

25 TEXAS ADMINISTRATIVE CODE (TAC)

§289.230

**Certification of Mammography Systems and Mammography Machines
Used for Interventional Breast Radiography**

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

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25 TEXAS ADMINISTRATIVE CODE

§289.230. Certification of Mammography Systems and Mammography Machines Used for Interventional Breast Radiography.

(a) Purpose.

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

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

(b) Scope.

(1) In addition to the requirements of this section, all registrants are subject to the requirements of §289.203 of this title (relating to Notices, Instructions, and Reports to Workers; Inspections), §289.204 of this title (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services), §289.205 of this title (relating to Hearing and Enforcement Procedures), §289.226 of this title (relating to Registration of Radiation Machine Use and Services), and §289.231 of this title (relating to General Provisions and Standards for Protection Against Machine-Produced Radiation). Mammography facilities choosing to be accredited by the agency accreditation body will be subject to §289.234 of this title (relating to Mammography Accreditation).

(2) The procedures found in §289.205 of this title for modifications, suspensions, revocations, denials, and hearings regarding certificates of registration are applicable to certifications issued by the agency.

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

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

(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 FDA-approved accreditation body.

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

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

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

(A) clinical image review with interpretation; or

(B) clinical image review without interpretation.

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

(A) poor image quality;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(21) Direct instruction--Instruction that includes:

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

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

(22) Direct supervision--Oversight of operations that include the following.

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

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

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

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

(24) 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.

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

(26) Final assessment categories--The overall final assessment of findings in a report of a mammography examination, classified in one of the following categories:

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

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

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

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

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

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

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

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

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

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

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

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

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

(32) Institutional review board (IRB)--Any board, committee, or other group formally designated by an institution to review, approve the initiation of, and conduct periodic review of biomedical research involving human subjects.

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

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

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

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

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

(38) Lead interpreting physician--The interpreting physician assigned the general responsibility for ensuring that a facility's quality assurance program meets all of the requirements of subsections (u), (v), and (w) of this section.

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

(40) Mammographic modality--A technology for radiography of the breast. Examples are screen-film mammography and full-field digital mammography.

(41) 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 subsection (gg) of this section; or

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

(42) 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.

(43) Mammography medical outcomes audit--A systematic collection of mammography results compared with outcomes data.

(44) 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;

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

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

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

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

(47) 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 subsection (r)(3) of this section.

(48) 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 subsection (r)(2) of this section.

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

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

(51) Optical density (OD)--A measure of the fraction of incident light transmitted through a developed film and defined by the equation:

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

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

(52) 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.

(53) 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.

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

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

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

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

(58) Provisional certification--A provisional authorization described in subsection (g) of this section.

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

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

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

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

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

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

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

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

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

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

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

(d) Prohibitions.

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

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

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

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

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

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

(e) Exemptions.

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

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

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

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

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

(f) Requirements for mammography systems certification.

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

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(2) Each person having a mammography machine shall submit an application in accordance with §289.226(e)(1)-(3) and (5)-(7) and (f)(4)-(5) of this title, and receive certification from the agency certifying body before beginning use of the mammography machine on humans.

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

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

(5) Each applicant shall submit documentation of the following:

(A) personnel qualifications, including dates of licensure or certification, in accordance with subsection (r) of this section;

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

(C) evidence that a medical physicist:

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

(ii) has performed a survey and a mammography equipment evaluation in accordance with subsection (v)(10) and (11) of this section; and

(iii) has determined that the average glandular dose for one craniocaudal-caudal view for each machine does not exceed the value in subsection (v)(5)(F) of this section;

(D) self-referral program information in accordance with subsection **(bb)** of this section, if the facility offers self-referral mammography; and

(E) items required for authorization of a mobile service operation in accordance with §289.226(g) of this title, if the facility provides a mobile service.

(g) Issuance of certification and provisional certification.

(1) Certification. A certification will be issued if the agency certifying body determines that an application meets the requirements of the Act and the requirements of this chapter. The certification authorizes the proposed activity in such form and contains such conditions and limitations as the agency certifying body deems appropriate or necessary. The certification may include **one of the following**:

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

(B) certification of **interventional breast radiography machines**.

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

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

(B) require additional reports and the keeping of additional records as may be appropriate or necessary; and

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

(3) Additional information. The agency certifying body may request, and the registrant shall provide, additional information after the certification has been issued to enable the agency certifying body to determine whether the certification should be modified in accordance with §289.226(r) of this title.

(4) Provisional certification application. A new facility is eligible to apply for a provisional certification. The provisional certification will enable the facility to perform mammography and to obtain the clinical images needed to complete the accreditation process. To apply for and receive a provisional certification, a facility must meet the requirements of this chapter and submit the necessary information to an FDA-approved accreditation body. If the facility chooses to be accredited by the agency accreditation body, the facility shall submit the information required in subsection (f) of this section and §289.234(d) of this title to the agency accreditation body.

(5) Issuing provisional certifications. Following the agency certifying body's receipt of the accreditation body's decision that a facility has submitted the required information, the agency certifying body may issue a provisional certification to a facility upon determination that the facility has satisfied the requirements of the Act and this chapter. A provisional certification shall be effective for up to six months from the date of issuance. A provisional certification cannot be renewed, but a facility may apply for a 90-day extension of the provisional certification.

(6) Extension of provisional certification. Extension of provisional certifications shall be in accordance with the following.

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

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

(C) There can be no renewal of a provisional certification beyond the 90-day extension.

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

(A) Unless prohibited from reinstatement under subsection (h)(5) of this section, a facility applying for reinstatement shall:

(i) contact an FDA-approved accreditation body for reapplication for accreditation;

(ii) fully document its history as a previously provisionally certified or certified mammography facility, including the following information:

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

(II) name of previous owner/lessor;

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

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

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

(B) The agency certifying body may issue a provisional certification to the facility if the agency determines that the facility:

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

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

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

(h) Suspension or revocation of certification.

(1) Except as provided in paragraph (2) of this subsection, the agency certifying body may suspend or revoke a certification issued by the agency certification body if it finds, after providing the owner or operator of the facility with notice and opportunity for a hearing in accordance with §289.205 of this title, that the owner, operator, or any employee of the facility:

(A) has been guilty of misrepresentation in obtaining the certification;

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

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

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

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

(F) has failed to comply with prior sanctions imposed by the agency certifying body under §289.205 of this title.

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(2) The agency certifying body may suspend a certification of a facility before holding a hearing if it makes a finding described in paragraph (1) of this subsection and also determines that:

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

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

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

(3) If the agency certifying body suspends a certification in accordance with paragraph (2) of this subsection:

(A) the agency certifying body shall provide the facility with an opportunity for a hearing under §289.205 not later than 60 days from the effective date of this suspension; and

(B) the suspension shall remain in effect until the agency certifying body determines that:

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

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

(iii) the certification is revoked in accordance with paragraph (4) of this section.

(4) After providing a hearing in accordance with paragraph (3)(A) of this subsection, the agency certifying body may revoke the certification if the agency determines that the facility:

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

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

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

§289.230(i)

(i) 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 subsection (h) of this section.

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

(3) A facility that has been denied accreditation or reaccreditation and cannot achieve satisfactory resolution of an adverse accreditation decision through the FDA-approved 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.

(j) Denial of certification.

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

(A) the facility will not be operated in accordance with the provisions of subsections (r)-(aa) of this section;

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

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

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

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

(2) Before the agency certification body denies an application for certification, 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.

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

(k) Appeals of denial of certification.

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

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

(l) Modification of certification. Modification of certification shall be in accordance with §289.226(r) of this title.

(m) Specific terms and conditions of certification. Specific terms and conditions of certification shall be in accordance with §289.226(l) of this title.

(n) Responsibilities of registrant.

(1) In addition to the requirements of §289.226(m)(3)-(7) of this title, a registrant shall notify the agency certifying body in writing prior to any changes that would render the information contained in the application or the certification inaccurate. These include but are not limited to the following:

(A) name and mailing address;

(B) street address where machine(s) will be used; and

(C) mammography machines.

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

(A) radiation safety officer;

(B) lead interpreting physician;

(C) interpreting physicians;

(D) medical radiologic technologists; or

(E) medical physicist.

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

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

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

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

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

(o) Renewal of certification.

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

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

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

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

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

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

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

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

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

(p) Expiration of certification.

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

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

(A) terminate use of all mammography machines;

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

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

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

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

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

(2) request termination of the certification in writing;

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

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

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

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

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

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

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

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

(iii) have interpreted or multi-read, under the direct supervision of an interpreting physician, at least 240 mammographic examinations within the six-month period immediately prior to the date that the physician qualifies as an interpreting physician.

(B) Exemptions.

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

(ii) Physicians who have interpreted or multi-read at least 240 mammographic examinations under the direct supervision of an interpreting physician 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.

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

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

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

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

(III) any date in between the two;

(ii) interpreting or multi-reading at least 960 mammographic examinations that must be completed during the 24 months immediately preceding:

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

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

(III) any date in between the two; and

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

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

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

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

(I) at least 240 mammographic examinations; or

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

(E) Additional mandatory training. Additional mandatory training may be required by the agency based on the recommendations of the American College of Radiology or the FDA. Such training will be developed on a case by case basis.

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

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

(iii) Records of all additional mandatory training shall be maintained by the registrant for inspection by the agency in accordance with subsection (ee)(3) of this section.

(2) Medical radiologic technologists (operators of equipment). Each person performing mammographic examinations shall have current certification as a medical radiologic technologist under the Medical Radiologic Technologist Certification Act, Texas Occupations Code, Chapter 601, and shall meet the following qualifications.

(A) Initial requirements. Before performing mammographic examinations, the operator of equipment shall have:

(i) completed a minimum of 40 contact hours of training as outlined in subsection (hh)(1) of this section by a qualified instructor; and

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

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

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

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

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

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

(III) any date in between the two;

(ii) performing a minimum of 200 mammographic examinations that must be completed during the 24 months immediately preceding:

(I) the facility's annual inspection;

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

(III) any date in between the two; and

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

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

(i) obtaining a sufficient number of additional CEUs to bring their total up to the 15 CEU credits required in the previous 36 months, at least six of which shall be related to each modality used by the technologist in mammography; and/or

(ii) performing a minimum of 25 mammographic examinations under the direct supervision of a qualified medical radiologic technologist.

(E) Additional mandatory training. Additional mandatory training may be required by the agency based on the recommendations of the American College of Radiology or the FDA. Such training will be developed on a case by case basis.

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

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

(iii) Records of all additional mandatory training shall be maintained by the registrant for inspection by the agency in accordance with subsection (ee)(3) of this section.

(3) Medical physicist. Each medical physicist performing mammographic surveys, evaluating mammographic equipment, or providing oversight of the facility quality assurance program in accordance with subsection (u) of this section, shall hold a current Texas license under the Medical Physics Practice Act, Texas Occupations Code, Chapter 602, in diagnostic radiological physics and be registered with the agency or employed by an entity registered with the agency, in accordance with §289.226(j) of this title and the Act, unless exempted by §289.226(d)(6) of this title. Each medical physicist shall meet the following qualifications.

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

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

(ii) have 20 contact hours of documented specialized training in conducting surveys of mammography facilities; and

(iii) have experience conducting surveys of at least one mammography facility and a total of at least ten mammography machines. After April 28, 1999, experience conducting surveys must be acquired under the direct supervision of a medical physicist who meets the requirements of subparagraphs (A) and (C) 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 in accordance with the requirements of this section that were in effect prior to April 28, 1999, or any other equivalent state or federal requirements in effect prior to April 28, 1999, and have met the following additional qualifications prior to April 28, 1999, are determined to have met the initial qualifications of subparagraph (A) of this paragraph:

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

(ii) 40 contact hours of documented specialized training in conducting surveys of mammography facilities; and

(iii) experience conducting surveys of at least one mammography facility and a total of at least 20 mammography machines. No more than one survey of a specific machine within a period of 60 days can be counted towards the total mammography machine survey requirement. The training and experience requirements must be met after fulfilling the degree requirements.

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

(i) participating in education programs, either by teaching or completing at least 15 CEUs in mammography that shall include hours of training appropriate to each mammographic modality evaluated by the medical physicist during his or her surveys. CEUs earned through teaching a specific course can be counted only once during the 36-month period. The continuing education must be completed in the 36 months immediately preceding:

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

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

(III) any date in between the two;

(ii) performing surveys of two mammography facilities and a total of at least six mammography machines (no more than one survey of a specific facility within a ten-month period or a specific machine within a period of 60 days can be counted towards the total mammography machine survey requirement). The continuing experience must be completed during the 24 months immediately preceding:

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

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

(III) any date in between the two; and

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

(D) Re-establishing qualifications. Before resuming independent performance of surveys and equipment evaluations, medical physicists who fail to maintain the continuing education or experience requirements shall reestablish their qualifications by completing one or both of the following requirements, as applicable:

(i) obtaining a sufficient number of additional CEUs to bring their total up to the 15 CEU credits required in the previous 36 months; and/or

(ii) performing a sufficient number of surveys, under the direct supervision of a qualified medical physicist, to bring their total up to two mammography facilities and a total of at least six mammography machines for the prior 24 months. No more than one survey of a specific machine within a period of 60 days shall be counted towards the total mammography machine survey requirement.

(4) Retention of personnel records. Records documenting the qualifications, continuing education, and experience of personnel in subsection (r)(1) - (3) shall be maintained for inspection by the agency in accordance with subsection (ee) of this section.

(s) Equipment standards. Only systems meeting the following standards shall be used.

(1) System design. The equipment shall have been specifically designed and manufactured for mammography and in accordance with Title 21, CFR, §§1010.2, 1020.30, and 1020.31.

(2) Motion of tube-image receptor assembly. The assembly shall be capable of being fixed in any position where it is designed to operate. Once fixed in any such position, it shall not undergo unintended motion. In the event of power interruption, this mechanism shall not fail.

(3) Image receptors. Systems using screen-film image receptors shall, at a minimum, provide for the following:

(A) operation with image receptors of 18 x 24 cm and 24 x 30 cm;

(B) operable moving grids matched to all image receptor sizes provided;

(C) operation with the grid removed from between the source and image receptor for systems used for magnification procedures; and

(D) image receptors to rest, post-loading, 15 minutes between exposures.

(4) Magnification. Systems used to perform noninterventional problem solving procedures shall have radiographic magnification capability available for use with, at a minimum, at least one magnification value within the range of 1.4 to 2.0.

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

(A) When more than one focal spot is provided, the system shall indicate, prior to exposure, which focal spot is selected.

(B) When more than one target material is provided, the system shall indicate, prior to exposure, the preselected target material.

(C) When the target material and/or focal spot is selected by a system algorithm that is based on the exposure or on a test exposure, the system shall display, after the exposure, the target material and/or focal spot actually used during the exposure.

(6) Compression. All mammography systems shall incorporate a compression device.

(A) Application of compression. Effective October 28, 2002, and thereafter, each system shall provide the following features operable from both sides of the patient:

(i) an initial power-driven compression activated by hands-free controls; and

(ii) fine adjustment compression controls.

(B) Compression paddle.

(i) Systems shall be equipped with different sized compression paddles that match the sizes of all full-field image receptors provided for the system.

(ii) Compression paddles for special purposes, including those smaller than the full size of the image receptor (for example, spot compression) may be provided. Such paddles are not subject to the requirements of clauses (v) and (vi) of this subparagraph.

(iii) Except as provided in clause (iv) of this subparagraph, the compression paddle shall be flat and parallel to the breast support table and shall not deflect from parallel by more than 1.0 cm at any point on the surface of the compression paddle when compression is applied.

(iv) Equipment intended by the manufacturer's design to not be flat and parallel to the breast support table during compression shall meet the manufacturer's design specifications and maintenance requirements.

(v) The chest wall edge of the compression paddle shall be straight and parallel to the edge of the image receptor.

(vi) The chest wall edge may be bent upward to allow for patient comfort, but shall not appear on the image.

(7) Technique factor selection and display. Technique factor selection and display shall be as follows.

(A) Manual selection of milliamperere seconds (mAs) or at least one of its component parts, milliamperere (mA) and/or time, shall be available.

(B) The technique factors (peak tube potential in kilovolts (kV) and either tube current in mA and exposure time in seconds or the product of tube current and exposure time in mAs) to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure control (AEC) is used, in which case the technique factors that are set prior to the exposure shall be indicated.

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

(8) Automatic exposure control. Each screen-film system shall provide an AEC mode that is operable in all combinations of equipment configuration provided, for example, contact, magnification, and various image receptor sizes.

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

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

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

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

(9) X-ray film. The registrant shall use x-ray film for mammography that has been designated by the film manufacturer as appropriate for mammography.

(10) Intensifying screens. The registrant shall use intensifying screens for mammography that have been designated by the screen manufacturer as appropriate for mammography and shall use film that is matched to the screen's spectral output as specified by the manufacturer.

(11) Film processing solutions. For processing mammography films, the registrant shall use chemical solutions that are capable of developing the films used by the facility in a manner equivalent to the minimum requirements specified by the film manufacturer.

(12) Lighting. The registrant shall make available special lights for film illumination (hot lights) capable of producing light levels greater than that provided by the view box.

(13) Film masking devices. Registrants shall ensure that film masking devices that can limit the illuminated area to a region equal to or smaller than the exposed portion of the film are available to all interpreting physicians interpreting for the facility.

(14) Equipment variances. Registrants with mammography equipment that has been issued variances by FDA to Title 21, CFR, §§1020.2, 1020.30, 1020.31, or has had an alternative for a quality standard for equipment approved by the FDA under the provisions of Title 21, CFR, §900.18, shall maintain copies of those variances or alternative standards.

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

(t) Medical records and mammography reports.

(1) Contents and terminology. Each registrant shall prepare a written report of the results of each mammography examination that shall include the following information:

(A) name of the patient and **date of birth**;

(B) date of the examination;

(C) name and signature of the interpreting physician who interpreted the mammogram (electronic signatures are acceptable);

(D) overall final assessment of findings using the final assessment categories as defined in subsection (c) of this section; and

(E) recommendations made to the physician about what additional actions, if any, should be taken. All clinical questions raised by the referring physician shall be addressed in the report to the extent possible, even if the assessment is negative or benign.

(2) Communication of mammography results to the patient and health care providers or physicians, as applicable. Each registrant shall send reports as soon as possible, but no later than 30 days from the date of the mammography examination, to:

(A) patients advising them of the results of the mammography examination and any further medical needs indicated. The report shall include a summary written in language easily understood by a lay person; and

(B) referring physicians, or in the case of self-referral, to the physician indicated by the patient, advising them of the results of the mammography examination, containing the information specified in paragraph (1) of this subsection, and any further medical needs indicated.

(3) Follow-up with patients and physicians. Each registrant shall follow-up to confirm the following:

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

(B) that physicians have received proper notification of patients with positive findings or needing repeat exams.

(4) Retention of clinical images for current, closed or terminated registrants.

(A) Each registrant that performs mammograms shall maintain mammography films and reports in a permanent medical record for a minimum of five years. If no additional mammograms of the patient are performed at the facility, the films and reports shall be maintained for a minimum of ten years.

(B) Each registrant that performs mammograms shall, within 30 days of request by or on behalf of the patient, permanently or temporarily transfer the original mammograms and copies of the patient's reports to a medical institution, a physician, or to the patient directly.

(C) If the medical records are permanently forwarded, the receiving institution or physician shall maintain and become responsible for the original film until the fifth or tenth anniversary, as specified in subparagraph (A) of this paragraph.

(D) Upon closure or termination, the registrant shall maintain the mammography films for 5 years. If the facility complies with the following:

(i) within 180 days of closing, the registrant shall directly notify each patient or patient's representative with instructions on how to retrieve or authorize disposal of the patient's records; and

(ii) within 60 days of closing, the registrant shall publish a notice in one or more newspapers covering the geographical area served by the closing facility. The notice shall include:

(I) contact information on retrieving patient records; and

(II) information that the records will be destroyed if not retrieved by the patient or the patient's representative within 5 years; and

(iii) if records have not been retrieved by the patient or the patient's representative following the 5-year period after closing, the registrant may destroy the records.

(5) Mammographic image identification. Each mammographic image shall have the following information indicated on it in a permanent, legible manner and placed so as not to obscure anatomic structures:

(A) name of patient and date of birth;

(B) date of examination;

(C) view and laterality (this information shall be placed on the image in a position near the axilla);

(D) facility name and location (at a minimum the location shall include city, state, and zip code);

(E) technologist identification;

(F) cassette/screen identification; and

(G) mammography machine identification if there is more than one machine in the facility.

(6) Information shall also be maintained for each clinical image by utilizing a label on each film, recording on the film jacket, or maintaining a log or other means. The information shall include, but is not limited to, compressed breast thickness or degree of compression, and kVp.

(u) Quality assurance - general. Each registrant shall establish and maintain a written quality assurance program to ensure the safety, reliability, clarity, and accuracy of mammography services performed at the mammography facility, including corrective actions to be taken if images are of poor quality.

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

(A) Lead interpreting physician. The registrant shall identify a lead interpreting physician who shall have the general responsibility of:

(i) ensuring that the quality assurance program meets all requirements of this subsection and subsections (v) and (w) of this section;

(ii) reviewing and documenting the technologists' quality control test results at least every three months or more frequently if consistency has not yet been achieved;

(iii) reviewing the physicists' results within 60 days of the receipt of the results or more frequently when needed; and

(iv) assigning and determining the individual's qualifications to perform the quality assurance tasks in subparagraphs (B)-(D) of this paragraph.

(B) Interpreting physicians. All interpreting physicians interpreting mammograms for the registrant shall:

(i) follow the registrant's procedures for corrective action when the images they are asked to interpret are of poor quality. These procedures shall be included in the facility's operating and safety procedures; and

(ii) participate in the medical outcomes audit program.

(C) Medical physicist. Each registrant shall use the services of a licensed medical physicist to survey mammography equipment and oversee the equipment-related quality assurance practices of the facility. At a minimum, the medical physicist shall be responsible for performing the surveys and the mammography equipment evaluations and providing the facility with the reports described in subsection (v)(10) and (11) of this section.

(D) Quality control technologist. The quality control technologist, designated by the lead interpreting physician, shall ensure performance of the items designated in subsection (v)(1)-(4), (7)-(9), (12), and (14) of this section. If other personnel are assigned the quality assurance tasks in accordance with subparagraph (A)(iv) of this paragraph, the quality control technologist shall insure that the requirements of subsection (v)(1)-(4), (7)-(9), (12), and (14) of this section are met.

(2) Quality assurance records. The lead interpreting physician, quality control technologist, and medical physicist shall ensure that records concerning mammography technique and procedures, quality control (include monitoring data, corrective actions, and the effectiveness of the corrective actions), safety, protection, and employee qualifications to meet assigned quality assurance tasks are properly maintained and updated. These quality control records shall be kept for each test specified in subsections (v) and (w) of this section, in accordance with subsection (ee) of this section.

(v) Quality assurance - equipment. Registrants with screen-film systems shall perform the following quality control tests at the intervals specified. In addition to the intervals specified in paragraphs (4)(B) and (5)(H) of this subsection, the tests shall be performed prior to initial use.

(1) Daily quality control tests. Film processors used to develop mammograms shall be adjusted and maintained to meet the technical development specifications for the mammography film in use. A processor performance test shall be completed and the results charted on each day that clinical films are processed before any clinical films are processed that day.

(A) Processor performance test. Using mammography film used clinically at the facility, sensitometer tests shall include assessment of the following:

(i) base plus fog density that shall be within plus 0.03 of the established operating level;

(ii) mid-density that shall be within plus or minus 0.15 of the established operating level; and

(iii) density difference that shall be within plus or minus 0.15 of the established operating level.

(B) Film processors being used for mammography at multiple locations, such as a mobile service operation, shall be subject to the requirements of this paragraph.

(C) Film processors utilized for mammography shall be adjusted to and operated at the specifications recommended by the mammographic film manufacturer, or at other settings such that the sensitometric performance is at least equivalent.

(D) Each registrant shall utilize the same film processor for clinical and phantom images. Clinical images shall be processed within an interval not to exceed 24 hours from the time the first clinical image is taken. Facilities utilizing batch processing shall do the following:

(i) use a container to transport clinical images that will protect the film from exposure to light and radiation; and

(ii) maintain a log to include each patient name and unique identification number, date, and time of the first exam of each batch, and date and time of batch development.

(2) Weekly quality control tests. These tests shall be performed at an interval no greater than seven days. If mammography is not being performed on the date the test is due and more than seven days have past since the last test, the tests shall be performed prior to resuming mammography. An image quality evaluation test, using an FDA-accepted phantom, shall meet the following parameters.

(A) The optical density of the film at the center of an image of a standard FDA-accepted phantom shall be at least 1.20 when exposed under a typical clinical condition and shall not change by more than plus or minus 0.20 from the established operating level.

(B) The density difference between the background of the phantom and an added test object, used to assess image contrast, shall be measured and shall not vary by more than plus or minus 0.05 from the established operating level.

(C) The phantom image shall be made on the standard mammographic film in use at the facility with techniques used for clinical images of a standard breast. The phantom image shall meet the requirements in subparagraphs (A) and (B) of this paragraph and clause (i) of this subparagraph. No mammograms shall be taken on patients if any of these minimums are not met.

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(i) The mammographic machine shall be capable of producing images of the mammographic phantom in accordance with the phantom image scoring protocol in subsection (hh)(4) of this section or paragraph (7) of this subsection.

(ii) Each phantom image and a record of the evaluation of that image shall be maintained at the location where the mammography image was produced or with the radiographic equipment for mobile service operations.

(3) Quarterly quality control tests. These tests shall be performed within the calendar quarter at an interval not to exceed 90 days.

(A) Fixer retention in film. The residual fixer shall be no more than 5 micrograms per square cm.

(B) Repeat analysis. A repeat analysis on clinical images repeated or rejected shall be performed, analyzed, and documented. The total repeat or reject rate shall not exceed 5.0%. If the total repeat or reject rate changes from the previously determined rate by more than 2.0% of the total films included in the analysis, the reason(s) for the change shall be determined. Corrective action shall be taken and documented if the total repeat or reject rate for the facility exceeds 5.0% or changes from the previously determined rate by more than 2.0% of the total films included in the analysis. Test films, cleared films, or film processed as a result of exposure of a film bin are not to be included in the count for repeat analysis. Films included in the repeat analysis are not required to be kept after completion of the analysis.

(4) Semiannual quality control tests. These tests shall be performed at an interval not to exceed six months.

(A) Darkroom fog. The optical density attributable to darkroom fog shall not exceed 0.05 when a mammography film of the type used in the facility, which has a mid-density of no less than 1.2 OD, is exposed to typical darkroom conditions for two minutes while such film is placed on the counter top, emulsion side up. If the darkroom has a safelight used for mammography film, it shall be on during this test.

(B) Screen-film contact. Testing for screen-film contact shall be conducted using 40 mesh copper screen. The entire area of the cassette that may be clinically exposed shall be tested. This shall include all cassettes used for mammography in the facility.

(C) Compression device performance. The maximum compression force for the initial power drive shall be between 25 pounds and 45 pounds. The system shall be capable of compressing the breast with a force of at least 25 pounds and shall be capable of maintaining this compression for at least 15 seconds.

(5) Annual quality control tests. These tests shall be performed at an interval not to exceed (14) months.

(A) Automatic exposure control performance. The AEC shall be capable of maintaining film optical density within plus or minus 0.15 of the mean optical density when thickness of a homogeneous material is varied over a range of 2 to 6 cm and the kVp is varied appropriately for such thicknesses over the kVp range and in the AEC mode used clinically in the facility.

(B) Kilovoltage peak accuracy and reproducibility. At the most commonly used clinical settings of kVp, the coefficient of variation of reproducibility of the kVp shall be equal to or less than 0.02. The kVp shall be accurate to within plus or minus 5.0% of the indicated or selected kVp at the following:

(i) the lowest clinical kVp that can be measured by a kVp test device;

(ii) the most commonly used clinical kVp; and

(iii) the highest available clinical kVp.

(C) Focal spot condition. Facilities shall evaluate focal spot condition by determining the system resolution as follows.

(i) Each system used for mammography, in combination with the mammography screen-film combination used in the facility, shall provide a minimum resolution of 11 cycles/millimeter (mm) (line-pairs/mm) when a high contrast resolution bar test pattern is oriented with the bars perpendicular to the anode-cathode axis, and a minimum resolution of 13 line-pairs/mm when the bars are parallel to that axis.

(ii) The bar pattern shall be placed 4.5 cm above the breast support surface, centered with respect to the chest wall edge of the image receptor, and with the edge of the pattern within 1 cm of the chest wall edge of the image receptor.

(iii) When more than one target material is provided, the measurement in clause (i) of this subparagraph shall be made using the appropriate focal spot for each target material.

(iv) When more than one SID is provided, the test shall be performed at the SID most commonly used clinically.

(v) Test kVp shall be set at the value used clinically by the facility for a standard breast and shall be performed in the AEC mode, if available. If necessary, a suitable absorber may be placed in the beam to increase exposure times. The screen-film cassette combination used by the facility shall be used to test for this requirement and shall be placed in the normal location used for clinical procedures.

(D) Beam quality and half-value layer (HVL). The HVL shall meet the specifications of Title 21, CFR, §1020.30(m)(l) 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.

TABLE I X-ray Tube Voltage (kilovolt peak) and Minimum HVL		
Designed Operating Range (kV)	Measured Operating Voltage (kV)	Minimum HVL (mm of aluminum)
Below 50	20	0.20
	25	0.25
	30	0.30

(E) Breast entrance air kerma and AEC reproducibility. The coefficient of variation for both air kerma and mAs shall not exceed 0.05.

(F) Dosimetry. The average glandular dose delivered during a single craniocaudal view of an FDA accepted phantom simulating a standard breast shall not exceed 3.0 milligray (mGy) (0.3 rad) per exposure.

(G) X-ray field/light field/image receptor/compression paddle alignment. All systems shall meet the following.

(i) All systems shall have beam-limiting devices that allow the entire chest wall edge of the x-ray field to extend to the chest wall edge of the image receptor and provide means to assure that the x-ray field does not extend beyond any edge of the image receptor by more than 2.0% of the SID.

(ii) If a light field that passes through the x-ray beam limitation device is provided, it shall be aligned with the x-ray field so that the total of any misalignment of the edges of the light field and the x-ray field along either the length or the width of the visually defined field at the plane of the breast support surface shall not exceed 2.0% of the SID.

(iii) The chest wall edge of the compression paddle shall not extend beyond the chest wall edge of the image receptor by more than 1.0% of the SID when tested with the compression paddle placed above the breast support surface at a distance equivalent to standard breast thickness. The shadow of the vertical edge of the compression paddle shall not be visible on the image.

(H) Uniformity of screen speed. Uniformity of screen speed of all the cassettes in the facility shall be tested and the difference between the maximum and minimum optical densities shall not exceed 0.30. Screen artifacts shall also be evaluated during this test.

(I) System artifacts. System artifacts shall be evaluated with a high-grade, defect-free sheet of homogeneous material large enough to cover the mammography cassette and shall be performed for all cassette sizes used in the facility using a grid appropriate for the cassette size being tested. System artifacts shall also be evaluated for all available focal spot sizes and target filter combinations used clinically.

(J) Radiation output. The system shall be capable of producing a minimum output of 7.0 mGy air kerma per second (800 milliroentgen (mR) per second) when operating at 28 kVp in the standard mammography mode at any SID where the system is designed to operate. The system shall be capable of maintaining the required minimum radiation output averaged over a 3.0 second period.

(K) Decompression. If the system is equipped with a provision for automatic decompression after completion of an exposure or interruption of power to the system, the system shall be tested to confirm that it provides the following:

- (i) an override capability to allow maintenance of compression;
- (ii) a continuous display of the override status; and
- (iii) a manual emergency compression release that can be activated in the event of power or automatic release failure.

(L) The technique settings used for subparagraph (F) of this paragraph and paragraph (2) of this subsection shall be those used by the facility for its clinical images of a standard breast.

(6) Densitometer and sensitometer. The calibration of the densitometer and sensitometer must be in accordance with the manufacturer's specifications.

(7) Quality control tests - other modalities. For systems with image receptor modalities other than screen-film, the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems in paragraph (5)(F) of this subsection.

(8) Mobile service operation. The registrant shall verify that mammography machines used to produce mammograms at more than one location meet the requirements in paragraphs (1)-(7) of this subsection. In addition, at each examination location, before any examinations are conducted, the registrant shall verify satisfactory performance of the mammography machines by using a test method that establishes the adequacy of the image quality produced by the machine. Processor performance shall be in accordance with paragraph (1) of this subsection.

(9) Use of test results. After completion of the tests specified in paragraphs (1) - (8) of this subsection, the following shall occur.

(A) The registrant shall compare the test results to the corresponding specified action limits; or, for nonscreen-film modalities, to the manufacturer's recommended action limits; or for post-move, pre-examination testing of mobile mammography machines, to the limits established in the test method used by the facility.

(B) Components of the mammography system that fail quality assurance tests shall have corrective actions as indicated in the following.

(i) If components in subclause (I) and (II) of this clause fail, corrective action shall be taken before any mammography films are processed:

(I) paragraph (1) of this subsection describing processor quality control; and

(II) paragraph (4)(A) of this subsection describing darkroom fog;

(ii) If components in subclause (I)-(VI) of this clause fail, corrective action shall be taken before any mammography examinations are performed:

(I) paragraph (2) of this subsection describing phantom image quality;

(II) paragraph (4)(B) of this subsection describing screen-film contact;

(III) paragraph (4)(C) of this subsection describing compression device performance;

(IV) paragraph (5)(F) of this subsection describing dosimetry;

(V) paragraph (7) of this subsection describing quality control tests of other modalities; and

(VI) paragraph (8) of this subsection describing quality control tests for mobile mammography machines.

(iii) If components in the remaining quality assurance tests in subsection (v) of this section fail, corrective action shall be taken within 30 days of the test date.

(C) Documentation of the tests and the corrective actions described in subparagraph (B) of this paragraph shall be maintained in accordance with subsection (ee) of this section.

(10) Surveys. At least once a year, each facility shall undergo a survey by a medical physicist or by an individual under the direct supervision of a medical physicist.

(A) At a minimum, this survey shall include the following:

(i) performance of tests to ensure that the facility meets the quality assurance requirements of the weekly phantom image quality test described in paragraph (2) of this subsection, the annual tests described in paragraph (5) of this subsection, and if applicable, quality control tests as described for other modalities in paragraph (7) and for mobile service operations as described in paragraph (8) of this subsection; and

(ii) evaluation of the adequacy of the results of all tests conducted by the facility as well as written documentation of any corrective actions taken and their results in accordance with paragraphs (1)-(4) of this subsection, and, if applicable, paragraphs (7) and (8) of this subsection.

(B) The medical physicist shall provide a written survey report to the facility within 30 days of the date of the survey. The report shall include a summary of the test performed, all test conditions, specifications, results and recommendations for corrective actions, in accordance with subparagraph (A)(i) and (ii) of this paragraph.

(C) If the following tests indicate deficiencies, the physicist shall give a preliminary oral or written report to the facility within 72 hours of the survey:

(i) processor quality control in accordance with paragraph (9)(B)(i)(I) of this subsection;

(ii) phantom images, screen-film contact, compression device performance, or dosimetry in accordance with paragraph (9)(B)(ii)(I)-(IV) of this subsection;

(iii) quality control tests for other modalities, if applicable, in accordance with paragraph (9)(B)(ii)(V) of this subsection; or

(iv) quality control tests for mobile mammography machines, if applicable, in accordance with paragraph (9)(B)(ii)(VI) of this subsection.

(D) The survey report shall be dated and signed by the medical physicist performing or supervising the survey. If the survey was performed entirely or in part by another individual under the direct supervision of the medical physicist, that individual and the part of the survey that individual performed shall also be identified in the survey.

(E) The survey report shall be maintained by the registrant in accordance with subsection (ee) of this section.

(11) Mammography equipment evaluations. Additional evaluations of mammography machines or image processors shall be conducted whenever a new mammography machine or processor is installed, a mammography machine or processor is disassembled and reassembled at the same or a new location, major components of mammography machine are changed or repaired, or a processor is overhauled or reconditioned. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in this subsection and subsection (s) of this section.

(A) All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing.

(B) The mammography equipment evaluation and dosimetry shall be performed by a medical physicist or by an individual under the direct supervision of a medical physicist.

(12) Facility cleanliness. The registrant shall establish and implement adequate protocols for maintaining darkroom, screen, and view box cleanliness and shall document that all cleaning procedures are performed at the frequencies specified in the protocols.

(13) Calibration of air kerma measuring instruments. Instruments used by medical physicists in their annual survey to measure the air kerma or air kerma rate from a mammography machine shall be calibrated at least once every two years and each time the instrument is repaired. The instrument calibration must be traceable to a national standard and calibrated with an accuracy of plus or minus 6.0% (95% confidence level) in the mammography energy range.

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

(A) comply with all applicable federal, state, and local regulations pertaining to infection control; and

(B) comply with the manufacturer's recommended procedures for the cleaning and disinfection of the mammography equipment used in the facility; or

(C) if adequate manufacturer's recommendations are not available, comply with generally accepted guidance on infection control, until such recommendations become available.

(w) Quality assurance - mammography medical outcomes audit. Each registrant shall establish and maintain a mammography medical outcomes audit program to follow-up positive mammographic assessments and to correlate pathology results with the interpreting physician's findings. This program shall be designed to ensure the reliability, clarity, and accuracy of the interpretation of mammograms.

(1) General requirements. Each registrant shall establish a system to collect and review outcome data for all mammograms performed, including follow-up on the disposition of all positive mammograms and correlation of pathology results with the interpreting physician's mammography report. Analysis of these outcome data shall be made individually and collectively for all interpreting physicians at the facility. In addition, any cases of breast cancer among women imaged at the facility that subsequently become known to the facility shall prompt the facility to initiate follow-up on surgical and/or pathology results and review of the mammograms taken prior to the diagnosis of a malignancy.

(2) Frequency of audit analysis. The facility's first audit analysis shall be initiated no later than 12 months after the date the facility becomes certified or 12 months after April 28, 1999, whichever date is the latest. This audit analysis shall be complete within an additional 12 months to permit completion of diagnostic procedures and data collection. Subsequent audit analyses will be conducted at least once every 12 months. These shall be maintained in accordance with subsection (ee) of this section.

(3) Reviewing interpreting physician. Each lead interpreting physician or an interpreting physician designated by the lead interpreting physician shall review the medical outcomes audit data at least once every 12 months. This individual shall analyze the results of the audit and shall be responsible for the following:

(A) recording the dates of the audit period(s);

(B) documenting the results;

(C) notifying other interpreting physicians of their results and the registrant's aggregate results; and

(D) documenting any follow up actions and the nature of the follow up.

(x) Mammographic procedure and techniques for mammography of patients with breast implants. Each registrant shall have a procedure to inquire whether or not the patient has breast implants prior to the mammographic exam. Except where contraindicated, or unless modified by a physician's directions, patients with breast implants shall have mammographic views to maximize the visualization of breast tissue.

(y) Complaints. Each accredited facility 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 subsection (ee) of this section; and

(3) report unresolved serious complaints to the facility's FDA-approved accreditation body within 30 days of receiving the complaint.

(z) 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.

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

(1) If the agency certifying 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, for review by the FDA-approved accreditation body.

(2) If the agency certifying body determines that mammography quality at a facility has 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, for review by the FDA-approved accreditation body. The agency certifying body may require such facility to notify patients who received mammograms, and their referring physicians. The notification shall include the deficiencies presenting such risk, the potential consequences to the patient, appropriate remedial measures, and such other relevant information as the agency certifying body may require. Such notification shall occur within a time frame and in a manner specified by the agency.

(3) The agency certifying body, the agency accreditation body or another FDA-approved accreditation body, or the FDA may request a targeted clinical image review due to, but not limited to, serious complaints or severe items of non-compliance.

(bb) Self-referral mammography. Any person proposing to conduct a self-referral mammography program shall not initiate such a program without prior approval of the agency. When requesting such approval, that person shall submit the following information:

(1) the number and type of views (or projections);

(2) the age of the population to be examined and the frequency of the exam following established, nationally recognized criteria, such as those of the American Cancer Society, American College of Radiology (ACR), or the National Council on Radiation Protection and Measurements;

(3) written procedures to include methods of:

(A) advising patients and private physicians of the results of the mammography examination in accordance with subsection (t)(2) of this section;

(B) follow-up with patients and physicians in accordance with subsection (t)(3) of this section; and

(C) recommending to patients who do not have a physician means of selecting a physician; and

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

(cc) Medical research and investigational devices.

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

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

(A) 21 CFR, Part 812, Investigational Device Exemptions;

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

(C) 21 CFR, Part 56, Institutional Review Boards;

(D) 21 CFR, Part 54, Financial Disclosure by Clinical Investigators; and

(E) 21 CFR, Part 821, Subpart C, Design Controls of the Quality System Regulation.

(dd) Other operating procedures.

(1) Operating and safety procedures. Each registrant shall have and implement written operating and safety procedures that shall be made available to each individual operating x-ray equipment, including any restrictions of the operating technique required for the safe operation of the particular system. These procedures shall include, but are not limited to, the items in subsection (hh)(3) of this section.

(2) Technique chart. A chart or manual shall be provided or electronically displayed in the vicinity of the control panel of each machine that specifies technique factors to be utilized versus patient's anatomical size. The technique chart shall be used by all operators.

(3) Receipt, transfer, and disposal of mammography machines. Each registrant shall maintain records showing the receipt, transfer, and disposal of mammographic machines. These records shall include the date of receipt, transfer, or disposal; the name and signature of the individual making the record; and the manufacturer's model **name** and serial number from the control panel of the mammographic machine. Records shall be maintained in accordance with subsection **(ee)** of this section for inspection by the agency.

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

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

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

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

(B) Protective devices, including aprons, gloves, and shields shall be checked annually for defects such as holes, cracks, and tears. These checks may be performed by the registrant by visual or tactile means, or x-ray imaging. If a defect is found, protective devices shall be replaced or removed from service until repaired. A record of this test shall be made and maintained by the registrant in accordance with subsection **(ee)** of this section for inspection by the agency.

(7) Holding of patient or image receptor.

(A) When a patient or image receptor must be held in position during radiography, mechanical supporting or restraining devices shall be used when the exam permits.

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

(C) The registrant's written operating and safety procedures required by paragraph (1) of this subsection shall include the following:

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(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 shall be protected by not less than 0.25 mm lead equivalent material.

(8) Calibration, maintenance, and modifications. Each registrant shall maintain records showing calibrations, maintenance, and modifications performed on each mammographic machine. These records shall include the date of the calibration, maintenance, or modification performed; the name of the individual making the record; and the manufacture's model name and serial number of the control panel of the mammographic machine. These records shall be maintained in accordance with subsection (ee) of this section.

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

(1) Records for mammography machines authorized for mobile service operations.

(A) Copies of the following shall be kept with mammography machines authorized for mobile services:

(i) operating and safety procedures in accordance with subsection (dd)(1) of this section;

(ii) medical radiologic technologists' credentials;

(iii) current quality control records for at least the last 90 calendar days for on-board processors in accordance with subsection (v)(1) of this section;

(iv) current §289.203 of this title, §289.226 of this title, §289.230 of this title, §289.231 of this title, and §289.234 of this title if accredited by the agency accreditation body;

(v) copy of certification;

(vi) certification of inspection in accordance with subsection (ff)(5) of this section;

(vii) notice of failure from last inspection in accordance with subsection (ff)(6) of this section, if applicable; and

(viii) copy of mammography accreditation.

(B) Copies of all other records required by this section shall be maintained at a specified location.

(2) Records required at separate authorized use locations. Copies of the following shall be kept at each separate authorized use location:

(A) credentials for interpreting physicians operating at that location in accordance with subsection (r)(1) of this section;

(B) credentials for medical radiologic technologists operating at that location in accordance with subsection (r)(2) of this section;

(C) credentials for medical physicists operating at that location in accordance with subsection (r)(3) of this section;

(D) continuing education and experience records for interpreting physicians, medical radiologic technologists, and medical physicists operating at that location in accordance with subsection (r)(1)(C), (2)(C), and (3)(C) of this section;

(E) mandatory training records for interpreting physicians and medical physicists operating at that location in accordance with subsection (r)(1)(E) and (2)(E) of this section, if applicable;

(F) current physicist annual survey of the mammography system;

(G) current §289.203 of this title, §289.226 of this title, §289.230 of this title, §289.231 of this title, and §289.234 of this title if accredited by the agency accreditation body;

(H) copy of certification;

(I) quality assurance program in accordance with subsections (u), (v), and (w) of this section;

(J) quality control records in accordance with subsection (u)(2) of this section;

(K) operating and safety procedures in accordance with subsection (dd)(1) of this section;

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(L) records of receipts, transfers, and disposal in accordance with subsection (dd)(3) of this section;

(M) calibration, maintenance, and modification records in accordance with subsection (dd)(8) of this section;

(N) certification of inspection in accordance with subsection (ff)(5) of this section;

(O) notification of failure in accordance with subsection (ff)(6), if applicable;

(P) records of notification of patients in accordance with subsection (ff)(10) this section; and

(Q) copy of mammography accreditation.

(3) Time requirements for record keeping. Time requirements for record keeping shall be according to the following chart.

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Specific Subsection	Name of Record	Time Interval for Record Keeping
(r)(1)(A)	Interpreting Physician Qualifications	Until termination of certification or 2 years after physician leaves facility
(r)(1)(C)	Interpreting Physician Continuing Education and Experience	6 years
(r)(1)(E)	Mandatory training for Interpreting Physician, if applicable	6 years
(r)(2)(A)	Medical Radiologic Technologist Qualifications	Until termination of certification or 2 years after technologist leaves facility
(r)(2)(C)	Medical Radiologic Technologist Continuing Education and Experience	6 years
(r)(2)(E)	Mandatory training for Medical Radiologic Technologist, if applicable	6 years
(r)(3)(A)	Medical Physicist Qualifications	Until termination of certification or 2 years after physicist is no longer associated with the facility
(r)(3)(C)	Medical Physicist Continuing Education and Experience	6 years
(s)(14)	FDA Variances	Until termination of certification or equipment is replaced
(u)(2)	Quality Assurance (QA) Records	Until the next annual inspection has been completed and the agency has determined that the facility is in compliance with the QA requirements or until the test has been performed two additional times at the required frequency, whichever is longer.
(v)(10)	Physicist Mammography Survey	7 years

Specific Subsection	Name of Record	Time Interval for Record Keeping
(v)(11)	Physicist Mammography Equipment Evaluation	2 years
(w)(2)	Medical Outcomes Audit	2 years
§289.234(o)	Complaints	3 years
(dd)(1)	Operating & Safety Procedures	Until termination of certification
(dd)(3); (gg)(15)	Records of Receipt, Transfer, and Disposal	Until termination of certification
(dd)(6)	Protective Devices Annual Check	3 years
(dd)(8)	Records on Calibration, Maintenance and Modifications Performed on Mammography Machines	2 years
(ee)(2)(I)	Current §§289.203, 289.204, 289.205, 289.226, 289.227, 289.230, 289.231, 289.234	Until termination of certification
(ee)(2)(J)	Current Certification of Mammography Systems	Until termination of certification
(ee)(2)(N)	Current Accreditation of Mammography Systems	Until termination of certification
(ff)(5)	Certification of Inspection	Until termination of certification
(ff)(6)	Notice of Failure	Until termination of certification
(ff)(10)	Patient Notification	Until termination of certification
(gg)(16)	Records of Calibration, Maintenance, and Modifications Performed on Interventional Breast Radiography Machines	Until termination of certification

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

(1) The agency may inspect each mammography system that receives a certification in accordance with this chapter not later than the 60th day after the date the certification is issued.

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

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

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

(5) After each satisfactory inspection, the agency shall issue a certificate of inspection for each mammography system inspected. The certificate of inspection shall be posted at a conspicuous place on or near the place where the mammography system is used. The certificate of inspection may include the following:

(A) specific identification of the mammography system inspected;

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

(C) the date of the inspection.

(6) Any severity level I violation involving a mammography system, found by the agency, in accordance with §289.205 of this title, constitutes grounds for posting notice of failure of the mammography system to satisfy agency requirements.

(A) Notification of such failure shall be posted:

(i) on the mammography machine at a conspicuous place if the violation is machine-related; or

(ii) near the place where the mammography system practices if the violation is personnel-related; and

(iii) in a sufficient number of places to permit the patient to observe the notice.

(B) The notice of failure shall remain posted until the facility is authorized to remove it by the agency. A facility may post documentation of corrections of the violations submitted to the agency along with the notice of failure until approval to remove the notice of failure is received from the agency.

(7) Facilities that receive a severity level I violation shall notify patients on whom the facility performed a mammogram during the **period in which the system failed to meet the agency's certification standards**. The facility shall:

(A) inform the patient that the mammography system failed to satisfy the agency certifying body's standards;

(B) recommend that the patient **consult with the patient's physician regarding the need for another mammogram**; and

(C) list the three facilities closest to the original testing facility that have a certified mammography system.

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

(9) The patient notification shall include the following:

(A) an explanation of the mammography system failure to the patient; and

(B) the potential consequences to the mammography patient.

(10) The registrant shall make a record of the mammography patients notified in accordance with paragraphs (7) and (8) of this subsection for inspection by the agency. The records shall include the name and address of each mammography patient notified, date of notification, and a copy of the text sent to the individual. The records shall be maintained in accordance with subsection **(ee)** of this section.

(gg) Requirements for interventional breast radiography machines.

(1) Prohibitions.

(A) The agency may prohibit use of interventional breast radiography machines that pose a significant threat or endanger public health and safety, in accordance with §289.231 and §289.205 of this title.

(B) Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed physician. The provision specifically prohibits intentional exposure of an individual for training, demonstration, or other non-healing arts purposes.

(2) Exemptions.

(A) Machines used exclusively for interventional breast radiography are not required to be accredited by an FDA-approved accreditation body.

(B) Loaner machines as described in subsection (n)(6) of this section are exempt for the inspection requirements in subsection (ff) of this section.

(C) All interventional breast radiography registrants are exempt from the posting of radiation area requirements of §289.231(x) of this title provided that the operator has continuous surveillance and access control of the radiation area.

(3) Requirements for interventional breast radiography machine certification.

(A) Each person having an interventional breast radiography machine shall submit an application in accordance with §289.226(e)(1) - (3), (5), and (7) of this title, and shall receive certification from the agency within 30 days of beginning use.

(B) An application for certification shall be signed by a licensed physician, the applicant and the RSO.

(C) An application for certification may contain information on multiple interventional breast radiography machines. Each machine must be identified by referring to the machine's manufacturer, model name and serial number on the control panel.

(D) Each applicant shall submit documentation of evidence that a medical physicist's survey has been performed in accordance with paragraph (13) of this subsection.

(4) Issuance of certification.

(A) Certification. A certification for interventional breast radiography machines will be issued if the agency determines that an application meets the requirements of the Act and the requirements of this chapter. The certification authorizes the proposed activity in such form and contains such conditions and limitations as the agency deems appropriate or necessary.

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

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

(ii) require additional reports and the keeping of additional records as may be appropriate or necessary; and

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

(C) Additional information. The agency may request, and the registrant shall provide, additional information after the certification has been issued to enable the agency to determine whether the certification should be modified in accordance with §289.226(r) of this title.

(5) Modification, suspension, or revocation of certification. Modification, suspension, or revocation of certification shall be in accordance with §289.226(r) of this title.

(6) Specific terms and conditions of certification. Specific terms and conditions of certification shall be in accordance with §289.226(l) of this title.

(7) Responsibilities of registrant.

(A) The registrant shall comply with the following:

(i) purpose and scope in accordance with subsections (a) and (b) of this section; and

(ii) applicable definitions in subsection (c) of this section.

(B) In addition to the requirements of §289.226(m)(3) - (7) of this title, a registrant shall notify the agency in writing prior to any changes that would render the information contained in the application or the certification inaccurate. These include but are not limited to the following:

(i) name and mailing address;

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

(iii) interventional breast radiography machine(s).

(C) If a facility makes a change in the RSO, the qualifications of the RSO shall be submitted to the agency within 30 days of such change.

(D) A facility with an existing certification may begin using a new or replacement interventional breast radiography machine before receiving an updated certification if the registrant submits to the agency (required/prescribed) documentation with a medical physicist's report in accordance with paragraph (13) of this subsection, verifying compliance of the new interventional breast radiography machine with this section. The medical physicist's report is required prior to using the interventional breast radiography machine on patients.

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

(8) Renewal of certification. The registrant shall file an application for renewal of certification as follows.

(A) Each person having an interventional breast radiography machine shall submit an application for renewal in accordance with §289.226(e)(1) - (3), (5), and (7) of this title.

(B) An application for renewal shall be signed by the RSO, licensed physician, and the applicant.

(C) An applicant for renewal shall submit a medical physicist's survey in accordance with paragraph (13) of this subsection.

(D) If a registrant files an application for renewal in proper form at least 30 days before the existing certification expires, such existing certification shall not expire until the application status has been determined by the agency.

(9) Expiration of certification.

(A) Each certification of interventional breast radiography machine expires at the end of the day in the month and year stated on the certificate. Expiration of the certification does not relieve the registrant of the requirements of this chapter.

(B) If a registrant does not submit an application for renewal of the certification under paragraph (8) of this subsection, as applicable, the registrant shall on or before the expiration date specified in the certification:

- (i) terminate use of all interventional breast radiography machines;
- (ii) pay any outstanding fees in accordance with §289.204 of this title; and

(iii) submit a record of the disposition of the interventional breast radiography machine(s) to the agency. If the machine(s) was transferred, include to whom it was transferred.

(10) Termination of certification. When a registrant decides to terminate all activities involving interventional breast radiography machine(s) authorized under the certification, the registrant shall notify the agency immediately and do the following:

(A) request termination of the certification in writing signed by the RSO, owner, or an individual authorized to act on behalf of the registrant;

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

(C) submit a record of the disposition of the interventional breast radiography machine(s) to the agency certifying body. If the machine(s) was transferred, include to whom it was transferred.

(11) Personnel requirements.

(A) A medical radiologic technologist (operators of equipment) shall hold a current general certificate in accordance with the Medical Radiologic Technologist Certification Act, Texas Occupations Code, Chapter 601.

(B) A medical physicist shall hold a current Texas license under the Medical Physics Practice Act, Texas Occupations Code, Chapter 602, in diagnostic radiological physics and be registered with the agency or employed by an entity registered with the agency, in accordance with §289.226(j) of this title and the Act, unless exempted by §289.226(d)(6) of this title.

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

(A) If any failures are noted, corrective actions shall be taken within the time frame indicated/established by the manufacturer or medical physicist. In the event, that no time frames are indicated, corrective action shall be completed within 30 days of the failure.

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

(13) Interventional breast radiography machine evaluations and annual survey.

(A) Interventional breast radiography machines are required to have a medical physicist perform a survey:

(i) whenever a new interventional breast radiography machine is installed, 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) on an annual basis.

(B) The following quality assurance tests shall be performed: AEC, kVp, focal spot condition, HVL, collimation, alignments, and dosimetry tests in accordance with subsection (v)(5)(A) - (G) of this section.

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

(D) The medical physicist shall prepare a written report for the facility within 30 days of the date of the survey to include the following:

(i) a written survey report that includes a summary of the tests performed, all test conditions, specifications, results, and recommendations for corrective actions; and

(ii) date and signature of the medical physicist performing or supervising the survey. If the survey was performed entirely or in part by another individual under the direct supervision of the medical physicist, that individual and the part of the survey that individual performed shall also be identified in the survey.

(14) Operating and safety procedures. Each registrant shall have and implement written operating and safety procedures that shall be made available to each individual operating x-ray equipment, including any restrictions of the operating technique required for the safe operation of the particular system. These procedures shall include, but are not limited to:

(A) posting notices to workers in accordance with §289.203(b) of this title;

(B) instructions to workers in accordance with §289.203(c) of this title;

(C) notifications and reports to individuals in accordance with §289.203(d) of this title;

(D) ordering x-ray exams in accordance with §289.231(b) of this title;

(E) occupational dose requirements in accordance with §289.231(m) of this title;

(F) personnel monitoring requirements in accordance with §289.231(n) and (q) of this title;

(G) credentialing requirements for medical radiologic technologists, and medical physicists in accordance with paragraph (11) of this subsection;

(H) use of a technique chart in accordance with paragraph (22) of this subsection;

(I) exposure of individuals other than the patient in accordance with paragraph (18) of this subsection; and

(J) holding of patients or image receptors in accordance with subsection (dd)(7) of this section.

(15) Receipt, transfer, and disposal of interventional breast radiography machines. Each registrant shall maintain records showing the receipt, transfer, and disposal of interventional breast radiography machines. These records shall include the date of receipt, transfer, or disposal; the name and signature of the individual making the record; and the manufacturer's model name and serial number on the control panel. These records shall be maintained in accordance with subsection (ee) of this section for inspection by the agency.

(16) Calibration, maintenance, and modifications. Each registrant shall maintain records showing calibrations, maintenance, and modifications performed on each interventional breast radiography machine. These records shall include the date of the calibration, maintenance, or modification performed; the name of the individual making the record; and the manufacturer's model name and serial number on the control panel. These records shall be maintained in accordance with subsection (ee) of this section for inspection by the agency.

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

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

(19) Maintenance of records. Maintenance of applicable records in subsection (ee) of this section.

(20) Inspection requirements. Inspection requirements in accordance with subsection (ff)(2) - (4) of this section.

(21) Equipment requirements. Equipment requirements in accordance with §289.227(h) of this title (relating to Use of Radiation Machines in the Healing Arts).

(22) Technique chart. A chart or manual shall be provided or electronically displayed in the vicinity of the control panel of each interventional breast radiography machine that specifies technique factors to be utilized versus patient's anatomical size. The technique chart shall be used by all operators.

(hh) Appendices.

(1) Subjects to be included in mammography training for medical radiologic technologists shall include, but not be limited to, the following:

- (A) breast anatomy and physiology;
- (B) positioning and compression;
- (C) quality assurance/quality control techniques;
- (D) imaging of patients with breast implants; and

(E) at least eight hours of training in each mammography modality to be used by the technologist in performing mammography exams.

(2) Subjects to be included in mammography training for interpreting physicians shall include, but not be limited to, the following:

- (A) radiation physics, including radiation physics specific to mammography;
- (B) radiation effects;
- (C) radiation protection; and

(D) interpretation of mammograms. This shall be under the direct supervision of a physician who meets the requirements of subsection (r)(1) of this section.

(3) Operating and safety procedures. The registrant's operating and safety procedures shall include, but are not limited to, the following procedures as applicable:

- (A) posting notices to workers in accordance with §289.203(b) of this title;
- (B) instructions to workers in accordance with §289.203(c) of this title;

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(C) notifications and reports to individuals in accordance with §289.203(d) of this title;

(D) ordering x-ray exams in accordance with §289.231(b) of this title;

(E) occupational dose requirements in accordance with §289.231(m) of this title;

(F) personnel monitoring requirements in accordance with §289.231(n) and (q) of this title;

(G) posting of a radiation area in accordance with §289.231(x) and (y) of this title;

(H) credentialing requirements for lead interpreting physicians, interpreting physicians, medical radiologic technologists, and medical physicists in accordance with subsection (r) of this section;

(I) retention of clinical images in accordance with subsection (t)(4) of this section;

(J) quality assurance program in accordance with subsections (u)-(w) of this section;

(K) image quality and corrective action for images of poor quality in accordance with subsection (u)(1)(B)(i) of this section;

(L) repeat analysis in accordance with subsection (v)(3)(B) of this section;

(M) procedures and techniques for mammography patients with breast implants in accordance with subsection (x) of this section;

(N) procedure to handle complaints in accordance with subsection (y) of this section;

(O) self-referral mammography in accordance with subsection (bb) of this section;

(P) use of a technique chart in accordance with subsection (dd)(2) of this section;

(Q) exposure of individuals other than the patient in accordance with subsection (dd)(5) of this section;

(R) use of protective devices in accordance with subsection (dd)(6) of this section; and

(S) holding of patients or image receptors in accordance with subsection (dd)(7) of this section.

(4) Phantom image scoring protocol for film-screen modality. Each of the following object groups are to be scored separately. In order to receive a passing score on the phantom image, all three test object groups must pass. A failure in any one of the areas results in a phantom failure.

(A) Fibers. A score of 4.0 for fibers is required to meet the evaluation criteria. The diameter size of fibers are 1.56 mm, 1.12 mm, 0.89 mm, 0.75 mm, 0.54 mm, and 0.40 mm. Score the fibers as follows.

(i) Begin with the largest fiber and move down in size, adding one point for each full fiber until a score of zero or one half is given. Stop counting at the first point where you lose visibility of objects.

(ii) If the entire length of the fiber can be seen and its location and orientation are correct, that fiber receives a score of one.

(iii) If at least half, but not all, of the fiber can be seen and its location and orientation are correct, that fiber receives a score of one half.

(iv) If less than one half of a fiber can be seen or if the location or orientation are incorrect, that fiber receives a score of zero.

(v) After determining the last fiber to be counted, look at the overall background for artifacts. If there are background objects that are fiber-like in appearance and are of equal or greater brightness than the last visible half or full fiber counted, subtract the last half or full fiber scored.

(B) Speck groups. A score of 3.0 for speck groups is required to meet the evaluation criteria. Diameter sizes of speck groups are 0.54 mm, 0.40 mm, 0.32 mm, 0.24 mm, and 0.16 mm. There are six specks per group. Score the speck groups as follows.

(i) Begin with the largest speck group and move down in size adding one point for each full speck group until a score of one half or zero is given, then stop.

(ii) If at least four of the specks in any group are visualized, the speck group is scored as one.

(iii) If two or three specks in a group are visualized, the score for the group is one half.

(iv) If one speck or no specks from a group are visualized, the score is zero.

(v) After determining the last speck group to receive a full or one-half point, look at the overall background for artifacts. If there are speck-like artifacts within the insert region of the phantom that are of equal or greater brightness than individual specks counted in the last visible half or full speck group counted, subtract the artifact speck from the observed specks in the last group scored, one by one. Note that the highest number of speck-like artifacts that can potentially be subtracted is the number of visible specks that were scored in the last group. Repeat the scoring of the last visible speck group after these deductions.

(C) Masses. A score of 3.0 is required to meet the evaluation criteria. Diameter sizes of masses are 2.00 mm, 1.00 mm, 0.75 mm, 0.50 mm, and 0.25 mm. Score the masses as follows.

(i) Begin with the largest mass and add one point for each full mass observed until a score of one half or zero is assigned.

(ii) Score one for each mass that appears as a minus density object in the correct location that can be seen clearly enough to observe round, circumscribed borders.

(iii) Score one half if the mass is clearly present in the correct location, but the borders are not visualized as circular.

(iv) After determining the last full or half mass to be counted, look at the overall background for artifacts. If there are background objects that are mass-like in appearance and are of equal or greater visibility than the last visible mass, subtract the last full or half point assigned from the original score.