x) of this section.

(w) Requirements for interventional breast radiography machines.

(1) Interventional breast radiography machine certificate of registration (COR).

(A) A person who receives, possesses, uses, owns, or acquires an interventional breast radiography machine must apply for a certificate of registration as specified in §289.226(e) of this subchapter, relating to general requirements for application and registration, and must receive a COR from the department before using an interventional breast radiography machine on humans.

(B) An application for a COR must be signed by:

(i) a licensed physician, and

(ii) the RSO.

(C) An application for a COR 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 submit documentation of a survey performed by a medical physicist, as specified in paragraph (11) of this subsection.

(2) Issuance of a certificate of registration.

(A) A COR for interventional breast radiography machines will be issued if the department determines the application meets the requirements of the Act and this chapter. The COR authorizes the proposed operations and includes conditions and limitations the department deems necessary.

(B) Conditions. The department may incorporate in the COR at the time of issuance, or by amendment, additional requirements and conditions for the facility's possession, use, and transfer of radiation machines necessary to:

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

(ii) require additional reports and maintain additional records as necessary; and

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

(C) Additional information. The department may request additional information after the certification has been issued to enable the department to determine whether the certification should be modified as specified in §289.226(r) of this subchapter relating to renewal of a certificate of registration.

(3) Modification, suspension, or revocation of the certificate of registration. Modification, suspension, or revocation of the COR must occur as specified in §289.226(s) of this subchapter.

(4) Specific terms and conditions of the certificate of registration. Specific terms and conditions of the COR, as specified in §289.226 of this subchapter, must be followed.

(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) Responsibilities of registrant.

(A) In addition to the requirements of §289.226(m)(3) - (7) of this subchapter, a facility must notify the department in writing before any changes rendering the information in the application or the COR inaccurate, including the:

(i) name and mailing address;

(ii) street address where the interventional breast radiography machine will be used; and

(iii) addition or removal of any interventional breast radiography machine.

(B) If a facility makes a change in the RSO, the qualifications of the RSO must be submitted to the department within 30 days of such change.

(C) 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 documentation with a medical physicist's report as specified in paragraph (11) of this subsection, verifying compliance of the new interventional breast radiography machine with this section. The medical physicist's report is required before using the interventional breast radiography machine on patients.

(D) Loaner interventional breast radiography machines may be used on patients for 60 days without adding the interventional breast radiography machine to the COR. A medical physicist's report verifying compliance of the loaner interventional breast radiography machine with this section must be completed before use on patients. If the use period exceeds 60 days, the facility must add the interventional breast radiography machine to its certification and a fee will be assessed.

(9) Personnel requirements.

(A) An operator must maintain a current general certificate as required by the Medical Radiologic Technologist Certification Act, Texas Occupations Code Chapter 601.

(B) A medical physicist must maintain a current Texas license as required by the Medical Physics Practice Act, Texas Occupations Code Chapter 602, in diagnostic radiological physics and be registered with the department or employed by an entity registered with the department, as specified in §289.226(j) of this subchapter, relating to application for registration of radiation machine services, and the Act, unless exempted by §289.226(d)(7) of this subchapter, relating to exemptions.

(10) Requirements to have a written quality assurance program. Requirements to have a written QA program as described by the manufacturer or the medical physicist to ensure the safety, reliability, clarity, and accuracy of services performed at the facility must comply with the following.

(A) If any failures are noted, corrective actions must be taken within the time frame established by the manufacturer or medical physicist. If a time frame is not indicated, corrective action must be completed within 30 days of the failure.

(B) If any component tested fails the dosimetry test, the corrective action must be taken before any further interventional breast radiography examinations are performed.

(11) 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.

(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.

(C) The medical physicist must provide the facility with a preliminary written report of deficiencies within 72 hours of the survey if it involves dosimetry.

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(D) The medical physicist must 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:

(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 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) Operating and safety procedures (OSP). Each facility must have and implement written OSP that must 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:

(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) paragraph (9) of this subsection, related to credentialing requirements for operators and medical physicists;

(H) paragraph (19) 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; and

(J) subsection (u)(7) of this section, related to holding of patients or image receptors.

(13) Receipt, transfer, and disposal of interventional breast radiography machines. Each facility must maintain records showing the receipt, transfer, and disposal of interventional breast radiography machines. These records must be maintained as specified in subsection (x) of this section for inspection by the department and include the:

(A) date of receipt, transfer, or disposal;

(B) name and signature of the individual making the record; and

(C) manufacturer's model name and serial number on the control panel.

(14) Calibration, maintenance, and modifications. Each facility must 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 include the:

(A) date of the calibration, maintenance, or modification performed;

(B) name of the individual making the record; and

(C) manufacturer's model name and serial number on the control panel.

(15) Viewing system. Windows, mirrors, closed circuit television, or an equivalent system must be provided to permit the operator to continuously observe the patient during irradiation. The operator must maintain verbal, visual, and aural contact with the patient.

(16) Exposure of individuals other than the patient. Only the staff and ancillary personnel required for the medical procedure or training are allowed in the room during the radiation exposure unless such individual's assistance is required.

(17) Inspection requirements. Inspections of interventional breast radiography machines are specified in subsection (v)(2) - (4) of this section.

(18) Equipment requirements. Interventional breast radiography machines must meet the equipment requirements specified in §289.227(h) of this subchapter, relating to certified x-ray systems.

(19) Technique chart. A chart or manual must 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 patient's anatomical size. The technique chart must 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.

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(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).

Specific Subsection	Name of Record	Time Interval for Record Keeping
(h)(1)(A)	Interpreting Physician Qualifications	Until 2 years after terminating certification or 2 years after the physician becomes inactive at the facility
(h)(1)(C)	Interpreting Physician Continuing Education and Experience	6 years
(h)(1)(E)	Mandatory training for Interpreting Physician, if applicable	6 years
(h)(2)(A)	Medical Radiologic Technologist (MRT) Qualifications	Until 2 years after terminating certification or 2 years after the MRT becomes inactive at the facility.
(h)(2)(C)	Medical Radiologic Technologist Continuing Education and Experience	6 years
(h)(2)(E)	Mandatory training for Medical Radiologic Technologist, if applicable	6 years
(h)(3)(A)	Medical Physicist Qualifications	Until 2 years terminating certification or 2 years after the physicist becomes inactive at the facility
(h)(3)(C)	Medical Physicist Continuing Education and Experience	6 years
(i)(10)	FDA Variances	Until termination of certification or equipment is replaced
(k)(2)	Quality Assurance (QA) Records	Until the next annual inspection has been completed and the department has determined that the facility is compliant with the QA requirements or until the test has been performed two additional times at the required frequency, whichever is longer.

Figure: 25 TAC §289.230(x)(3)

Specific Subsection	Name of Record	Time Interval for Record Keeping
(l)(10)	Physicist Mammography Survey	7 years
(l)(11)	Physicist Mammography Equipment Evaluation	2 years
(m)(2)	Medical Outcomes Audit	2 years
(o)	Complaints	3 years
(t)(1)	Operating & Safety Procedures	Until termination of certification
(t)(5); (w)(13)	Records of Receipt, Transfer, and Disposal	Until termination of certification
(t)(8)(B)	Protective Devices Annual Check	3 years
(t)(10)	Records on Calibration, Maintenance and Modifications Performed on Mammography Machines	2 years
(t)(1)(A)	Current §§289.203, 289.204, 289.205, 289.226, 289.227, 289.230, and 289.231.	Until termination of certification
(k)(2)	Current Certification of Mammography Systems	Until termination of certification
(f)(2)	Current Accreditation of Mammography Systems	Until termination of certification
(v)(5)	Certification of Inspection	Until termination of certification
(v)(6)	Notice of Failure	Until termination of certification
(v)(7)	Patient Notification	Until termination of certification
(w)(14)	Records of Calibration, Maintenance, and Modifications Performed on Interventional Breast Radiography Machines	Until termination of certification