

The Agency is seeking your input regarding the following noted suggested rule changes. These suggested changes are NOT final rule changes.

Legend: (Proposed Amendments)

Single Underline = Proposed new language

[Bold, Print and Brackets] = Current language proposed for deletion

Regular Print = Current language

(No change.) = No changes are being considered for the designated subdivision

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

(a) (No change.)

(b) Scope.

(1) - (3) (No change.)

(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) - (5) (No change.)

(6) Agency accreditation body--For the purpose of this section, the agency as approved by the FDA under Title 21, CFR, §900.3(d) [**Code of Federal Regulations (CFR), Part 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 [**Part 900.21**], to certify facilities within the State of Texas to perform mammography services.

(8) - (24) (No change.)

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

(26) - (34) (No change.)

(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) **[501(k)]** Premarket Notification submission to FDA.

(36) - (40) (No change.)

(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) **[(bb)]** of this section; or

(B) (No change.)

(42) - (69) (No change.)

(d) Prohibitions.

(1) - (2) (No change.)

(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) (No change.)

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

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

(e) Exemptions.

(1) (No change.)

(2) Mammography machines used exclusively for interventional breast radiography are exempt from the requirements of this section except for those listed in subsection (gg) **[(bb)]** 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) [(gg)] 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) [(dd)] 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) (No change.)

(f) Requirements for mammography systems certification.

(1) - (3) (No change.)

(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 [number], 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) (No change.)

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

(C) (No change.)

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

(E) (No change.)

(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 [or both] of the following:

(A) (No change.)

(B) certification of interventional breast radiography machines [mammography machines used for interventional breast radiography].

(2) - (7) (No change.)

(h) - (m) (No change.)

(n) Responsibilities of registrant.

(1) - (6) (No change.)

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

(o) Renewal of certification.

(1) - (3) (No change.)

(4) A facility with mammography machines used for interventional breast radiography shall file an application for renewal in accordance with subsection (gg)(8) [(bb)(9)] 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 [of **registration**]. 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) (No change.)

(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) [(t)(4)] of this section will be met;

(C) - (D) (No change.)

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

(1) - (3) (No change.)

(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)~~ [(t)(4)] of this section will be met; and

(5) (No change.)

(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) - (D) (No change.)

(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.

[(E) Any mandatory training required by the agency certifying body or an FDA-approved accreditation body shall be completed prior to independently interpreting mammograms. Records of any mandatory training shall be maintained in accordance with subsection (ff)(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) - (D) (No change.)

(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.

[(E) Any mandatory training required by the agency certifying body or an FDA-approved accreditation body shall be completed prior to independently performing mammograms. Records of any mandatory training shall be maintained in accordance with subsection (ff)(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) - (D) (No change.)

[(E) Any mandatory training required by the agency certifying body or an FDA-approved accreditation body shall be completed prior to independently performing mammographic surveys, evaluating mammographic equipment, or providing oversight of a facility's quality assurance program. Records of any mandatory training shall be maintained in accordance with subsection (ff)(3) of this section.]

(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) **[(ff)]** of this section.

(s) (No change.)

(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 **[an additional patient identifier];**

(B) - (E) (No change.)

(2) - (3) (No change.)

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

(A) - (C) (No change.)

(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 **[an additional patient identifier]**;

(B) - (G) (No change.)

(6) (No change.)

(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) (No change.)

(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)~~ [(ff)] 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) - (8) (No change.)

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

(A) - (B) (No change.)

(C) Documentation of the tests and the corrective actions described in subparagraph (B) of this paragraph shall be maintained in accordance with subsection ~~(ee)~~ [(ff)] 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) (No change.)

(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. **[The report shall include a summary of the tests performed by the medical physicist in subparagraph (A)(i) of this paragraph and the review of the tests performed by the facility in subparagraph (A)(ii) of this paragraph. The report shall also contain recommendations for any required corrective actions.]**

(C) - (D) (No change.)

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

(11) - (14) (No change.)

(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) (No change.)

(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) **[(ff)]** of this section.

(3) (No change.)

(x) (No change.)

(y) Complaints. Each accredited facility shall do the following:

(1) (No change.)

(2) maintain a record of each serious complaint received by the facility in accordance with subsection (ee) **[(ff)]** of this section; and

(3) (No change.)

(z) - (aa) (No change.)

[(bb) Requirements for machines used exclusively for interventional breast radiography. Machines used exclusively for interventional breast radiography, including mobile service operations, are not included in the definition of mammography systems. These machines are not required to be accredited or to receive certification by the agency certifying body in accordance with 21 CFR, Part 900.11. However, each facility using such machines shall apply for and receive a certification from the agency. The facility shall comply with the following:]

[(1) purpose and scope in accordance with subsections (a) and (b) of this section;]

[(2) applicable definitions in subsection (c) of this section;]

[(3) prohibitions in accordance with subsection (d)(2) and (3) of this section;]

[(4) exemptions in accordance with subsection (e)(2), (3), and (5) of this section;]

[(5) certification requirements in accordance with subsection (f)(2) - (4) and (5)(B) of this section and the requirement to submit a medical physicist's survey in accordance with paragraph (13) of this subsection;]

[(6) issuance of certification and specific terms and conditions of certification in accordance with subsections (g)(1) and (1)(B), (2), (3), and (m) of this section;]

[(7) responsibilities of a registrant in accordance with subsection (n)(1), (2)(A), (D) and (E), and (4) - (6) of this section;]

[(8) expiration, termination, modification and revocation of certification in accordance with subsections (l), (p), and (q) of this section;]

[(9) renewal of certification as follows:]

[(A) the registrant shall file an application for renewal of certification in accordance with subsection (f)(2) - (4) and (5)(B) of this section and submit a medical physicist's survey in accordance with paragraph (13) of this subsection; and]

[(B) if a registrant files an application 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 certifying body;]

[(10) personnel requirements for a general certificate, medical radiologic technologist in accordance with the Medical Radiologic Technologist Certification Act, Texas Occupational Code, Chapter 601;]

[(11) personnel requirements for medical physicists in accordance with subsection (r)(3) of this section;]

[(12) requirement to have a written quality assurance program to ensure the safety, reliability, clarity, and accuracy of services performed at the facility, including corrective actions to be taken if images are of poor quality;]

[(13) requirement to have a medical physicist perform an annual survey of AEC, kVp, focal spot condition, HVL, and dosimetry tests in accordance with subsection (v)(5)(A) - (F) of this section. The medical physicist shall provide a preliminary oral or written report of deficiencies within 72 hours of the survey if it involves dosimetry. The medical physicist shall prepare a written report for the facility within 30 days of the date of the survey to include the following:]

[(A) a summary of the tests in the annual survey with recommendations for corrective actions; and]

[(B) 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) the requirement to correct deficiencies indicated in the test results for dosimetry in accordance with subsection (v)(9)(B)(ii)(IV) of this section before any further examinations are performed;]

[(15) operating and safety procedures in accordance with subsection (ee)(1) of this section;]

[(16) occupational dose limits and personnel monitoring in accordance with §289.231 of this title;]

[(17) provision of a technique chart in accordance with subsection (ee)(2) of this section;]

[(18) the requirement to maintain receipt, transfer, disposal, calibration, and maintenance records in accordance with subsection (ee)(3) and (8) of this section;]

[(19) requirement to have a viewing system in accordance with subsection (ee)(4) of this section;]

[(20) requirement to prevent exposure of individuals other than the patient in accordance with subsection (ee)(5) of this section;]

[(21) maintenance of applicable records in subsection (ff) of this section;]

[(22) inspection requirements in accordance with subsection (gg) of this section, except for subsection (gg)(1) of this section; and]

[(23) equipment requirements in accordance with §289.227(h) of this title (relating to Use of Radiation Machines in the Healing Arts).]

(bb) [(cc)] 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) **[(dd)]** 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 [**Code of Federal Regulations (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) **[(ee)]** 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) [(ff)] 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) [(ff)] 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:

(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) **[(ff)]** of this section.

(ee) **[(ff)]** 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) **[(ee)(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)

[(gg)(5)] of this section;

(vii) notice of failure from last inspection in accordance with subsection (ff)(6) of this section [(gg)(6)], 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[, **medical radiologic technologists,**] and medical physicists operating at that location in accordance with subsection (r)(1)(E)[,] and (2)(E)[, **and (3)(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) **[(ee)(1)]** of this section;

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

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

(N) certification of inspection in accordance with subsection (ff)(5) **[(gg)(5)]** of this section;

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

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

(Q) copy of mammography accreditation.

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

Figure: 25 TAC §289.230(ee)(3) **[Figure: 25 TAC §289.230(ff)(3)]**

(ff) **[(gg)]** 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 **[30 days preceding the date of the inspection that revealed the failure]**. 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 **[have another mammogram performed at a facility with a certified mammography system]**; 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) ~~[(ff)]~~ 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) - (2) (No change.)

(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) - (N) (No change.)

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

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

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

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

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

(4) (No change.)

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

§289.234. Mammography Accreditation.

(a) – (b) (No change.)

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

(1) - (4) (No change.)

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

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

(7) - (10) (No change.)

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

(12) - (30) (No change.)

(d) – (k) (No change.)

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

(1) (No change.)

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

(3) (No change.)

(m) – (n) (No change.)

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

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

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

(2) - (4) (No change.)