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

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

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

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

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

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

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

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

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

(b) Scope.

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

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

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

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

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

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

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

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

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

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

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

(c) Prohibitions.

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

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

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

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

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

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

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

(d) Exemptions.

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

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

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

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

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

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

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

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

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

(4) Additional mammography review (AMR)--A [~~(includes targeted clinical image reviews) --At the request of the agency certification body or an FDA-approved~~

~~accreditation body, a~~] review [~~by the FDA-approved accreditation body~~] of clinical images and other relevant facility information necessary to assess compliance [~~conformation~~] with [~~the~~] accreditation standards. [~~The reviews include the following:~~]

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

[~~(B) clinical image review without interpretation.~~]

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

(A) poor image quality;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

mammography.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Figure: 25 TAC §289.230(e)(50)

[~~Figure: 25 TAC §289.230(c)(51)~~]

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

or is self-referred.

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

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

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

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

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

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

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

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

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

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

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

(62)[~~(63)~~] Serious adverse event--An adverse event that may significantly compromise clinical outcomes, or an adverse event for which a facility fails to take

appropriate corrective action in a timely manner.

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

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

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

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

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

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

[~~(d) Prohibitions.~~]

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

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

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

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

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

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

[~~(e) Exemptions.~~]

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

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

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

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

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

(f) Mammography systems certification.

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

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

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

(C)[~~(3)~~] An application for certification must [~~shall~~] be signed by the:

(i) LIP;

(ii) applicant; and

(iii) radiation safety officer (RSO) [~~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.~~]

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

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

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

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

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

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

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

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

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

(vi) proof of current accreditation.

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

[~~(1) Certification.~~] A certification will be issued if the department [~~agency certifying body~~] determines the [~~that an~~] application meets the requirements of the Act and [~~the requirements of~~] this chapter. The certification authorizes the

proposed operations and includes [~~activity in such form and contains such~~] conditions and limitations deemed necessary by [~~as~~] the department [~~agency certifying body deems appropriate or necessary~~].

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

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

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

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

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

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

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

(C)[~~(3)~~] Additional information. The department [~~agency certifying body~~] may request[~~, and the registrant shall provide,~~] additional information after the certification has been issued to enable the department [~~agency certifying body~~] to determine whether the certification should be modified as specified in [~~accordance with~~] §289.226(r) of this subchapter, relating to renewal of certificates of registration [~~title~~].

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

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

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

(i) A provisional certification is [~~shall be~~] effective for up to six months as

noted on the certificate[~~from the date of issuance~~].

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

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

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

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

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

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

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

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

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

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

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

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

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

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

provisional certification; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(E)[~~(5)~~] If a facility's certification was revoked based on [~~on the basis of~~] an act described in §289.205 of this chapter, a [~~title, no~~] person who owned or

operated that facility at the time the act occurred is prohibited from owning [~~may own or operate~~] a mammography facility for [~~within~~] two years following [~~of~~] the [~~date of~~] revocation date.

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

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

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

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

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

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

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

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

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

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

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

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

(B)[~~(2)~~] Before the department [~~agency certification body~~] denies an

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

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

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

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

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

(9)[~~(l)~~] Modification of certification. Modification of a certification will follow the requirements in §289.226(s) of this subchapter, relating to modification, suspension, and revocation of certificates of registration [~~shall be in accordance with §289.226(r) of this title~~].

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

(11) Renewal of certification.

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

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

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

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

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

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

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

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

(12) Expiration of certification.

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

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

(i) terminate use of all mammography machines;

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

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

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

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

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

(B) request termination of the certification in writing;

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

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

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

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

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

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

(B) mailing address;

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

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

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

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

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

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

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

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

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

(E) medical physicist.

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

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

~~accreditation for that machine has been denied, or if the accreditation has been suspended or expired~~].

(5) For certification, a facility with an existing certificate may begin using a new or replacement machine before receiving an updated certificate if the facility submits to the department and AB an application with a medical physicist report as specified in subsection (l)(5) and (6) of this section[~~A facility with an existing certification may begin using a new or replacement machine before receiving an updated certification if the registrant submits to the agency certifying body and to the FDA-approved accreditation body, documentation with a medical physicist's report in accordance with subsection (v)(10) and (11) of this section, verifying compliance of the new machine with this section. The medical physicist's report is required prior to using the machine on patients~~].

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

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

[~~(o) Renewal of certification.~~]

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

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

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

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

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

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

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

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

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

[~~(p) Expiration of certification.~~]

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

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

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

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

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

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

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

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

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

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

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

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

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

interpretation of mammograms.

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

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

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

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

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

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

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

(ii) radiation effects;

(iii) radiation protection; and

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

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

(i) A physician [~~Physicians who~~] qualified as an IP as specified [~~interpreting physicians~~] in [~~accordance with~~] the requirements of §289.230 that were in effect before [~~prior to~~] April 28, 1999, or any other equivalent state or

federal requirements in effect before [~~prior to~~] April 28, 1999, is [~~are~~] considered to have met the initial requirements of subparagraph (A) of this paragraph.

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

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

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

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

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

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

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

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

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

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

~~immediately preceding:~~]

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

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

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

(E) Continuing experience.

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

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

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

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

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

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

(III) any date in between the two.

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

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

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

(I) at least 240 mammographic examinations; or

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

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

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

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

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

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

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

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

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

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

(i) breast anatomy and physiology;

(ii) positioning and compression;

(iii) QA/QC techniques;

(iv) imaging of patients with breast implants; and

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

(C)[~~(B)~~] Exemptions. MRTs [~~Equipment operators who~~] qualified [~~as medical radiologic technologists~~] to perform mammography as specified in [~~accordance~~

~~with~~] the requirements of §289.230 that were in effect before [~~prior to~~] April 28, 1999, and any other federal requirements in effect before [~~prior to~~] April 28, 1999, are considered to have met the initial requirements of subparagraph (A) of this paragraph.

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

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

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

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

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

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

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

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

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

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

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

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

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

(E) Continuing experience.

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

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

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

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

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

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

(III) any date in between the two.

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

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

(ii) perform [~~performing~~] a minimum of 25 mammographic examinations under the direct supervision of a qualified MRT[~~medical radiologic technologist~~].

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

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

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

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

(3) Medical physicist. Each medical physicist performing mammographic surveys, evaluating mammographic equipment, or providing oversight of the facility QA [~~quality assurance~~] program as specified in [~~accordance with~~] subsection (k) [~~(u)~~] of this section must[~~, shall~~] hold a current Texas license under the Medical Physics Practice Act, Texas Occupations Code[~~,~~] Chapter 602, in diagnostic radiological physics. The medical physicist must [~~and~~] be registered with the department [~~agency~~] or employed by an entity registered with the department [~~agency~~], as specified in [~~accordance with~~] §289.226(j) of this subchapter [~~title~~] and the Act, unless exempted by §289.226(d)(7)[~~(6)~~] of this subchapter[~~title~~]. Each medical physicist must [~~shall~~] meet the following qualifications.

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

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

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

(iii) [~~have~~] experience conducting surveys of at least one mammography facility and a total of at least 10 [~~ten~~] mammography machines. Experience [~~After April 28, 1999, experience~~] conducting surveys must be acquired under the direct supervision of a medical physicist who meets the requirements of subparagraphs (A), [~~and~~] (C), and (D) of this paragraph. No more than one survey of a specific machine within a period of 60 days can be counted towards the total mammography machine survey requirement.

(B) Alternative initial qualifications. Individuals who qualified as a medical physicist as specified in [~~accordance with~~] the requirements of this section that were in effect before [~~prior to~~] April 28, 1999, or any other equivalent state or federal requirements in effect before [~~prior to~~] April 28, 1999, and have met the following additional qualifications before [~~prior to~~] April 28, 1999, are determined to have met the initial qualifications of subparagraph (A) of this paragraph:

(i) a bachelor's degree or higher in a physical science from an accredited institution with no less than 10 [~~ten~~] semester hours or equivalent of college undergraduate or graduate level physics;

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

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

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

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

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

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

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

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

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

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

(ii) Each medical physicist must also complete at least eight hours of training in any mammography modality in which the medical physicist has not been

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

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

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

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

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

(D) Continuing experience.

(i) Each medical physicist must perform a survey of two mammography facilities and at least six mammography machines. No more than one survey of a specific facility within a 10-month period or a specific machine within 60 days can be counted toward the total mammography machine survey requirement.

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

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

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

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

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

(III) any date in between the two.

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

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

(ii) perform [~~performing a sufficient number of~~] surveys, under the direct supervision of a qualified medical physicist, to bring their total up to two

mammography facilities and a total of at least six mammography machines for the prior 24 months. No more than one survey of a specific machine within a period of 60 days may [~~shall~~] be counted towards the total mammography machine survey requirement.

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

(A) Facilities must maintain records of training and experience relevant to their qualifications, as specified in subsection (h)(1) - (3) of this section, for personnel who work or have worked at the facility as IPs, MRTs, or medical physicists for review by the department.

(B) Records of personnel no longer employed by the facility must be maintained for at least 24 months from the date of the departure of the employee, and these records must be available for review at the time of an annual inspection occurring during those 24 months. Personnel records must be maintained by the facility for inspection by the department as specified in subsection (x) of this section.

(i) The facility must provide copies of these personnel records to current IPs, MRTs, and medical physicists upon their request.

(ii) The facility must provide personnel records to a former employee if the former employee communicates their request within 24 months of the date of their departure.

(I) If it has been greater than 24 months and the facility has maintained those records, the facility must provide those records to former employees upon request.

(II) If a facility closes or stops providing mammography services, it must arrange for current and former personnel to access their personnel qualification records before closing. Access may be provided by a permanent transfer of records to the personnel or the transfer of the records to a facility or other entity that will provide access to these records for at least 24 months from the date of facility closure of mammography services.

(i)[~~(s)~~] Machine Requirements. Mammographic machines must meet the following requirements[~~Equipment standards. Only systems meeting the following standards shall be used~~].

(1) System design. The equipment must be [~~shall have been~~] specifically designed and manufactured for mammography and as required by [~~in accordance with Title~~] 21[~~,~~] CFR[~~,~~] §§1010.2, 1020.30, and 1020.31.

(2) A mammography machine converted from one mammographic modality to another is considered a new machine at the facility under this subsection.

(A) Before clinical use, the mammography machine must undergo a mammography equipment evaluation and demonstrate compliance with applicable requirements.

(B) The facility must also follow the accreditation body's procedures for applying for accreditation of the unit.

(3) Screen-film mammography systems must meet the requirements of 21 CFR Part 900.

(4)[~~(2)~~] Motion of tube-image receptor assembly. The x-ray tube must remain physically stable during exposures. In cases where tubes are designed to move during exposure, the facility must ensure proper and free movement of the unit [~~The assembly shall be capable of being fixed in any position where it is designed to operate. Once fixed in any such position, it shall not undergo unintended motion~~]. In the event of power interruption, this mechanism must [~~shall~~] not fail.

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

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

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

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

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

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

(6)[~~(5)~~] Focal spot and target material selection. Selection of the focal spot or target material must [~~shall~~] be as follows.

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

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

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

(7)[~~(6)~~] Compression. All mammography systems must [~~shall~~] incorporate a compression device.

(A) Application of compression. Each [~~Effective October 28, 2002, and~~

~~thereafter, each~~] system must [~~shall~~] provide the following features operable from both sides of the patient:

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

(ii) fine adjustment compression controls.

(B) Compression paddle.

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

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

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

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

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

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

(8)[(~~7~~)] Technique factor selection and display. Technique factor selection and display must [~~shall~~] be as follows.

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

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

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

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

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

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

(ii) The selected position of the detector must [~~shall~~] be clearly indicated.

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

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

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

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

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

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

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

(11) Each mammography machine must meet the following technical specifications.

(A) Kilovoltage peak accuracy and reproducibility. At the most used clinical settings of kVp, the coefficient of variation of reproducibility of the kVp must be equal to or less than 0.02. The kVp must be accurate to within plus or minus 5.0

percent of the indicated or selected kVp at the following:

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

(ii) the most used clinical kVp; and

(iii) the highest available clinical kVp.

(B) Beam quality and half-value layer (HVL). The HVL must meet the specifications of 21 CFR §1020.30(m)(1) for the minimum HVL. These values, extrapolated to the mammographic range, are shown as follows. This test is performed using the clinical kVp on the standard breast. Values not shown in Table I may be determined by linear interpolation or extrapolation.

Figure: 25 TAC §289.230(i)(11)(B)

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

(D) Dosimetry. The average glandular dose delivered during a single view or DBT exposure of an FDA-accepted phantom simulating a standard breast must not exceed 3.0 milligray (mGy) (0.3 rad) per exposure.

(E) X-ray field, light field, image receptor, and compression paddle alignment. All systems must meet the following.

(i) Beam-limiting devices that allow the entire chest wall edge of the x-ray field to extend to the chest wall edge of the image receptor must provide means to ensure the x-ray field does not extend beyond any edge of the image receptor by more than 2.0 percent of the SID.

(ii) The light field passing through the x-ray beam limitation device must be aligned with the x-ray field so the total of any misalignment of the edges, along the length or the width of the visually defined field at the plane of the breast support surface, does not exceed 2.0 percent of the SID.

(iii) When tested with the compression paddle placed above the breast support surface at a distance equivalent to standard breast thickness, the chest wall edge of the compression paddle does not extend beyond the edge of the image receptor by greater than 1.0 percent of the SID. The shadow of the vertical edge of the compression paddle must not be visible in the image.

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

(j)[~~(t)~~] Medical records and mammography reports.

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

[~~mammography examination that shall include the following information:~~]

(2) The mammographic examination presented for interpretation must be in the original mammographic modality in which it was performed and must not consist of digital images produced through copying or digitizing hardcopy original images.

(3) The mammography report must include the:

(A) patient name [~~of the patient~~] and an additional patient identifier [~~date of birth~~];

(B) [~~date of the~~] examination date;

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

(D)[~~(C)~~] name and signature of the IP [~~interpreting physician~~] who interpreted the mammogram (electronic signatures are acceptable);

(E)[~~(D)~~] overall final assessment of findings using the final assessment categories as defined in clauses (i) - (vii) [~~subsection (c)~~] of this subparagraph, [~~section;~~] and classified in one of the following categories with the assessment statement, including only the word or phrase within the quotation marks:

(i) "Negative" indicates nothing to comment upon (if the IP is aware of clinical findings of symptoms, despite the negative assessment, these must be documented and addressed);

(ii) "Benign" indicates a normal result, with benign findings present, but no evidence of malignancy (if the IP is aware of clinical findings or symptoms, despite the benign assessment, these must be documented and addressed);

(iii) "Probably Benign" indicates a finding that has a high probability of being benign;

(iv) "Suspicious" indicates a finding without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant;

(v) "Highly suggestive of malignancy" indicates a finding that has a high probability of being malignant;

(vi) "Known biopsy proven malignancy" is reserved for known malignancies being mammographically evaluated for definitive therapy; or

(vii) "Post procedure mammogram for marker placement" indicates a mammogram to confirm the deployment and position of a breast tissue marker; or

(F) in cases where the final assessment category cannot be assigned due to incomplete work-up, the IP must assign one of the following classification statements and reasons why the final assessment cannot be made:

(i) "Incomplete: Need additional imaging evaluation" is reserved for examinations where additional imaging needs to be performed before an assessment category identified in subparagraph (E)(i)-(vii) of this paragraph can be given; or

(ii) "Incomplete: Need prior mammograms for comparison" is reserved for examinations where comparison with prior mammograms should be performed before an assessment category identified in subparagraph (E) of this paragraph can be given; if this assessment category is used, a follow-up report with an assessment category identified in subparagraph (E)(i)-(v) of this paragraph must be issued within 30 calendar days of the initial report whether or not comparison views can be obtained;

(G) overall assessment of breast density, classified in one of the following categories:

(i) "The breasts are almost entirely fatty";

(ii) "There are scattered areas of fibroglandular density";

(iii) "The breasts are heterogeneously dense, which may obscure small masses"; or

(iv) "The breasts are extremely dense, which lowers the sensitivity of mammography"; and

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

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

(A) Each facility must send a mammography report to referring healthcare providers, or patients who do not name a healthcare provider to receive the mammography report, the report described in subsection (j)(3) of this section within 30 days of the mammography examination. If the assessment of the mammography report is "Suspicious" or "Highly suggestive of malignancy," the facility must send this report within seven calendar days of the mammography examination. [~~patients advising them of the results of the mammography examination and any further medical needs indicated. The report shall include a summary written in language easily understood by a lay person; and~~]

(B) Each facility must send a mammography report summary, written in plain language, to patients advising them of the results of the mammography examination and any further medical needs within 30 days of the mammography examination. If the assessment of the mammography report is "Suspicious" or

"Highly suggestive of malignancy," the facility must send this report summary within seven calendar days of the final interpretation of the mammogram[~~referring physicians, or in the case of self-referral, to the physician indicated by the patient, advising them of the results of the mammography examination, containing the information specified in paragraph (1) of this subsection, and any further medical needs indicated~~].

(5) A summary of the report written in plain language must be provided within 30 days of interpretation and include:

(A) patient name;

(B) name, address, and telephone number of the facility performing the mammographic examination; and

(C) assessment of breast density as described in subsection (j)(3)(G) of this section, as applicable.

(i) If the mammography report identifies the patient's breast density as "The breasts are almost entirely fatty" or "There are scattered areas of fibroglandular density," the summary must include the statement, "Breast tissue can be either dense or not dense. Dense tissue makes it harder to find breast cancer on a mammogram and also raises the risk of developing breast cancer. Your breast tissue is not dense. Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation."

(ii) If the mammography report identifies the breast density as "The breasts are heterogeneously dense, which may obscure small masses" or "The breasts are extremely dense, which lowers the sensitivity of mammography," the summary must include the statement, "Breast tissue can be either dense or not dense. Dense tissue makes it harder to find breast cancer on a mammogram and also raises the risk of developing breast cancer. Your breast tissue is dense. In some people with dense tissue, other imaging tests in addition to a mammogram may help find cancers. Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation."

(6)[~~(3)~~] Follow-up with patients and healthcare provider [~~physicians~~]. Each facility must [~~registrant shall~~] follow-up to confirm if [~~the following~~]:

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

(B) healthcare providers [~~that physicians~~] have received proper notification of patients with positive findings or needing repeat examinations [~~exams~~].

(7)[~~(4)~~] Retention of clinical images for a current, closed, or terminated facility [~~registrants~~].

(A) A facility must implement policies and procedures to minimize the possibility of loss of these records. The original mammograms must be retained, in retrievable form in the mammographic modality in which they were produced, for a

minimum of five years. Original mammograms cannot be produced by copying or digitizing hardcopy originals[~~Each registrant that performs mammograms shall maintain mammography films and reports in a permanent medical record for a minimum of five years~~]. If [~~no~~] additional mammograms of the patient are not performed at the facility, the images [~~films~~] and reports must [~~shall~~] be maintained for a minimum of 10 [~~ten~~] years as specified in subsection (x) of this section.

(B) Each facility performing [~~registrant that performs~~] mammograms must [~~shall~~], within 15 calendar [~~30~~] days of request by or on behalf of the patient, permanently or temporarily transfer the original mammograms and copies of the patient's reports to a medical institution, a physician, or to the patient directly.

(i) Transferred mammograms must be in the mammographic modality in which they were produced and cannot be produced by copying or digitizing hardcopy originals.

(ii) For digital mammograms or DBT, if the examination is being transferred for final interpretation purposes, the facility must be able to provide the recipient with original digital images electronically.

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

(D) Any fee charged to a patient for providing the services in subparagraphs (B) - (C) of this paragraph must not exceed the documented costs associated with this service.

(E)[~~(D)~~] Closure [~~Upon closure~~] or termination.[~~,~~]

(i) The facility must [~~the registrant shall~~] maintain the mammography images [~~films~~] for five [~~5~~] years. [~~If the facility complies with the following:~~]

(ii)[~~(i)~~] Within [~~within~~] 180 days of closing, the facility must [~~registrant shall directly~~] notify each patient or patient's representative with instructions on how to access [~~retrieve~~] or authorize disposal of the patient's records.[~~; and~~]

(I) Access may be provided by the permanent transfer of mammographic records to the patient, the patient's healthcare provider, or a facility or other entity that will provide access to patients and healthcare providers. Access to the records must be provided by the facility or other entity for the remainder of the time periods specified in subparagraph (A) of this paragraph.

(II) If a facility ceases to perform mammography but continues to operate as a medical entity and is able to satisfy the record keeping requirements of subparagraph (A) of this paragraph, it may choose to continue to retain the medical records rather than transfer them to another facility, unless a transfer is requested by, or on behalf of, the patient. The facility must notify the AB and department in writing of the arrangements it has made and must make reasonable

efforts to notify all affected patients.

(iii)[~~(ii)~~] Within [~~within~~] 60 days of closing, the facility must [~~registrant shall~~] publish a notice in at least one newspaper, or publicly available media, [~~or more newspapers~~] covering the geographical area served by the closing facility. The notice must [~~shall~~] include:

(I) contact information for [~~on~~] retrieving patient records; and

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

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

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

(A) patient name [~~name of patient~~] and date of birth;

(B) date of examination;

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

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

(E) MRT [~~technologist~~] identification;

(F) cassette [~~cassette/screen~~] identification, if applicable; [~~and~~]

(G) mammography machine identification, if there is more than one machine in the facility;[~~.~~]

(H) compressed breast thickness or degree of compression; and

(I) kVp.

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

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

(1) Responsible individuals. Responsibility for the QA [~~quality assurance~~]

program and [~~for~~] each of its elements must [~~shall~~] be assigned to individuals who are qualified for their assignments and [~~who shall be~~] allowed adequate time to perform these duties.

(A) Lead interpreting physician. The facility must [~~registrant shall~~] identify a LIP [~~lead interpreting physician~~] who is responsible for [~~shall have the general responsibility of~~]:

(i) ensuring [~~that~~] the QA [~~quality assurance~~] program meets all requirements of this subsection and subsections (l) and (m)[~~(v) and (w)~~] of this section;

(ii) reviewing and documenting, with date and signature, the MRTs' QC [~~technologists' quality control~~] test results at least every three months or more frequently if consistency has not yet been achieved;

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

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

(B) Interpreting physicians. All [~~interpreting~~] physicians interpreting mammograms for a facility must [~~the registrant shall~~]:

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

(ii) participate in the medical outcomes audit program.

(C) Medical physicist. Each facility must [~~registrant shall~~] use the services of a licensed medical physicist to survey mammography equipment and oversee the equipment-related QA [~~quality assurance~~] practices of the facility. At a minimum, the medical physicist is [~~shall be~~] responsible for performing the surveys, performing [~~and the~~] mammography equipment evaluations, and providing the facility with the reports described in subsection (l)(5) and (6)[~~(v)(10) and (11)~~] of this section.

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

(2) Quality assurance records.

(A) The LIP [~~lead interpreting physician~~], QC [~~quality control~~] technologist, and medical physicist must [~~shall~~] ensure [~~that~~] records concerning mammography technique and procedures, QC [~~quality control~~] (include monitoring data, corrective actions, and the effectiveness of the corrective actions), safety, protection, and employee qualifications related to [~~meet~~] assigned QA [~~quality assurance~~] tasks are properly maintained and updated.

(B) The QC [~~These quality control~~] records must [~~shall~~] be kept for each test specified in subsections (l) and (m)[~~(v) and (w)~~] of this section, as specified in [~~accordance with~~] subsection (x)[~~(ee)~~] of this section.

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

(1) Facilities with screen-film systems must perform QC tests as specified in 21 CFR Part 900[~~Daily quality control tests. Film processors used to develop mammograms shall be adjusted and maintained to meet the technical development specifications for the mammography film in use. A processor performance test shall be completed and the results charted on each day that clinical films are processed before any clinical films are processed that day~~].

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

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

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

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

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

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

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

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

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

(2) Systems with image receptor modalities, other than screen-film, must follow a QA program that is substantially the same as the one recommended by the image receptor manufacturer[~~Weekly quality control tests. These tests shall be performed at an interval no greater than seven days. If mammography is not being performed on the date the test is due and more than seven days have past since the last test, the tests shall be performed prior to resuming mammography. An image quality evaluation test, using an FDA-accepted phantom, shall meet the following parameters~~].

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

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

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

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

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

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

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

[~~(B) Repeat analysis. A repeat analysis on clinical images repeated or rejected shall be performed, analyzed, and documented. The total repeat or reject rate shall not exceed 5.0%. If the total repeat or reject rate changes from the previously determined rate by more than 2.0% of the total films included in the analysis, the reason(s) for the change shall be determined. Corrective action shall~~

be taken and documented if the total repeat or reject rate for the facility exceeds 5.0% or changes from the previously determined rate by more than 2.0% of the total films included in the analysis. Test films, cleared films, or film processed as a result of exposure of a film bin are not to be included in the count for repeat analysis. Films included in the repeat analysis are not required to be kept after completion of the analysis.]

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

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

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

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

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

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

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

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

[(ii) the most commonly used clinical kVp; and]

[(iii) the highest available clinical kVp.]

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

[(i) Each system used for mammography, in combination with the

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

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

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

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

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

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

[~~Figure: 25 TAC §289.230(v)(5)(D)~~]

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

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

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

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

[~~(ii) If a light field that passes through the x-ray beam limitation device is provided, it shall be aligned with the x-ray field so that the total of any misalignment of the edges of the light field and the x-ray field along either the length or the width of the visually defined field at the plane of the breast support~~

surface shall not exceed 2.0% of the SID.]

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

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

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

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

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

[(i) an override capability to allow maintenance of compression;]

[(ii) a continuous display of the override status; and]

[(iii) a manual emergency compression release that can be activated in the event of power or automatic release failure.]

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

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

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

(3)[~~(8)~~] Mobile service operation.

(A) The mobile facility must [~~registrant shall~~] verify [~~that~~] mammography machines used to produce mammograms at more than one location meet the requirements in paragraphs (1) and (2)[~~(1) - (7)~~] of this subsection.

(B) At [~~In addition, at~~] each examination location, before any examinations are conducted, the facility must [~~registrant shall~~] verify satisfactory performance of the mammography machines by using a testing [~~test~~] method, as required by the manufacturer, establishing [~~that establishes~~] the adequacy of the image quality produced by the machine.

(C) Processor performance testing must be completed as required by 21 CFR Part 900 [~~shall be in accordance with paragraph (1) of this subsection~~].

(4)[~~(9)~~] Use of test results. After completion of the tests specified in paragraphs (1) and (2)[~~(1) - (8)~~] of this subsection, the following must [~~shall~~] occur.

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

(B) If components [~~Components~~] of the mammography system [~~that~~] fail QA [~~quality assurance~~] tests, the facility must follow [~~shall have~~] corrective actions required by 21 CFR Part 900, or the QA program recommended by the image receptor manufacturer[~~as indicated in the following~~].

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

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

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

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

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

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

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

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

[~~(V) paragraph (7) of this subsection describing quality control tests of~~

~~other modalities; and~~]

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

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

(C) Documentation of the tests and the corrective actions described in subparagraph (B) of this paragraph must [~~shall~~] be maintained as specified in [~~accordance with~~] subsection (x)[~~(ee)~~] of this section.

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

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

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

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

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

(B)[~~(C)~~] If any deficiencies require immediate corrective action as specified in paragraphs (1) - (3) of this subsection[~~the following tests indicate deficiencies~~], the physicist must [~~shall~~] give a preliminary [~~oral or~~] written report to the facility within 72 hours of the survey.[~~:~~]

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

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

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

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

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

(i) date, name, and signature of the medical physicist performing or supervising the survey;

(ii) name and signature of each individual under the direct supervision of the medical physicist performing any part of the survey, as applicable;

(iii) name of the facility;

(iv) address of facility;

(v) registration number of the facility;

(vi) make, model, and serial number from the machine control panel;

(vii) registration number of the service provider performing the survey;

(viii) service provider email address;

(ix) business mailing address of the service provider performing the survey; and

(x) date of the last calibration of testing equipment.

(D)[~~(E)~~] The facility must maintain the survey report as specified [~~shall be maintained by the registrant~~] in [~~accordance with~~] subsection (x)[~~(ee)~~] of this section.

(6)[~~(11)~~] Mammography equipment evaluations. Additional evaluations of mammography machines must follow manufacturer specifications. Screen-film mammography machines must follow applicable requirements in 21 CFR Part 900. The mammography equipment evaluation and dosimetry must be performed by a medical physicist or an individual under the direct supervision of a medical physicist[~~or image processors shall be conducted whenever a new mammography machine or processor is installed, a mammography machine or processor is disassembled and reassembled at the same or a new location, major components of mammography machine are changed or repaired, or a processor is overhauled or reconditioned. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in this subsection and subsection (s) of this section~~].

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

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

(7) Each diagnostic review workstation (RWS) used to interpret images must follow manufacturer specifications for display conditions and quality control. If the RWS manufacturer does not specify QC procedures, then a QA program that is substantially the same as the QA program recommended by the image receptor manufacturer must be established and followed.

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

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

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

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

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

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

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

(1) General requirements.

(A) Each facility must [~~registrant shall~~] establish a system to collect and review outcome data for all mammograms performed, including follow-up on the disposition of all positive mammograms and correlation of pathology results with the IP's [~~interpreting physician's~~] mammography report.

(B) For cases of breast cancer among patients imaged at the facility that become known to the facility, the facility must initiate a follow-up on surgical and pathology results and a review of the mammographic examinations taken before the diagnosis of a malignancy.

(C) The [~~Analysis of these~~] outcome data must [~~shall~~] be made individually and collectively for all IPs [~~interpreting physicians~~] at the facility and include determinations of the following. [~~In addition, any cases of breast cancer among women imaged at the facility that subsequently become known to the facility shall prompt the facility to initiate follow-up on surgical and/or pathology results and review of the mammograms taken prior to the diagnosis of a malignancy.~~]

(i) Positive predictive value. The percent of patients with positive mammograms who are diagnosed with breast cancer within one year of the date of the mammographic examination.

(ii) Cancer detection rate. Of the patients initially examined with screening mammograms who receive an assessment of "Incomplete: Need additional imaging evaluation," "Suspicious," or "Highly Suggestive of Malignancy" on the screening mammogram or on a subsequent diagnostic mammogram, the number of patients who are diagnosed with breast cancer within one year of the date of the initial screening mammogram, expressed as a ratio per 1,000 patients.

(iii) Recall rate. The percentage of screening mammograms given an assessment of "Incomplete: Need additional imaging evaluation."

(2) Frequency of audit analysis. The facility's first audit analysis must begin within [~~shall be initiated no later than~~] 12 months of the facility becoming certified, and completed within the following 12 months [~~after the date the facility becomes certified or 12 months after April 28, 1999, whichever date is the latest. This audit analysis shall be complete within an additional 12 months~~] to permit completion of diagnostic procedures and data collection.

(A) Subsequent audit analyses will be conducted at least once every 12 months.

(B) The facility must maintain the audit analysis as specified in [~~These shall be maintained in accordance with~~] subsection (x)[~~(ee)~~] of this section.

(3) Reviewing interpreting physician. Each LIP [~~lead interpreting physician~~] or an interpreting physician designated by the LIP must [~~lead interpreting physician shall~~] review the medical outcomes audit data at least annually, not to exceed [~~once every~~] 12 months following the data collection period. This individual must [~~shall~~]

analyze the results of the audit and is [~~shall be~~] responsible for the following:

(A) recording the dates of the audit period [~~period(s)~~];

(B) documenting the results;

(C) notifying other IPs [~~interpreting physicians~~] of their results and the facility's collective [~~registrant's aggregate~~] results;[~~and~~]

(D) documenting any follow up actions and the nature of the follow up; and[~~.~~]

(E) recording the audit completion by providing a signature and date on the audit.

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

(o)[~~(y)~~] Complaints. Each accredited facility must [~~shall~~] do the following:

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

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

(3) provide the consumer with adequate directions for filing serious complaints with the facility's AB if the facility is unable to resolve a serious complaint to the consumer's satisfaction; and

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

(p)[~~(z)~~] Clinical image quality. Clinical images produced by any certified facility must continue to comply with the standards for clinical image quality established by the [~~that~~] facility's AB [~~accreditation body~~].

(q)[~~(aa)~~] Additional mammography review, targeted clinical reviews, and patient notification.

(1) If the department [~~agency certifying body~~] believes the [~~that~~] mammography quality at a facility is [~~may have been~~] compromised and presents a serious risk to human health, the facility must [~~shall~~] provide clinical images and other relevant information, as specified by the department [~~agency certifying body~~], for review by the AB[~~FDA-approved accreditation body~~]. The additional mammography review will assist the department with determining:

(A) the facility's compliance with this section; and

(B) if there is a need to notify affected patients, their healthcare provider, or the public that the reliability, clarity, and accuracy of the interpretation of mammograms has been compromised.

(2) If the department [~~agency certifying body~~] determines the [~~that~~] mammography quality at a facility has been compromised and presents a serious risk to human health, the facility must [~~shall~~] provide clinical images and other relevant information, as specified by the department[~~agency certifying body~~], for review by the AB[~~FDA-approved accreditation body~~]. The department [~~agency certifying body~~] may require such facility to notify patients who received mammograms[~~,~~] and their referring healthcare provider[~~physicians~~]. The notification must occur within a time frame and in a manner specified by the department. The notification must: [~~shall include the deficiencies presenting such risk, the potential consequences to the patient, appropriate remedial measures, and such other relevant information as the agency certifying body may require. Such notification shall occur within a time frame and in a manner specified by the agency.~~]

(A) inform the patient the mammography system failed to satisfy the department and AB's standards;

(B) recommend the patient consult with the patient's healthcare provider regarding the need for another mammogram;

(C) list three non-affiliated facilities closest to the original testing facility that have a certified mammography system; and

(D) include the deficiencies presenting such risk, the potential consequences to the patient, appropriate remedial measures, and other relevant information required by the department.

(3) If the facility is unable or unwilling to perform such notification, the department may notify patients and their referring physicians or other healthcare providers individually or through the mass media.

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

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

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

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

Radiation Protection and Measurements;

(3) written procedures to include methods of:

(A) advising a patient [~~patients~~] and healthcare provider [~~private physicians~~] of the results of the mammography examination as specified in [~~accordance with~~] subsection (j)(4)[~~(t)(2)~~] of this section;

(B) follow-up with patients and healthcare provider as specified [~~physicians~~] in [~~accordance with~~] subsection (j)(6)[~~(t)(3)~~] of this section; and

(C) recommending a healthcare provider to patients who do not have a healthcare provider when clinically indicated, to include when a patient's mammogram assessment is probably benign, suspicious, or highly suggestive of malignancy[~~physician means of selecting a physician~~]; and

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

(s)[~~(cc)~~] Medical research and investigational devices.

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

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

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

(A) [~~(B)~~] 21 CFR[~~,~~] Part 50, Protection of Human Subjects;

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

(B) [~~(D)~~] 21 CFR[~~,~~] Part 54, Financial Disclosure by Clinical Investigators;

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

(D) 21 CFR Part 812, Investigational Device Exemptions; and

(E) 21 CFR[~~,~~] Part 820 [~~821~~], Subpart C, Design Controls [~~of the Quality System Regulation~~].

(t)[~~(dd)~~] Operating and safety [~~Other operating~~] procedures (OSP).

(1) Each facility must implement and maintain written OSP[~~Operating and safety procedures. Each registrant shall have and implement written operating and safety~~

~~procedures that shall be made available to each individual operating x-ray equipment, including any restrictions of the operating technique required for the safe operation of the particular system. These procedures shall include, but are not limited to, the items in subsection (hh)(3) of this section~~].

(2) The OSP must be available to each individual operating x-ray equipment, including any restrictions of the operating technique required for the safe operation of the particular system.

(3) The facility's OSP must address the following requirements, as applicable:

(A) §289.203(b) of this chapter, related to posting notices to workers;

(B) §289.203(c) of this chapter, related to instructions to workers;

(C) §289.203(d) of this chapter, related to notifications and reports to individuals;

(D) §289.231(b) of this subchapter, related to ordering x-ray examinations;

(E) §289.231(m) of this subchapter, related to occupational dose requirements;

(F) §289.231(n) and (q) of this subchapter, related to personnel monitoring requirements;

(G) §289.231(x) and (y) of this subchapter, related to posting of a radiation area;

(H) subsection (h) of this section, related to credentialing requirements for LIPs, IPs, MRTs, and medical physicists;

(I) subsection (j)(7) of this section, related to retention of clinical images;

(J) subsections (k) - (m) of this section, related to quality assurance program;

(K) subsection (k)(1)(B)(i) of this section, related to image quality and corrective action for images of poor quality;

(L) subsection (l)(1) - (3) of this section, related to repeat analysis;

(M) subsection (n) of this section, related to procedures and techniques for mammography patients with breast implants;

(N) subsection (o) of this section, related to the procedure to handle complaints;

(O) subsection (r) of this section, related to self-referral mammography;

(P) subsection (u)(2) of this section, related to the use of a technique chart;

(Q) subsection (u)(5) of this section, related to exposure of individuals other

than the patient;

(R) subsection (u)(6) of this section, related to use of protective devices; and

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

(u) Other operating procedures.

(1) Phantom image scoring protocol must be performed as specified in (l)(1) - (3).

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

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

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

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

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

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

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

(7) Holding of patient or image receptor.

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

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

(C) The facility's [~~registrant's~~] written OSP specified in subsection (t) [~~operating and safety procedures required by paragraph (1)~~] of this section must [~~subsection shall~~] include the following:

(i) a list of circumstances in which mechanical holding devices cannot be routinely utilized; and

(ii) a procedure used for selecting an individual to hold or support the patient or image receptor.

(D) In those cases where the patient must hold the image receptor, any portion of the body other than the area of clinical interest struck by the useful beam must [~~shall~~] be protected by not less than 0.25 mm lead equivalent material.

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

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

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

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

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

[~~(ii) medical radiologic technologists' credentials;~~]

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

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

~~accreditation body;~~]

[~~(v) copy of certification;~~]

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

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

[~~(viii) copy of mammography accreditation.~~]

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

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

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

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

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

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

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

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

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

[~~(H) copy of certification;~~]

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

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

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

[~~(L) records of receipts, transfers, and disposal in accordance with subsection~~

~~(dd)(3) of this section;~~]

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

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

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

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

[~~(Q) copy of mammography accreditation.~~]

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

[~~Figure: 25 TAC §289.230(ee)(3)~~]

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

(1) The department [~~agency~~] may inspect each mammography system that receives a certification as specified in [~~accordance with~~] this chapter no [~~not~~] later than the 60th day after the date the certification is issued.

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

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

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

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

(A) specific identification of the mammography system inspected;

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

(C) [~~the~~] date of the inspection.

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

(A) Notification of such failure must [~~shall~~] be posted:

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

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

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

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

(7) Facilities that receive a severity level I violation and are deemed a serious risk to human health must [~~shall~~] notify patients as specified in (q)(2) of this section. [~~on whom the facility performed a mammogram during the period in which the system failed to meet the agency's certification standards. The facility shall:~~]

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

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

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

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

(9) The patient notification must [~~shall~~] include the following:

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

(B) the potential consequences to the mammography patient.

(10) The facility must [~~registrant shall~~] make a record of the mammography patients notified as specified in [~~accordance with~~] paragraphs (7) and (8) of this subsection for inspection by the department[~~agency~~].

(A) The record must [~~records shall~~] include the name and address of each

mammography patient notified, date of notification, and a copy of the text sent to the individual.

(B) The record must [~~records shall~~] be maintained as specified in [~~accordance with~~] subsection (x)[~~(ee)~~] of this section.

(w)[~~(gg)~~] Requirements for interventional breast radiography machines.

[~~(1) Prohibitions.~~]

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

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

[~~(2) Exemptions.~~]

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

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

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

(1)[~~(3)~~] Interventional [~~Requirements for interventional~~] breast radiography machine certificate of registration (COR)[~~certification~~].

(A) A person who receives, possesses, uses, owns, or acquires [~~Each person having~~] an interventional breast radiography machine must apply for a certificate of registration as specified [~~shall submit an application~~] in [~~accordance with~~] §289.226(e) [~~(1) - (3), (5), and (7)~~] of this subchapter, relating to general requirements for application and registration [~~title~~], and must [~~shall~~] receive a COR [~~certification~~] from the department before using an interventional breast radiography machine on humans[~~agency within 30 days of beginning use~~].

(B) An application for a COR must [~~certification shall~~] be signed by:

(i) a licensed physician, and

(ii) the RSO [~~applicant and the RSO~~].

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

(D) Each applicant must [~~shall~~] submit documentation of [~~evidence that~~] a [~~medical physicist's~~] survey [~~has been~~] performed by a medical physicist, as specified in [~~accordance with~~] paragraph (11)[~~(13)~~] of this subsection.

(2)[~~(4)~~] Issuance of a certificate of registration[~~certification~~].

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

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

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

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

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

(C) Additional information. The department [~~agency~~] may request[~~, and the registrant shall provide,~~] additional information after the certification has been issued to enable the department [~~agency~~] to determine whether the certification should be modified as specified in [~~accordance with~~] §289.226(r) of this subchapter relating to renewal of a certificate of registration[~~title~~].

(3)[~~(5)~~] Modification, suspension, or revocation of the certificate of registration [~~certification~~]. Modification, suspension, or revocation of the COR must occur as specified [~~certification shall be~~] in [~~accordance with~~] §289.226(s)[~~(r)~~] of this subchapter[~~title~~].

(4)[~~(6)~~] Specific terms and conditions of the certificate of registration [~~certification~~]. Specific terms and conditions of the COR, as specified [~~certification shall be~~] in [~~accordance with~~] §289.226 [~~(l)~~] of this subchapter, must be followed [~~title~~].

(5) Renewal of certification. The registrant must file an application for renewal of the COR as follows.

(A) A person who receives, possesses, uses, owns, or acquires an interventional breast radiography machine must apply for renewal as specified in §289.226(e)(1) - (3), (5), and (7) of this subchapter.

(B) An application for renewal must be signed by a licensed physician and the RSO.

(C) An application for renewal must include a medical physicist's survey as specified in paragraph (11) of this subsection.

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

(6) Expiration of the certificate of registration.

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

(B) If a registrant does not apply for renewal of the certification under paragraph (8) of this subsection, as applicable, the registrant must:

(i) terminate use of all interventional breast radiography machines;

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

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

(7) Termination of certification. When a registrant decides to terminate all activities involving an interventional breast radiography machine authorized under the COR, the registrant must notify the department immediately and:

(A) request termination of the COR in writing signed by the RSO, owner, or a person authorized to act on behalf of the registrant;

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

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

(8)[~~(7)~~] Responsibilities of registrant.

[~~(A) The registrant shall comply with the following:~~]

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

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

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

(i) name and mailing address;

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

(iii) addition or removal of any interventional breast radiography machine [~~machine(s)~~].

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

(C)[~~(D)~~] A facility with an existing certification may begin using a new or replacement interventional breast radiography machine before receiving an updated certification if the registrant submits to the department the required [~~agency (required/prescribed)~~] documentation with a medical physicist's report as specified in [~~accordance with~~] paragraph (11)[~~(13)~~] of this subsection, verifying compliance of the new interventional breast radiography machine with this section. The medical physicist's report is required before [~~prior to~~] using the interventional breast radiography machine on patients.

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

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

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

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

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

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

[~~(9) Expiration of certification.~~]

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

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

[~~(i) terminate use of all interventional breast radiography machines;~~]

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

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

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

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

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

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

(9)[~~(11)~~] Personnel requirements.

(A) An operator must maintain[~~A medical radiologic technologist (operators of equipment) shall hold~~] a current general certificate as required by [~~in accordance with~~] the Medical Radiologic Technologist Certification Act, Texas Occupations Code[~~,~~] Chapter 601.

(B) A medical physicist must maintain [~~shall hold~~] a current Texas license as required by [~~under~~] the Medical Physics Practice Act, Texas Occupations Code[~~,~~] Chapter 602, in diagnostic radiological physics and be registered with the department [~~agency~~] or employed by an entity registered with the department [~~agency~~], as specified in [~~accordance with~~] §289.226(j) of this subchapter, relating to application for registration of radiation machine services,[~~title~~] and the Act, unless exempted by §289.226(d)(7)[~~(6)~~] of this subchapter, relating to exemptions [~~title~~].

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

(A) If any failures are noted, corrective actions must [~~shall~~] be taken within the time frame established [~~indicated/established~~] by the manufacturer or medical

physicist. If a time frame is not [~~In the event, that no time frames are~~] indicated, corrective action must [~~shall~~] be completed within 30 days of the failure.

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

(11)[~~(13)~~] Interventional breast radiography machine evaluations and annual survey.

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

(i) whenever a new interventional breast radiography machine is installed, or disassembled[~~,~~] and reassembled, at the same or a new location;

(ii) whenever major components of an interventional breast radiography machine are changed or repaired; and

(iii) annually or at intervals not to exceed 14 months from the date of the previous survey[~~on an annual basis~~].

(B) Annual survey. Annual surveys for interventional mammography machines must be conducted as specified, or substantially the same as specified, in the machine's QA program recommended by the manufacturer[~~The following quality assurance tests shall be performed: AEC, kVp, focal spot condition, HVL, collimation, alignments, and dosimetry tests in accordance with subsection (v)(5)(A) - (G) of this section~~].

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

(D) The medical physicist must [~~shall~~] prepare a written report for the facility within 30 days of the date of the survey. The survey report must include a summary of the tests performed, all test conditions, specifications, results, and recommendations for corrective actions and [~~to include the following~~]:

(i) date, name, and signature of the medical physicist performing or supervising the survey; [~~a written survey report that includes a summary of the tests performed, all test conditions, specifications, results, and recommendations for corrective actions; and~~]

(ii) name and signature of each individual under the direct supervision of the medical physicist performing any part of the survey, as applicable; [~~date and signature of the medical physicist performing or supervising the survey. If the survey was performed entirely or in part by another individual under the direct supervision of the medical physicist, that individual and the part of the survey that individual performed shall also be identified in the survey.~~]

(iii) name of the facility;

(iv) address of facility;

(v) registration number of the facility;

(vi) make, model, and serial number from the machine control panel;

(vii) registration number of physicist and service company performing the survey;

(viii) service provider email address;

(ix) mailing or business address of the service provider performing the survey; and

(x) date of the last calibration of testing equipment.

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

(A) [~~posting notices to workers in accordance with~~] §289.203(b) of this chapter, related to posting notices to workers[~~title~~];

(B) [~~instructions to workers in accordance with~~] §289.203(c) of this chapter, related to instructions to workers[~~title~~];

(C) §289.203(d) of this chapter, related to notifications and reports to individuals [~~in accordance with §289.203(d) of this title~~];

(D) [~~ordering x-ray exams in accordance with~~] §289.231(b) of this subchapter, related to ordering x-ray examinations[~~title~~];

(E) §289.231(m) of this subchapter, related to occupational dose requirements [~~in accordance with §289.231(m) of this title~~];

(F) [~~personnel monitoring requirements in accordance with~~] §289.231(n) and (q) of this subchapter, related to personnel monitoring requirements[~~title~~];

(G) paragraph (9) of this subsection, related to credentialing requirements for operators [~~medical radiologic technologists,~~] and medical physicists [~~in accordance with paragraph (11) of this subsection~~];

(H) [~~use of a technique chart in accordance with~~] paragraph (19)[~~(22)~~] of this subsection, related to use of a technique chart;

(I) paragraph (16) of this subsection, related to exposure of individuals other than the patient [~~in accordance with paragraph (18) of this subsection~~]; and

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

receptors [~~in accordance with subsection (dd)(7) of this section~~].

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

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

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

(C) [~~the~~] manufacturer's model name and serial number on the control panel. [~~These records shall be maintained in accordance with subsection (ee) of this section for inspection by the agency.~~]

(14)[~~(16)~~] Calibration, maintenance, and modifications. Each facility must [~~registrant shall~~] maintain records showing calibrations, maintenance, and modifications performed on each interventional breast radiography machine. These records must be maintained as specified in subsection (x) of this section for inspection by the department and [~~shall~~] include the:

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

(B) [~~the~~] name of the individual making the record; and

(C) [~~the~~] manufacturer's model name and serial number on the control panel. [~~These records shall be maintained in accordance with subsection (ee) of this section for inspection by the agency.~~]

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

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

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

(17)[~~(20)~~] Inspection requirements. Inspections of interventional breast radiography machines are specified [~~Inspection requirements~~] in [~~accordance with~~] subsection (v)(2) - (4)[~~(ff)(2) - (4)~~] of this section.

(18)[~~(21)~~] Equipment requirements. Interventional breast radiography machines must meet the equipment [~~Equipment~~] requirements specified in [~~accordance with~~] §289.227(h) of this subchapter,[~~title (~~] relating to certified x-ray systems [~~Use of Radiation Machines in the Healing Arts)~~].

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

(x) Record requirements. Records specified in this section must be maintained for inspection by the department as specified in paragraph (3) of this subsection. Records may be maintained electronically as specified in §289.231(ff)(3) of this subchapter.

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

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

(i) OSP as specified in subsection (t)(1) of this section;

(ii) operator's credentials;

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

(iv) current copies of §289.203, §289.226, §289.230, and §289.231 of this chapter;

(v) copy of certification;

(vi) certification of inspection as specified in subsection (v)(5) of this section;

(vii) notice of failure from last inspection as specified in subsection (v)(6) of this section, if applicable; and

(viii) copy of mammography accreditation.

(B) Copies of all other records specified in this section must be maintained at a specified location.

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

(A) credentialing, continuing education, and continuing experience records for IPs, MRTs, and medical physicists operating at the location specified in subsection (h) of this section;

(B) mandatory training records for IPs and medical physicists operating at the location specified in subsection (h) of this section, if applicable;

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

(D) current copies of §289.203, §289.226, §289.230, and §289.231 of this chapter;

(E) copy of certification;

(F) QA program as specified in subsections (k), (l), and (m) of this section;

(G) quality control records as specified in subsection (k)(2) of this section;

(H) OSP as specified in subsection (t)(1) of this section;

(I) records of receipts, transfers, and disposal as specified in subsection (u)(3) of this section;

(J) calibration, maintenance, and modification records as specified in subsection (t)(8) of this section;

(K) certification of inspection as specified in subsection (v)(5) of this section;

(L) notification of failure as specified in subsection (v)(6), if applicable;

(M) records of notification of patients as specified in subsection (v)(10) this section; and

(N) copy of mammography accreditation.

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

Figure: 25 TAC §289.230(x)(3).

[~~(hh) Appendices.~~]

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

[~~(A) breast anatomy and physiology;~~]

[~~(B) positioning and compression;~~]

[~~(C) quality assurance/quality control techniques;~~]

[~~(D) imaging of patients with breast implants; and~~]

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

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

[~~(A) radiation physics, including radiation physics specific to mammography;~~]

[~~(B) radiation effects;~~]

[~~(C) radiation protection; and~~]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

~~section;~~]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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