

25 TEXAS ADMINSTRATIVE CODE (TAC)

§289.234

Mammography Accreditation

Texas Regulations for Control of Radiation (revisions effective April 29, 2012 are shown as shaded text)

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§289.234. Mammography Accreditation.

(a) Purpose. This section provides for the accreditation of mammography machines and facilities. The use of all mammography machines accredited in accordance with this section shall be by or under the supervision of a physician licensed by the Texas Medical Board.

(b) Scope. In addition to the requirements of this section, all mammography machines and facilities are subject to the requirements of §289.204 of this title (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services), §289.205 of this title (relating to Hearing and Enforcement Procedures), §289.230 of this title (relating to Certification of Mammography Systems and Mammography Machines Used for Interventional Breast Radiography), and §289.231 of this title (relating to General Provisions and Standards for Protection Against Machine-Produced Radiation). This section does not apply to an entity under the jurisdiction of the federal government.

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

(1) Accreditation--An approval of a mammography machine within a mammography facility by an accreditation body. A facility may be accredited by the agency accreditation body or another United States Food and Drug Administration (FDA)-approved accreditation body.

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

(3) Additional mammography review--At the request of the FDA or an accreditation body, a review by the accreditation body of clinical images and other relevant facility information necessary to assess conformation with the accreditation standards. The reviews include the following:

(A) additional mammography review with interpretation; or

(B) additional mammography review without interpretation.

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

(A) poor image quality;

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

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(C) use of personnel who do not meet the applicable requirements of §289.230(r) of this title.

(5) Agency accreditation body--For the purpose of this section, the agency as approved by the FDA under Title 21, Code of Federal Regulations (CFR), §900.3(d), to accredit mammography facilities in the State of Texas.

(6) Agency certifying body--For the purpose of this section, the agency, as approved by FDA, under Title 21, CFR, §900.21, that certifies facilities within the State of Texas to perform mammography services.

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

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

(9) Consumer--An individual who chooses to comment or complain in reference to a mammography examination. The individual may be the patient or a representative of the patient, such as a family member or referring physician.

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

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

(B) processing of film;

(C) initial interpretation of the mammogram; or

(D) maintaining the viewing conditions for that interpretation.

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

(12) 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.

(13) Image review board--A group of qualified review physicians and other individuals who review the clinical and phantom images and whose qualifications have been established by the accreditation body and the accreditation body's qualifications have been approved by the FDA.

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(14) Interpreting physician--A licensed physician who interprets mammographic images and who meets the requirements of §289.230(r)(1) of this title.

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

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

(A) during invasive interventions for localization or biopsy procedures except as specified in §289.230(z) of this title; or

(B) with an investigational mammography device as part of a scientific study conducted in accordance with FDA's investigational device exemption regulations.

(17) Mammography machine(s)--A unit consisting of components assembled for the production of x-rays for use during mammography. These include, at a minimum, the following:

(A) an x-ray generator;

(B) an x-ray control;

(C) a tube housing assembly;

(D) a beam limiting device; and

(E) supporting structures.

(18) Mammography system--A system that includes the following:

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

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

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

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

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(E) a medical radiologic technologist who performs mammography; and

(F) a physician who engages in, and who meets the requirements of this section relating to the reading, evaluation, and interpretation of mammograms.

(19) Medical physicist--An individual who performs surveys and evaluations of mammographic equipment and facility quality assurance programs in accordance with this section and who meets the qualifications in §289.230(r)(3) of this title.

(20) Medical radiologic technologist (operator of equipment)--An individual specifically trained in the use of radiographic equipment and the positioning of patients for radiographic examinations, who performs mammography examinations in accordance with this section and who meets the qualifications in §289.230(r)(2) of this title.

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

(22) Phantom--A test object used to simulate radiographic characteristics of compressed breast tissue and containing components that radiographically model aspects of breast disease and cancer.

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

(24) Radiation machine--For the purposes of this part, radiation machine also means mammography machine.

(25) Reinstatement fee--The fee in accordance with §289.204(h) of this title charged to reinstate an application for a mammography machine that has been denied accreditation or whose application has been abandoned in accordance with subsection (h)(3) of this section.

(26) Review physician--An individual who is qualified to review clinical images on behalf of the accreditation body. To be qualified, this individual shall comply with the following:

(A) meet the interpreting physician requirements of §289.230(r)(1) of this title;

(B) be trained and evaluated in the clinical image review process for the types of clinical images to be evaluated by a review physician by the accreditation body before designation as a review physician and periodically thereafter; and

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(C) clearly document findings and reasons for assigning a particular score to any clinical image and provide information to the facility for use in improving the attributes for which significant deficiencies were identified.

(27) 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.

(28) Serious complaint--A report of a serious adverse event.

(29) Survey--An on-site physics consultation and evaluation of a facility quality assurance program performed by a medical physicist.

(30) Targeted clinical image review--A review of a minimum of two sets of "negative" clinical images from a specific date, or date range, at the request of the agency.

(d) Accreditation of mammography facilities.

(1) All mammography facilities shall be accredited by an FDA-approved accreditation body and shall meet the quality standards in §289.230(r)-(aa) of this title. In order to qualify for certification in accordance with §289.230 of this title, new facilities applying to the agency accreditation body shall receive acceptance of the accreditation application.

(2) The facility shall submit the following information in addition to the information required in subsection §289.230(f) of this title:

(A) an application for accreditation on forms and in accordance with accompanying instructions prescribed by the agency accreditation body;

(B) the appropriate accreditation fee prescribed in §289.204 of this title;
and

(C) evidence that the medical physicist's survey and mammography equipment evaluation in accordance with §289.230(v)(10) and (11) of this title was performed within the following time frames:

(i) no more than six months before the date of the accreditation application for new facilities seeking accreditation;

(ii) no more than 14 months before the date of the application for accreditation for facilities changing accreditation to one issued by the agency accreditation body;
or

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(iii) no more than 14 months before the date of the application for renewal of accreditation for facilities accredited by the agency accreditation body.

(3) Upon notification by the agency accreditation body, each applicant shall submit clinical and phantom images directly to the image review board.

(e) Issuance of accreditation of a mammography facility. An accreditation document will be issued when the mammography facility meets the requirements of subsection (d) of this section and §289.204 of this title and becomes accredited by the agency accreditation body. In order for an accreditation to be issued, the agency accreditation body must receive acceptable dose evaluation information from the dosimetry processor and be notified by the image review board that the applicant met the criteria for clinical images and phantom images, and dose evaluation.

(f) Denial or abandonment of an application for accreditation of mammography facilities.

(1) Any application for accreditation may be denied by the agency accreditation body when the applicant fails to meet established criteria for accreditation in accordance with subsection (d) of this section.

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

(3) Action on an accreditation application will be abandoned due to lack of response by the applicant to a request for information by the agency accreditation body. Abandonment of such actions does not provide an opportunity for a hearing; however, the applicant retains the right to resubmit the application and pay a reinstatement fee at any time.

(g) Suspension and revocation of accreditation of mammography facilities.

(1) Suspension of accreditation of mammography facilities.

(A) An accreditation of a mammography facility may be suspended or revoked for any of the following reasons:

(i) any material false statement in the application or any statement of fact required under provision of the Act;

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(ii) conditions revealed by such application or statement of fact or any report, record, inspection, or other means that would warrant the agency accreditation body to refuse to grant an accreditation of mammography facility on an original application; or

(iii) failure to observe any of the terms and conditions of the Act, this chapter, or order of the agency.

(B) Before the agency accreditation body suspends or revokes an accreditation of a mammography facility, the agency accreditation body shall give notice by personal service or by certified mail, addressed to the last known address, of the facts or conduct alleged to warrant the suspension or revocation by complaint, and order the accredited mammography facility to show cause why the mammography facility accreditation should not be suspended or revoked. The accredited mammography facility shall be given an opportunity to request a hearing on the matter no later than 30 days after receipt of the notice.

(C) Any accredited mammography facility against whom the agency accreditation body contemplates an action described in subparagraph (A) of this paragraph may request a hearing by writing the director within 30 days of receipt of the notice.

(i) The written request for a hearing must contain the following:

(I) a statement requesting a hearing; and

(II) the name, address, and identification number of the accredited mammography facility against whom the action is being taken.

(ii) Failure to submit a written request for a hearing within 30 days will render the agency accreditation body action final.

(D) If the agency accreditation body suspends the accreditation of a mammography facility in accordance with subparagraph (A) of this paragraph, the suspension shall remain in effect until the agency accreditation body determines the following:

(i) that allegations of violations or misconduct were not substantiated;

(ii) that violations of required standards have been corrected to the agency accreditation body's satisfaction; or

(iii) the facility's accreditation is revoked in accordance with §289.205 of this title.

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(2) Revocation of accreditation of mammography facilities shall be in accordance with §289.205(g) of this title.

(h) Appeal of adverse accreditation or reaccreditation decisions that preclude certification or recertification.

(1) The appeal process described in this subsection is available only for adverse accreditation or reaccreditation decisions that preclude certification by the agency certifying body. Agency certifying body decisions to suspend or revoke certificates that are already in effect will be handled in accordance with §289.230(h) of this title.

(2) A facility that has been denied accreditation or reaccreditation is entitled to an appeals process from the agency accreditation body, in accordance with §289.205 of this title. A facility must avail itself of the accreditation body's appeal process before requesting reconsideration from the agency certifying body.

(3) A facility that cannot achieve satisfactory resolution of an adverse accreditation decision through the accreditation body's appeal process is entitled to further appeal to the FDA.

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

(i) Specific terms and conditions of accreditation of mammography facilities.

(1) Each accreditation document issued in accordance with this section shall be subject to the applicable provisions of the Act, now or hereafter in effect, and to the applicable requirements and orders of the agency accreditation body.

(2) No accreditation document issued by the agency accreditation body under this section shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, to any person.

(j) Responsibilities of an accredited facility. A facility shall notify the agency accreditation body of any changes that would render the information contained in the application inaccurate.

(k) Expiration and renewal of accreditation of mammography facilities.

(1) The accreditation expires at the end of the day in the month and year stated on the accreditation document.

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(2) An application for renewal of accreditation with the agency accreditation body shall be filed in accordance with subsection (d) of this section and with fees in accordance with §289.204 of this title.

(3) A mammography facility filing an application for renewal in accordance with subsection (d) of this section and with fees in accordance with §289.204 of this title before the existing accreditation expires, may continue to perform mammography until the review process is complete and the accreditation status has been determined by the agency accreditation body.

(4) Accreditation for a mammographic facility is valid for three years from the date of issuance, unless accreditation of the facility is suspended or revoked prior to such deadline.

(5) Issuance of renewal of accreditation shall be in accordance with subsection (e) of this section.

(l) Complaints. Each facility accredited by the agency accreditation body shall do the following:

(1) establish a written procedure for collecting and resolving consumer complaints;

(2) maintain a record of each serious complaint received by the facility in accordance with §289.230(ee)(3) of this title; and

(3) report unresolved serious complaints to the accreditation body within 30 days of receiving the complaint.

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

(n) Additional mammography review and patient notification. If the agency certifying body or the agency accreditation body believes that mammography quality at a facility may have been compromised and presents a serious risk to human health, the facility shall provide clinical images and other relevant information, as specified by the agency certifying body or the agency accreditation body for review by the accreditation body.

(o) Record requirements. Records required by this section shall be maintained for inspection by the agency in accordance with §289.230(ee)(3) of this title. Records may be maintained electronically in accordance with §289.231(ff)(3) of this title.

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(p) On-site facility visit, targeted clinical image review, and random clinical image review.

(1) Each accredited facility shall afford the agency accreditation body, at all reasonable times, **an** opportunity to audit the facility where mammography equipment or associated equipment is used or stored.

(2) Each accredited facility shall make available to the agency accreditation body for inspection, upon reasonable notice, records maintained in accordance with this chapter.

(3) Each accredited facility shall, upon request by the agency accreditation body or the agency certifying body, make clinical images available to the image review board for a targeted clinical image review or a random clinical image review. The agency certifying body, the agency accreditation body, another FDA-approved accreditation body, or the FDA may request a targeted clinical image review due to, but not limited to, serious complaints or severe items of non-compliance.

(4) Annually, the agency accreditation body shall conduct on-site visits and random clinical image reviews of a sample of facilities to monitor and assess their compliance with standards established by the accreditation body. Other on-site visits may be conducted based on problems identified through inspections, serious complaints received from consumers or others, a previous history of noncompliance, or any other information in the possession of the accreditation body, inspectors, or FDA.