

## 25 TEXAS ADMINISTRATIVE CODE

### §289.227

#### Use of Radiation Machines in the Healing Arts

(effective May 1, 2013)

(Shaded text is added text or significant changes to Sept 2004 rule)

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## 25 TEXAS ADMINISTRATIVE CODE

### §289.227. Use of Radiation Machines in the Healing Arts.

(a) Purpose. This section establishes requirements for the use of radiation machines in the healing arts.

(b) Scope.

(1) The registrant shall be responsible for directing the operation of the radiation machines under the administrative control of the registrant. The registrant shall assure that the requirements of this section are met in the operation of such radiation machines. All usage of such machines under this section shall be made by or under the supervision of a practitioner of the healing arts.

(2) In addition to the requirements of this section, all registrants, unless otherwise specified, are subject to the requirements of §289.203 of this title (relating to Notices, Instructions, and Reports to Workers; Inspections), §289.204 of this title (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services), §289.205 of this title (relating to Hearing and Enforcement Procedures), §289.226 of this title (relating to Registration of Radiation Machine Use and Services), and §289.231 of this title (relating to General Provisions and Standards for Protection Against Machine-Produced Radiation).

(3) The use of mammography radiation machines is subject to the requirements in §289.230 of this title (relating to Certification of Mammography Systems and Mammography Machines Used for Interventional Breast Radiography), and §289.234 of this title (relating to Mammography Accreditation). The use of dental radiation machines is subject to the requirements in §289.232 of this title (relating to Radiation Control Regulations for Dental Radiation Machines). However, dental radiation machines located in a facility that also has other healing arts radiation machines will be inspected at the intervals specified in §289.231(II)(2) of this title, and equipment performance evaluations performed at the interval specified for a medical facility in subsection (o)(1) of this section. The use of radiation machines for veterinary medicine is subject to the requirements in §289.233 of this title (relating to Radiation Control Regulations for Radiation Machines in Veterinary Medicine).

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

(c) Prohibitions.

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

(2) Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed practitioner of the healing arts. 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, except as authorized by §289.226(h) of this title; and

(C) exposure of an individual for the purpose of research, except as authorized by §289.226(t)(1) of this title.

(3) Non-image-intensified fluoroscopic systems shall not be used.

(d) Exemptions.

(1) Portable x-ray systems designed to be hand-held are exempt from the requirements of subsection (i)(11) of this section. The portable radiation machine shall be held by the tube housing support or handle.

(2) Individuals who are sole practitioners and sole operators and the only occupationally exposed individual are exempt from the following requirements:

(A) §289.203(b) of this title, "Posting of notices to workers;"

(B) §289.203(c) of this title, "Instructions to workers;" and

(C) operating and safety procedures in accordance with subsection (i)(2) of this section.

(3) Registrants are exempt from the posting of the radiation area requirements in §289.231(x)(1) of this title provided that the operator has continuous surveillance and access control of the radiation area.

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

(1) Accessible surface--The external surface of the enclosure or housing provided by the manufacturer.

(2) 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 SI unit of air kerma is joule per kilogram and the special name for the unit of kerma is the gray (Gy). For purposes of this section, when exposure in air measured in roentgen (R) is to be converted to dose in air measured in gray (Gy), a nationally recognized standard air conversion factor shall be used.

(3) Aluminum equivalent--The thickness of type 1100 aluminum alloy affording the same attenuation, under specified conditions, as the material in question. The nominal chemical composition of type 1100 aluminum alloy is 99% minimum aluminum, 0.12% copper.

(4) Attenuate--To reduce the exposure rate upon passage of radiation through matter.

(5) Attenuation block--A block or stack, having dimensions 20 centimeters (cm) by 20 cm by 3.8 cm, of type 1100 aluminum alloy or other materials having equivalent attenuation. The nominal chemical composition of type 1100 aluminum alloy is 99% minimum aluminum, 0.12% copper.

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

(7) Automatic exposure rate control (AERC)--A device that automatically controls one or more technique factors in order to obtain a required quantity of radiation per unit time at preselected locations.

(8) Barrier (See definition for protective barrier).

(9) Beam axis--A line from the source through the centers of the x-ray fields.

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

(11) Beam quality (diagnostic x-ray)--A term that describes the penetrating power of the x-ray beam. This is identified numerically by half-value layer and is influenced by kilovolt peak (kVp) and filtration.

(12) Bone densitometer--A device intended for medical purposes to measure bone density and mineral content by x-ray transmission measurements through the bone and adjacent tissues.

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

(14) Category 1 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) Central axis of the beam--A line passing through the virtual source and the center of the plane figure formed by the edge of the first beam-limiting device.

(16) Certified x-ray systems--X-ray systems that have been certified in accordance with Title 21, Code of Federal Regulations (CFR).

(17) Certified radiologist--A physician certified by the American Board of Radiology, the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or Le College des Medecins du Quebec.

(18) Coefficient of variation or C--The ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{\bar{X}} = \frac{1}{\bar{X}} \left[ \sum_{i=1}^n \frac{(X_i - \bar{X})^2}{n-1} \right]^{1/2}$$

where :  $s$  = estimated standard deviation of the population

$\bar{X}$  = mean value of observations in sample

$X_i$  =  $i$ th observation in sample

$n$  = number of observations in sample

(19) Collimator--A device or mechanism by which the x-ray beam is restricted in size.

(20) Computed tomography (CT)--The production of a tomogram by the acquisition and computer processing of x-ray transmission data.

(21) Computed tomography dose index (CTDI)--CTDI represents the average absorbed dose along the z-axis from a series of contiguous irradiations. CTDI approximates the average central dose values associated with a spatially complex dose distribution in a reference acrylic phantom for one particular set of exam techniques. CTDI is defined exclusively for axial scanning.

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

(23) CT conditions of operation--All selectable parameters governing the operation of a CT system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in this subsection.

(24) CT gantry--The tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames that hold these components.

(25) Cumulative air kerma (CAK)--The air kerma accumulated at a specific point in space relative to the fluoroscopic gantry during a procedure. CAK does not include tissue backscatter and is measured in Gy. Some manufacturers identify CAK as cumulative dose (CD).

(26) Diagnostic source assembly--The tube housing assembly with a beam-limiting device attached.

(27) Diagnostic x-ray system--An x-ray system designed for irradiation of any part of the human body for the purpose of diagnosis or visualization.

(28) Dose-area product (DAP)--Dose-area product is the integral of air kerma (absorbed dose to air) across the entire x-ray beam emitted from the x-ray tube. DAP is a surrogate measurement for the entire amount of energy delivered to the patient by the beam. DAP is measured in  $R \times cm^2$  ( $cGy \times cm^2$ ).

(29) Dose-length product (DLP)--DLP is the  $CTDI_{vol}$  multiplied by the scan length (slice thickness x number of slices) in centimeters. It reflects the total energy absorbed attributable to the complete scan acquisition but is independent of what is actually scanned.

(30) Entrance exposure (Entrance air kerma)--The entrance exposure in air expressed in roentgens (R) or the entrance dose in air (air kerma) expressed in gray (Gy), measured at the point where the center of the useful beam enters the patient.

(31) Entrance exposure rate (air kerma rate)--The exposure (air kerma) per unit time at the point where the center of the useful beam enters the patient.

(32) Field emission equipment--Equipment that uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

(33) Field size--The dimensions along the major axes of an area in a plane perpendicular to the central axis of the beam at the normal treatment or examination source-to-image distance and defined by the intersection of the major axes and the 50% isodose line.

(34) Filter--Material placed in the useful beam to preferentially absorb selected radiations.

(35) Fluoroscopic system--A system in which x-ray photons produce a fluoroscopic image. It includes the image receptors such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

(36) Fluoroscopically-Guided Interventional (FGI) Procedures--An interventional diagnostic or therapeutic procedure performed via percutaneous or other access routes, usually with local anesthesia or intravenous sedation, which uses external ionizing radiation in the form of fluoroscopy to localize or characterize a lesion, diagnostic site, or treatment site, to monitor the procedure, and to control and document therapy. FGI procedures may include but not be limited to:

(A) TIPS creation (transjugular intrahepatic portosystemic shunt);

(B) Embolization (any location, any lesion);

(C) Stroke therapy;

(D) Biliary drainage;

(E) Angioplasty with or without stent placement;

(F) Stent-graft placement;

(G) Chemoembolization;

(H) Angiography and intervention for gastrointestinal hemorrhage;

(I) Carotid stent placement;

(J) RF (radiofrequency) cardiac ablation;

(K) Complex placement of cardiac EP (electrophysiology) devices; and



(L) PCI (percutaneous coronary intervention) (single or multiple vessel).

(37) Focal spot--The area projected on the anode of the x-ray tube bombarded by the electrons accelerated from the cathode and from which the useful beam originates.

(38) General purpose x-ray system--Any x-ray system that is not limited by design to radiographic examinations of specific anatomical regions.

(39) Gonadal shield--A protective barrier for the testes or ovaries.

(40) Half-value layer (HVL)--The thickness of a specified material that attenuates the beam of radiation to an extent such that the exposure rate (air kerma rate) is reduced to one-half of its original value.

(41) 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.

(42) Healing arts screening--The testing of asymptomatic human beings using radiation machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment.

(43) High level control for fluoroscopy--Any selected mode having an entrance exposure rate (air kerma rate) above 10 roentgens per minute (R/min) or (100 mGy/min). This mode shall meet the high level requirements in subsection (m)(3)(A)(i)(II), (ii)(II), or (iii)(II) of this section.

(44) Image intensifier--A device, installed in its housing that instantaneously converts an x-ray pattern into a corresponding light or digital image.

(45) Image receptor--Any device, such as a fluorescent screen or radiographic film 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.

(46) Irradiation--The exposure of matter to ionizing radiation.

(47) kV--Kilovolt.

(48) kVp--Kilovolt peak (See definition for peak tube potential).

(49) kWs--Kilowatt-second. It is equivalent to  $10^3$  watt-second, where 1 watt-second = 1 kV x 1 milliamper (mA) x 1 second.

(50) Lead equivalent--The thickness of lead affording the same attenuation, under specified conditions, as the material in question.

(51) Leakage radiation--Radiation emanating from the diagnostic source assembly except for the useful beam and radiation produced when the exposure switch or timer is not activated.

(52) Leakage technique factors--The technique factors associated with the diagnostic source assembly that is used in measuring leakage radiation. They are defined as follows:

(A) for diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs (10 milliamperes-second (mAs)) or the minimum obtainable from the unit, whichever is larger;

(B) for diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential; or

(C) for all other diagnostic source assemblies, the maximum-rated peak tube potential and the continuous tube current for the maximum-rated peak tube potential.

(53) Licensed medical physicist--An individual holding a current Texas license under the Medical Physics Practice Act, Texas Occupations Code, Chapter 602, with a specialty in diagnostic medical physics.

(54) mA--Milliamperes.

(55) mAs--Milliamperes-second.

(56) Medical research--The investigation of various health risks and diseases.

(57) Mobile service operation--The provision of x-ray systems and personnel at temporary sites for limited time periods. The x-ray systems may be fixed inside a motorized vehicle or may be a radiation machine that may be removed from the vehicle and taken into a facility for use.

(58) Multiple slice tomogram system--A computed tomography x-ray system that obtains x-ray transmission data simultaneously during a single scan to produce more than one tomogram.

(59) Nominal tomographic section thickness--The full-width at half-maximum of the sensitivity profile taken at the center of the cross sectional volume over which x-ray transmission data are collected.

(60) Non-certified x-ray systems--X-ray systems manufactured and assembled prior to certification requirements of Title 21, CFR, effective as specified in Title 21, CFR, Part 1020.30(a).

(61) Patient--An individual subjected to healing arts examination, diagnosis, or treatment.

(62) Peak tube potential--The maximum value of the potential difference in kilovolts across the x-ray tube during an exposure.

(63) Phantom--A volume of material behaving in a manner that can be related to tissue with respect to the attenuation and scattering of radiation.

(64) Phototimer--A method for controlling exposures to image receptors by the amount of radiation that reaches a radiation detection device. The radiation detection device is part of an electronic circuit that controls the duration of time the tube is activated (See definition for automatic exposure control).

(65) Physician--An individual licensed by the Texas Medical Board.

(66) Portable x-ray systems--X-ray systems that are mounted on a permanent base with wheels and/or casters for moving while completely assembled. Portable x-ray systems may also include x-ray systems designed to be hand-carried.

(67) Practitioner of the healing arts (practitioner)--A person licensed to practice healing arts by either the Texas Medical Board as a physician, the Texas Board of Chiropractic Examiners, or the Texas State Board of Podiatric Medical Examiners.

(68) Primary protective barrier--(See definition for protective barrier).

(69) Protective apron--An apron made of radiation attenuating materials used to reduce radiation exposure.

(70) Protective barrier--A barrier of radiation absorbing materials used to reduce radiation exposure. The types of protective barriers are as follows:

(A) primary protective barrier--A barrier sufficient to attenuate the useful beam to the required degree.

(B) secondary protective barrier--A barrier sufficient to attenuate the stray radiation to the required degree.

(71) Protective glove--A glove made of radiation attenuating materials used to reduce radiation exposure.

(72) Radiation machine--Any device capable of producing ionizing radiation except those devices with radioactive material as the only source of radiation.

(73) Radiation oncologist--A physician with a specialty in radiation therapy.

(74) Radiograph--An image receptor on which the image is created directly or indirectly by an x-ray exposure and results in a permanent record.

(75) Radiologist--A physician with a specialty in using ionizing and non-ionizing radiation for medical imaging and interpretation for diagnostic and treatment purposes.

(76) Reference level--The suggested levels at which a facility should review its methods and determine if acceptable image quality can be achieved at a lower radiation output level as determined by measurements taken from a selected phantom. The specific purpose of the reference level is to provide a benchmark for comparison of imaging equipment performance under prescribed conditions and is not intended to define a maximum or minimum exposure limit for any patient.

(77) Reference plane--A plane that is displaced from and parallel to the tomographic plane.

(78) Roentgen (R)--The special unit of exposure. One roentgen (R) equals  $2.58 \times 10^{-4}$  C/kg of air.

(79) Scan--The complete process of collecting x-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.

(80) Scan increment--The amount of relative displacement of the patient with respect to the CT system between successive scans measured along the direction of such displacement.

(81) Scan sequence--A preselected set of 2 or more scans performed consecutively under preselected CT conditions of operation.

(82) Scan time--The period of time between the beginning and end of x-ray transmission data accumulation for a single scan.

(83) Scattered radiation--Radiation that has been deviated in direction during passage through matter.

(84) Secondary protective barrier (See definition for protective barrier).

(85) Shutter--A device attached to the tube housing assembly that can totally intercept the useful beam and that has a lead equivalency not less than that of the tube housing assembly.

(86) Single tomogram system--CT system that obtains x-ray transmission data during a scan to produce a single tomogram.

(87) Source--The focal spot of the x-ray tube.

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

(89) Source-to-skin distance (SSD)--The distance from the source to the skin of the patient.

(90) Special purpose x-ray system--Any x-ray system that is limited by design to radiographic examinations of specific anatomical regions. Special purpose x-ray systems include, but are not limited to, dedicated chest units, cystography units, and head and skull units.

(91) Special procedures--The application of special x-ray systems and specialized techniques to obtain required diagnostic information. Special procedures include, but are not limited to, angiography, cardiac catheterization, myelography, and surgery.

(92) Spot film--A radiograph that is made during a fluoroscopic examination to permanently record conditions that exist during that fluoroscopic procedure.

(93) Spot film device--A device intended to transport and/or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

(94) Stationary x-ray system--A stationary x-ray system that is installed in a fixed location.

(95) Stray radiation--The sum of leakage and scattered radiation.

(96) Supervision--The delegating, by the practitioner, of the task of applying radiation to persons who perform tasks under the practitioner's control and who are certified under the Medical Radiologic Technologist Act, Texas Occupations Code, Chapter 601. The practitioner assumes full responsibility for these tasks and shall assure that the tasks will be administered correctly.

(97) Target--The part of a radiation machine head that by design intercepts a beam of accelerated particles with subsequent emission of other radiation.

(98) Technique chart--A chart that provides technical factors, anatomical examination, patient thickness for examination being performed, and source-to-image distance needed to make clinical radiographs when the radiographic system is in manual mode.

(99) Technique factors--The conditions of operation that are specified as follows:

(A) for capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs.

(B) for field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses;

(C) for CT systems designed for pulsed operations, peak tube potential in kV, scan time in seconds, and either tube current in mA, x-ray pulse width in seconds, and the number of x-ray pulses per scan or the product of tube current, x-ray pulse width, and the number of x-ray pulses in mAs;

(D) for CT systems not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds or the product of tube current and exposure time in mAs when the scan time and exposure time are equivalent; and

(E) for all other x-ray systems, peak tube potential in kV and either tube current in mA and exposure time in seconds or the product of tube current and exposure time in mAs.

(100) Tomogram--The depiction of the x-ray attenuation properties of a section through the body.

(101) Tomographic plane--The geometric plane that is identified as corresponding to the output.

(102) Tomographic section--The volume of an object whose x-ray attenuation properties are imaged in a tomogram.

(103) Traceable to a national standard--This indicates that a quantity or a measurement has been compared to a national standard, for example, the National Institute of Standards and Technology, directly or indirectly through one or more intermediate steps and that all comparisons have been documented.

(104) Tube--An x-ray tube, unless otherwise specified.

(105) Tube housing assembly--The tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.

(106) Useful beam--Radiation that passes through the window, aperture, cone, or other collimating device of the source housing. Also referred to as the primary beam.

(107) X-ray control panel--A device that controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices that control the technique factors of an x-ray exposure.

(108) X-ray field--That area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate (air kerma rate) is 1/4th of the maximum in the intersection.

(109) X-ray high-voltage generator--A device that transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tubes, high-voltage switches, electrical protective devices, and other appropriate elements.

(110) X-ray system--An assemblage of components for the controlled production of x-rays and include a radiation machine. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components that function with the system are considered integral parts of the system.

(111) X-ray tube--Any electron tube that is designed to be used primarily for the production of x rays.

(f) Morgues, forensic medicine, and educational facilities.

(1) Morgues shall comply with the following requirements:

(A) subsection (b)(1) and (2) of this section concerning scope;

- (B) subsection (c) of this section concerning prohibitions;
- (C) subsection (e) of this section concerning definitions, as applicable;
- (D) subsection (i)(2) of this section concerning operating and safety procedures;
- (E) subsection (i)(4) of this section concerning protective devices;
- (F) subsection (i)(11) of this section concerning holding of tube;
- (G) subsection (k)(1) of this section concerning warning labels;
- (H) subsection (m)(1)(A) of this section concerning fluoroscopy; and
- (I) subsection (s)(1)(A) - (I), and (R) of this section concerning records.

(2) Facilities conducting training using non-humans shall comply with all the requirements of this section except for the following:

- (A) subsection (i)(5) of this section concerning operator credentialing;
- (B) subsection (j) of this section concerning radiographic entrance exposure (air kerma) limits;
- (C) subsections (p), (q) and (r) of this section concerning film processing; and
- (D) subsection (o) of this section concerning equipment performance evaluation.

(g) Requirements for bone densitometers. Bone densitometers shall be exempt from this chapter except for the following:

- (1) §289.203 of this title, §289.204 of this title, §289.205 of this title, §289.226 of this title, and §289.231 of this title;
- (2) healing arts screening and medical research in accordance with §289.226(h) and (t) of this title;
- (3) purpose and scope in accordance with subsections (a) and (b) of this section;
- (4) prohibitions in accordance with subsection (c)(1) and (2) of this section;



- (5) definitions in accordance with subsection (e) of this section, as applicable;
- (6) operating and safety procedures in accordance with subsection (i)(2) of this section;
- (7) operator training in accordance with §140.521 of this title (relating to Bone Densitometry Training);
- (8) gonadal shielding in accordance with subsection (i)(13) of this section;
- (9) warning labels in accordance with §289.231(z) of this title.
- (10) record requirements for authorized use locations and authorized records locations for mobile services in accordance with subsection (s)(1)(A) - (D), (G), (J), (R), and (s)(2) of this section; and
- (11) record requirements for mobile services in accordance with subsection (s)(1)(A), (D), (H), and (J) of this section. These records shall be maintained with the bone densitometer authorized to be used for mobile services.

(h) Certified x-ray systems. In addition to the requirements of this chapter, the registrant shall not make, nor cause to be made, any modification of components or installations of components certified in accordance with the United States Food and Drug Administration (FDA) Title 21, CFR, Part 1020, "Performance Standards for Ionizing Radiation Emitting Products," as amended, in any manner that could cause the installations or the components to fail to meet the requirements of the applicable parts of the standards specified in Title 21, CFR, Part 1020, except where a variance has been granted by the Director, Center for Devices and Radiological Health, FDA. A copy of the variance shall be maintained by the registrant in accordance with subsection (s)(1) of this section for inspection by the agency.

(i) General operating requirements.

(1) Technique chart. A technique chart relevant to the particular radiation machine shall be provided or electronically displayed in the vicinity of the control panel and used by all operators.

(2) Operating and safety procedures.

(A) Each registrant shall have and implement written operating and safety procedures. The procedures shall include, but are not limited to, the following as applicable:

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

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

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

(iv) ordering x-ray exams in accordance with §289.231(b)(1) of this title;

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

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

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

(viii) use of a technique chart in accordance with paragraph (1) of this subsection;

(ix) use of protective devices in accordance with paragraph (4) of this subsection;

(x) credentialing requirements for individuals operating radiation machines in accordance with paragraph (5) of this subsection;

(xi) exposure of individuals other than the patient in accordance with paragraph (7) of this subsection;

(xii) holding of patients or image receptors in accordance with 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.

(xiii) gonadal shielding in accordance with paragraph (13) of this subsection;

(xiv) control of scattered radiation in accordance with subsection (m)(8) of this section; and

(xv) film processing program or digital image processing protocols in accordance with subsections (p), (q), and (r) of this section.

(B) The registrant shall maintain the operating and safety procedures in accordance with subsection (s)(1) of this section for inspection by the agency.

(C) The procedures shall be made available to each individual operating a radiation machine, including any restrictions of the operating technique required for the safe operation of the particular x-ray system.

(D) The registrant shall document that each individual operating a radiation machine has read the operating and safety procedures at least annually and shall maintain this documentation for inspection by the agency. The documentation shall include the following:

(i) name and signature of individual;

(ii) date individual read the operating and safety procedures; and

(iii) initials of the RSO.

(3) Occupational dose limits and personnel monitoring. Except as otherwise exempted, all individuals who are associated with the operation of a radiation machine are subject to the occupational dose limits of §289.231(m) of this title regarding dose limits to individuals, and the personnel monitoring requirements of §289.231(n) of this title.

(4) Protective devices. Protective devices shall be utilized when required, as in paragraphs (8)(B) and (C), (10), and (13) of this subsection, and subsection (m)(8) of this section.

(A) Protective devices shall be of no less than 0.25 millimeter (mm) lead equivalent material except as specified in paragraph (13) of this subsection and subsection (m)(8)(B)(i) of this section.

(B) Protective devices, including aprons, gloves, and shields shall be checked annually for defects such as holes, cracks, and tears. These checks may be performed by the registrant by visual or tactile means, or x-ray imaging. If a defect is found, protective devices shall be replaced or removed from service until repaired. A record of this test shall be made and maintained by the registrant in accordance with subsection (s)(1) of this section for inspection by the agency.

(5) Operator credentialing. Individuals who operate radiation machines for human use shall meet the appropriate credentialing requirements of rules issued in accordance with the Medical Radiologic Technologist Certification Act, Texas Occupations Code, Chapter 601. Copies of the credentialing document shall be maintained at the location(s) where the individual is working.

(6) Practice of medical physics. Surveys, tests, or evaluations required by this section may constitute the practice of medical physics and, therefore, require a license from the Texas Board of Licensure for Professional Medical Physicists in accordance with the Medical Physics Practice Act, Texas Occupations Code, Chapter 602.

(7) Exposure of individuals other than the patient. No individual other than a patient, operator, and ancillary personnel shall be in the x-ray room or area while exposures are being made unless such individual's assistance is required.

(8) Holding of patient or image receptor.

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

(B) If a patient or image receptor must be held by an individual during an exposure, that individual shall be protected with appropriate shielding devices described in paragraph (4) of this subsection.

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

(9) Viewing system and contact with patient.

(A) Windows, mirrors, closed circuit television, or another method shall be provided to permit the operator to continuously observe the patient during irradiation.

(B) The operator shall be able to maintain verbal, visual, and aural contact with the patient.

(10) Operator position. The operator position during the exposure shall be such that the operator's exposure is as low as reasonably achievable (ALARA) and the operator is a minimum of 6 feet from the source of radiation or protected by an apron, gloves, or other shielding having a minimum of 0.25 mm lead equivalent material.

(11) Holding of tube. In no case shall an individual hold the tube or tube housing assembly supports during any radiographic exposure.

(12) Patient protection. Notwithstanding the provisions of paragraph (7) of this subsection, other patients who are in line with the primary beam and who cannot be removed from the room shall be protected by whole body protective barriers of a minimum of 0.25 mm lead equivalent material or so positioned that the nearest portion of their body is at least 6 feet from both the tube head and the nearest edge of the image receptor.

(13) Gonadal shielding. Gonadal shielding shall be used on patients when the gonads are in or within 5 cm of the useful beam. This requirement does not apply if the shielding will interfere with the diagnostic procedure. Gonadal shielding shall be of at least 0.5 mm lead equivalent material.

(14) Measurements of the radiation output for x-ray, fluoroscopic, and CT systems. Measurements of the radiation output of x-ray, fluoroscopic, and CT systems shall be performed with a calibrated dosimetry system in accordance with the following.

(A) The dosimetry system calibration shall be traceable to a national standard.

(B) Dosimetry systems shall be calibrated within 24 months from the date of the prior calibration.

(C) Measurements of radiation output shall be performed with a dosimetry system that has been calibrated within the 24 months preceding the date of the measurement.

(D) Record of the dosimetry system calibration shall include:

(i) manufacturer's name, model and serial number of each calibrated instrument;

(ii) date of the calibration; and

(iii) name of the individual recording the information.

(E) The registrant shall record the dosimetry system calibration information specified in subparagraph (D)(i) – (iii) of this paragraph and maintain that record in accordance with subsection (s)(1) of this section for inspection by the agency.

(j) Radiographic entrance exposure (air kerma) limits. The in-air exposure (air kerma) determined for the technique used by the registrant for the specified average human adult patient thickness for medical radiography shall not exceed the entrance exposure (air kerma) limits in the following Table I.

TABLE I- RADIOGRAPHIC ENTRANCE EXPOSURE LIMITS (AIR KERMA LIMITS)

Examination	Patient Thickness (cm)	Exposure Limit (mR)	(Air Kerma Limit) (mGy)
PA Chest (Non-Grid)	23	20	(0.2)
PA Chest (Grid)	23	30	(0.3)
Abdomen (KUB)	23	450	(4.5)
Lumbo-Sacral Spine (AP)	23	550	(5.5)
Cervical Spine (AP)	13	120	(1.2)
Thoracic Spine (AP)	23	325	(3.25)
Full Spine	23	300	(3.0)
Skull (lateral)	15	150	(1.5)
Foot (DP)	8	50	(0.5)

(k) Machine requirements for general x-ray and fluoroscopic systems.

(1) Warning label. The warning label will meet the requirements of §289.231(z) of this title.

(2) Mechanical support of tube head. The tube housing assembly shall be adjusted to remain stable during an exposure unless tube housing movement is a designed function of the x-ray system.

(3) Battery charge indicator. On battery-powered x-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

(4) Beam quality. The following requirements apply to beam quality.

(A) Half-value layer.

(i) The half-value layer of the useful beam for a given x-ray tube potential shall not be less than the values shown in the following Table II. If it is necessary to determine such half-value layer at an x-ray tube potential that is not listed in Table II, linear interpolation may be made.

TABLE II - HALF-VALUE LAYER FOR SELECTED kVp

X-ray Tube Voltage (kilovolt peak)		Minimum HVL (mm of aluminum)	
Designed operating range	Measured operating potential	X-ray systems manufactured before June 10, 2006	X-ray systems manufactured on or after June 10, 2006
Below 51	30	0.3	0.3
	40	0.4	0.4
	50	0.5	0.5
51 to 70	51	1.2	1.3
	60	1.3	1.5
	70	1.5	1.8
Above 70	71	2.1	2.5
	80	2.3	2.9
	90	2.5	3.2
	100	2.7	3.6
	110	3.0	3.9
	120	3.2	4.3
	130	3.5	4.7
	140	3.8	5.0
	150	4.1	5.4

(ii) For capacitor energy storage equipment, compliance with the requirements of this paragraph shall be determined with the maximum quantity of charge per exposure.

(B) Filtration controls.

(i) For x-ray systems that have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filters and shall prevent an exposure unless the minimum amount of filtration required by subparagraph (A) of this paragraph is in the useful beam for the given kVp that has been selected.

(ii) Any other system having removable filters shall be required to have the minimum amount of filtration as required by subparagraph (A)(i) of this paragraph permanently located in the useful beam during each exposure.

(5) Multiple tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes that have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the x-ray control panel and at or near the tube housing assembly that has been selected.

(6) Technique and exposure indicators.

(A) The technique factors to be used during an exposure shall be indicated before the exposure begins except when automatic exposure controls are used, in which case the technique factors that are set prior to the exposure shall be indicated.

(B) On x-ray systems having fixed technique factors, the requirement of subparagraph (A) of this paragraph may be met by permanent markings.

(C) The x-ray control panel shall provide visual indication of the production of x-rays.

(D) The indicated technique factors shall be accurate to meet manufacturer's specifications. If these specifications are not available from the manufacturer, the factors shall be accurate to within plus or minus 10% of the indicated setting.

(7) X-ray control. An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time except for an exposure of 0.5 seconds or less or during serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

(l) Additional machine requirements for x-ray systems. This subsection does not apply to fluoroscopic or CT systems.

(1) Beam limitation. Beam limitation shall be as follows.

(A) Stationary general purpose x-ray systems.

(i) Beam-limiting devices shall restrict the useful beam to the area of clinical interest as follows:

(I) the misalignment of the x-ray field for a manual rectangular collimator shall be within plus or minus 2.0% of the SID for the length or width of the image receptor;

(II) the x-ray field for a circular or polygon collimator shall not exceed the diagonal of the image receptor by more than 2.0% of the SID; or

(III) the misalignment of the x-ray field for an automatic or semi-automatic collimator shall be within plus or minus 3.0% of the SID for the length and width of the image receptor and shall be within plus or minus 4.0% of the SID, without regard to the sign, of the sum of the difference of the length and width of the image receptor.



(ii) If the area of clinical interest is smaller than the image receptor, the operator of the x-ray system shall use all beam limiting devices necessary to restrict the useful beam to the clinical area of interest.

(iii) A method shall be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges, either the length or width, of the x-ray field shall not exceed 2.0% of the SID.

(iv) A numerical SID indicator shall be present and shall be accurate to within plus or minus 2.0% of the SID.

(v) The system shall indicate when the axis of the x-ray field is perpendicular to the plane of the image receptor.

(vi) The center of the x-ray field, when perpendicular to the image receptor, shall be accurate to within plus or minus 2.0% of the SID with respect to the center of the image receptor.

(vii) The beam-limiting device shall numerically indicate the field size in the plane of the image receptor.

(viii) Indication of field size dimensions and SIDs shall be specified in inches and/or centimeters.

(ix) The field size indicated on the beam-limiting device shall be within plus or minus 2.0% of the SID along the width and length, separately, of the actual x-ray field size.

(B) Portable x-ray systems. Portable x-ray systems shall comply with the requirements in subparagraph (A) of this paragraph, as applicable, based on manufacturer's design.

(C) X-ray systems designed for one image receptor size. X-ray systems designed for only one image receptor size at a fixed SID shall provide a means to do the following:

(i) limit the x-ray field to no greater than the dimensions of the image receptor at the SID, and to align the center of the x-ray field with the center of the image receptor to within plus or minus 2.0% of the SID center; or

(ii) align the x-ray field such that the x-ray field does not extend beyond any edge of the image receptor at the SID.

(D) Special purpose x-ray systems.

(i) When the x-ray beam is perpendicular to the plane of the image receptor, a means shall be provided to do the following:

(I) limit the x-ray field such that the x-ray field does not exceed each dimension of the image receptor by more than 2.0% of the SID; and

(II) align the center of the x-ray field with the center of the image receptor to within plus or minus 2.0% of the SID.

(ii) The requirements of clause (i) of this subparagraph may be met with a system that meets the requirements for a general purpose x-ray system as specified in subparagraph (A)(i) - (iv) of this paragraph or, when alignment means are also provided, may be met with either of the following:

(I) an assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

(II) a beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the radiation machine is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

(2) Radiation exposure control devices. Radiation exposure control devices shall include the following:

(A) Timers. Means shall be provided to terminate the exposure at a preset time interval, a preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.

(B) AEC. When AEC is provided, the following shall occur.

(i) Indication shall be made on the control panel when AEC mode of operation is selected.

(ii) If the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to 2 pulses.

(iii) The minimum exposure time for all x-ray systems other than that specified in clause (ii) of this subparagraph shall be equal to or less than 0.0167 second or a time interval required to deliver 5 mAs, whichever is greater.

(iv) A visible and/or audible signal shall indicate when an exposure has been terminated.

(C) Exposure interval reproducibility. When all technique factors are held constant, including control panel selections associated with AEC systems, the coefficient of variation of exposure interval for both manual and AEC systems shall not exceed 0.05. This requirement applies to clinically used techniques.

(3) SSD. All portable x-ray systems shall be provided with means to limit the SSD to equal to or greater than 30 cm.

(4) Exposure reproducibility. When all technique factors are held constant, including control panel selections associated with AEC systems, the coefficient of variation of exposure for both manual and AEC systems shall not exceed 0.05. This requirement applies to clinically used techniques.

(5) Linearity. The average ratios of exposure (air kerma) mR/mGy to the indicated mAs product obtained at any 2 consecutive mA or mAs settings shall not differ by more than 0.10 times their sum, where  $\bar{X}_1$  and  $\bar{X}_2$  are the average mR/mAs (mGy/mAs) values obtained at each of 2 consecutive tube current settings:

$$|\bar{X}_1 - \bar{X}_2| \leq 0.10(\bar{X}_1 + \bar{X}_2)$$

(6) Radiation from capacitor. Radiation from capacitor energy storage equipment in standby status. Radiation emitted from the x-ray tube when the exposure switch or timer is not activated shall not exceed a rate of 2 milliroentgens per hour (mR/hr) or 0.02 milligray per hour (mGy/hr) at 5 cm from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

(7) X-ray systems needing correction or repair. In order to achieve compliance with this chapter, the correction or repair shall begin within 30 days following the failure and shall be performed according to a plan designated by the registrant. Correction or repair shall be completed no longer than 90 days from discovery unless authorized by the agency.

(8) Records of an x-ray system corrections or repairs. The registrant shall maintain records of corrections or repairs and any tests, measurements or numerical readings listed in subsection (o)(6) of this section in accordance with subsection (s)(1) of this section for inspection by the agency.

(m) Fluoroscopic systems and spot-film devices for all facilities.

(1) Limitation of the useful beam. Limitation of the useful beam shall be as follows.

(A) Primary barrier.

(i) The fluoroscopic imaging assembly shall be provided with a primary protective barrier that intercepts the entire cross section of the useful beam at any SID.

(ii) The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the useful beam and the imaging device is in place and operable.

(iii) The exposure rate (air kerma rate) due to transmission through the barrier with the attenuation block in the useful beam, combined with radiation through the image intensifier if provided, shall not exceed  $3.34 \times 10^{-3}\%$  of the entrance exposure rate (air kerma rate) at a distance of 10 cm from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor.

(B) Measuring compliance of barrier transmission.

(i) The exposure rate (air kerma rate) due to transmission through the primary protective barrier combined with radiation through the image intensifier shall be determined by measurements averaged over an area of  $100 \text{ cm}^2$  with no linear dimension greater than 20 cm.

(ii) If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 cm above the tabletop.

(iii) If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 cm.

(iv) Movable grids and compression devices shall be removed from the useful beam during the measurement.

(v) The attenuation block shall be positioned in the useful beam 10 cm from the point of measurement of entrance exposure rate (air kerma rate) and between this point and the input surface of the fluoroscopic imaging assembly.

(vi) The collimator shall be fully open when the measurement is made.

(C) X-ray field.

(i) Compliance with clauses (ii) - (vi) of this subparagraph shall be determined with the beam axis perpendicular to the plane of the image receptor.

(ii) Fluoroscopic systems with a fixed SID and the capability of a visible area of no greater than 300 cm<sup>2</sup> shall be provided with either stepless adjustment of the x-ray field or a means to further limit the x-ray field at the image receptor to 125 cm<sup>2</sup> or less. If the equipment is provided with stepless adjustment, the minimum x-ray field size at the maximum SID shall be less than or equal to 5 cm by 5 cm at the image receptor.

(iii) Fluoroscopic systems with a variable SID or a fixed SID with the capability of a visible area of greater than 300 cm<sup>2</sup> shall be provided with stepless adjustment of the field size. The minimum x-ray field size at the maximum SID shall be less than or equal to 5 cm by 5 cm at the image receptor.

(iv) Neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3.0% of the SID. The sum of the excess length and the excess width shall be no greater than 4.0% of the SID.

(v) For rectangular x-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the x-ray field that pass through the center of the visible area of the image receptor.

(vi) For fluoroscopic systems with only a manual mode of collimation, the x-ray field produced shall be limited to the area of the spot-film cassette at 16 inches above tabletop. Additionally, during fluoroscopy, the beam shall be restricted to the area of the input phosphor.

(vii) Spot-film devices shall meet the following additional requirements.

(I) Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the film to the size of that portion of the film that has been selected on the spot-film selector.

(-a-) Such adjustment shall be automatically accomplished except when the x-ray field size in the plane of the film is smaller than that of the selected portion of the film.

(-b-) The total misalignment of the edges of the x-ray field with the respective edges of the selected portion of the image receptor along the length or width dimensions of the x-ray field in the plane of the image receptor shall not exceed 3.0% of the SID when adjusted for full coverage of the selected portion of the image receptor.

(-c-) The sum, without regard to sign of the misalignment along any two orthogonal dimensions, shall not exceed 4.0% of the SID.

(II) The center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within plus or minus 2.0% of the SID.

(2) Activation of the fluoroscopic tube. X-ray production in the fluoroscopic mode shall be controlled by a device that requires continuous pressure by the fluoroscopist for the entire time of the exposure (continuous pressure type switch). When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposures at any time, but means may be provided to permit completion of any single exposure of the series in process.

(3) Entrance exposure rate (air kerma rate) allowable limits for fluoroscopic systems.

(A) The following requirements apply to fluoroscopic systems manufactured prior to May 19, 1995.

(i) Fluoroscopic systems with AERC. Fluoroscopic systems that are provided with AERC shall not be operable at any combination of tube potential and current that will result in an exposure rate (air kerma rate) in excess of  $2.58 \times 10^{-3}$  coulomb per kilogram per minute (C/kg/min) (10 roentgens per minute (10 R/min) or (100 mGy/min) at the point where the center of the useful beam enters the patient, except:

(I) during recording of fluoroscopic images, excluding last image hold; or

(II) when an optional high-level control is provided. When so provided, the fluoroscopic system shall not be operable at any combination of tube potential and current that will result in an exposure rate (air kerma rate) in excess of  $1.29 \times 10^{-3}$  C/kg/min (5 R/min or 50 mGy/min) at the point where the center of the useful beam enters the patient, unless the high-level control is activated. Special means of activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed.

(ii) Fluoroscopic systems without AERC (manual mode). Fluoroscopic systems that are not provided with AERC shall not be operable at any combination of tube potential and current that will result in an exposure rate (air kerma rate) in excess of  $1.29 \times 10^{-3}$  C/kg/min (5 R/min or 50 mGy/min) at the point where the center of the useful beam enters the patient, except:

(I) during recording of fluoroscopic images, excluding last image hold; or

(II) when an optional high-level control is activated. Special means of activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed.

(iii) Fluoroscopic systems with both an AERC mode and a manual mode. Fluoroscopic systems that are provided with both an AERC mode and a manual mode shall not be operable at any combination of tube potential and current that will result in an exposure rate (air kerma rate) in excess of  $2.58 \times 10^{-3}$  C/kg/min (10 R/min or 100 mGy/min) in either mode at the point where the center of the useful beam enters the patient except:

(I) during recording of fluoroscopic images, excluding last image hold; or

(II) when the mode or modes have an optional high-level control, in which case that mode or modes shall not be operable at any combination of tube potential and current that will result in an exposure rate (air kerma rate) in excess of  $1.29 \times 10^{-3}$  C/kg/min (5 R/min or 50 mGy/min) at the point where the center of the useful beam enters the patient, unless the high level control is activated. Special means of activation of high-level control shall be required. The high level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level is being employed.

(iv) Measuring compliance. Compliance of entrance exposure rate (air-kerma rate) for fluoroscopic systems shall be determined as follows.

(I) If the source is below the x-ray table, the exposure rate (air kerma rate) shall be measured at 1 cm above the tabletop or cradle.

(II) If the source is above the x-ray table, the exposure rate (air kerma rate) shall be measured at 30 cm above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

(III) In a C-arm fluoroscopic system, the exposure rate (air kerma rate) shall be measured at 30 cm from the input surface of the fluoroscopic imaging assembly provided that the end of the beam-limiting device or spacer is no closer than 30 cm from the input surface of the fluoroscopic imaging assembly. The applicable limit shall not be exceeded at any available SID.

(IV) In a lateral (horizontal) fluoroscopic system, the exposure rate (air kerma rate) shall be measured at a point 15 cm from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the table top is movable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than 15 cm to the centerline of the x-ray table.

(B) The following requirements apply to fluoroscopic systems manufactured on or after May 19, 1995.

(i) Fluoroscopic systems operable at any combination of tube potential and current that will result in an exposure rate (air kerma rate) greater than  $1.29 \times 10^{-3}$  C/kg/min (5 R/min or 50 mGy/min) at the point where the center of the useful beam enters the patient shall be equipped with AERC. Provision for manual selection of technique factors may be provided.

(ii) Fluoroscopic systems shall not be operable at any combination of tube potential and current that will result in an exposure rate (air kerma rate) in excess of  $2.58 \times 10^{-3}$  C/kg/min (10 R/min or 100 mGy/min) at the point where the center of the useful beam enters the patient except:

(I) for fluoroscopic systems manufactured prior to June 10, 2006, during the recording of images from an x-ray image-intensifier tube using photographic film or a video camera when the x-ray source is operated in a pulsed mode;

(II) for fluoroscopic systems manufactured on and after June 10, 2006, during the recording of images from the x-ray image-intensifier to provide the user with a recorded image(s) after termination of the exposure. Such recording does not include images resulting from a last-image-hold feature that are not recorded; and

(III) when the high-level control is activated, the fluoroscopic system shall not be operable at any combination of tube potential and current that will result in an exposure rate (air kerma rate) in excess of  $5.16 \times 10^{-3}$  C/kg/min (20 R/min or 200 mGy/min) at the point where the center of the useful beam enters the patient. Special means of activation of high-level controls shall be required. The high-level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed.



(iii) Measuring compliance of entrance exposure rate (air-kerma rate) for fluoroscopic systems shall be determined as follows.

(I) If the source is below the x-ray table, the exposure rate (air kerma rate) shall be measured at 1 cm above the tabletop or cradle.

(II) If the source is above the x-ray table, the exposure rate (air kerma rate) shall be measured at 30 cm above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

(III) In a C-arm fluoroscopic system, the exposure rate (air kerma rate) shall be measured at 30 cm from the input surface of the fluoroscopic imaging assembly provided that the end of the beam-limiting device or spacer is no closer than 30 cm from the input surface of the fluoroscopic imaging assembly. The applicable limit shall not be exceeded at any available SID.

(IV) In a lateral (horizontal) fluoroscopic system, the exposure rate (air kerma rate) shall be measured at a point 15 cm from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the table top is movable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than 15 cm to the centerline of the x-ray table.

(C) For hand-held fluoroscopic systems, the exposure rate (air kerma rate) shall be measured at the point closest to the source.

(D) Periodic measurement of entrance exposure rate (air kerma rate) for fluoroscopic systems shall be performed as follows by a licensed medical physicist.

(i) Such measurements shall be made within 30 days of installation and within 30 days after any maintenance of the system that might affect the exposure rate. Thereafter, the measurements shall be made annually or at intervals not to exceed 14 months from the date of the prior measurements.

(ii) Results of these measurements shall be posted where any fluoroscopist may have ready access to such results while using the fluoroscopic system and maintained in accordance with subsection (s)(1) of this section for inspection by the agency. The measurement results shall be stated in R/min or mGy/min and include the technique factors used in determining such results. The name of the person performing the measurements and the date the measurements were performed shall be included in the results.

(iii) Conditions of periodic measurement of entrance exposure rate (air kerma rate) are as follows.

(I) The measurement shall be made in accordance with subparagraph (A)(iv) or (B)(iii) of this paragraph, as applicable.

(II) Fluoroscopic systems that do not incorporate an AERC shall utilize a milliamperage and kVp typical of the clinical use of the fluoroscopic system. Materials should be placed in the useful beam between the detection and imaging systems when conducting these periodic measurements to protect the imaging system.

(III) Fluoroscopic systems that do incorporate an AERC shall have sufficient material placed in the useful beam to produce a milliamperage and kVp typical of the clinical use of the fluoroscopic system.

(4) Measurements of the output rate for fluoroscopic systems. Measurements of the output rate of the fluoroscopic system shall be performed with a calibrated dosimetry system in accordance with subsection (i)(14) of this section.

(5) Indication of potential and current. During fluoroscopy and cinefluorography, the kV and the mA shall be continuously indicated at the control panel and/or the fluoroscopist's position.

(6) Source-to-skin distance (SSD).

(A) Means shall be provided to limit the SSD to the following:

(i) not less than 38 cm on stationary fluoroscopic systems; and

(ii) not less than 30 cm on portable fluoroscopic systems.

(B) For image-intensified fluoroscopic systems intended for specific surgical application that would be prohibited at the SSDs specified in subparagraph (A) of this paragraph, provisions may be made for operation at shorter SSDs, but in no case less than 20 cm.

(C) For stationary or portable C-arm fluoroscopic systems manufactured on or after June 10, 2006, having a maximum source-to-image receptor distance of less than 45 cm, the following requirements shall be met.

(i) Means shall be provided to limit the SSD to not less than 19 cm.

(ii) Such systems will be labeled and used for extremity use only.

(iii) For those systems intended for specific surgical applications that would be prohibited at the SSD specified in clause (i) of the subparagraph, provisions may be made for operation at a shorter SSD, but in no case less than 10 cm.

(D) The registrant's written operating and safety procedures shall provide precautionary measures to be adhered to during the use of the shorter SSD, in accordance with manufacturer's precautions, if provided.

(E) The SSD shall not be less than the FDA approved variance for a specific manufacturer of a hand-held fluoroscope.

(7) Fluoroscopic system timer and display.

(A) Fluoroscopic systems manufactured prior to June 10, 2006 shall comply with the following requirements.

(i) Means shall be provided to preset the cumulative on-time of the fluoroscopic x-ray tube. The maximum cumulative time of the timing device shall not exceed 5 minutes without resetting.

(ii) A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while x rays are produced until the timing device is reset. In lieu of such signal, the timer shall terminate the beam after the preset cumulative on-time is completed.

(B) Fluoroscopic systems manufactured on or after June 10, 2006 shall meet the following requirements.

(i) A display of the irradiation time visible to the fluoroscopist shall meet the following requirements.

(I) When the x-ray tube is activated, the fluoroscopic irradiation time in minutes and tenths of minutes shall be continuously displayed and updated at least every 6 seconds.

(II) The fluoroscopic irradiation time shall also be displayed within 6 seconds of termination of an exposure, and remain displayed until reset.

(ii) Means shall be provided to display the last-image-hold (LIH) image following the termination of the fluoroscopic exposure.

(iii) A display of the exposure rate (air kerma rate) as well as the cumulative exposure (cumulative air kerma) shall be displayed at the fluoroscopist's working position and shall meet the following requirements.

(I) The display of the exposure rate (air kerma rate) shall be clearly distinguishable from the cumulative exposure (cumulative air kerma).

(II) Means shall be provided to reset to zero the display of cumulative exposure (cumulative air kerma) prior to the beginning of a new examination or procedure.

(iv) A signal audible to the fluoroscopist shall sound for each passage of 5 minutes of irradiation time during an examination or procedure. The signal shall sound until manually reset, or if automatically reset, for at least 2 seconds.

(8) Control of scattered radiation.

(A) Fluoroscopic system configuration, including fluoroscopic table designs, shall not permit any portion of any individual's body, except the head, neck, and extremities, to be exposed to scattered radiation emanating from above or below the tabletop unless the radiation has passed through not less than a total of 0.25 mm lead equivalent material. The material may be, but is not limited to, drapes, self-supporting curtains, or viewing shields, in addition to any lead equivalency provided by a protective apron.

(B) Where sterile fields or special procedures prohibit the use of normal protective barriers or drapes, all of the following conditions shall be met.

(i) All persons, except the patient, in the room where fluoroscopy is performed shall wear protective aprons that provide a shielding equivalent of 0.35 mm of lead.

(ii) The fluoroscopic field size shall be reduced to the absolute minimum required for the procedure being performed (area of clinical interest).

(iii) Operating and safety procedures shall reflect the above conditions, and fluoroscopy personnel shall exhibit awareness of situations requiring the use and/or nonuse of the protective drapes.

(C) For image-intensified fluoroscopic systems with only a manual mode of collimation, the x-ray field produced shall be limited to the area of the spot-film cassette at 16 inches above tabletop. Additionally, during fluoroscopy, the beam shall be restricted to the area of the input phosphor.

(9) Radiation protocol committee (RPC) for fluoroscopically-guided interventional (FGI) procedures.

(A) Development of a RPC.

(i) Each registrant utilizing FGI procedures shall develop a RPC in accordance with the following.

(I) The registrant may establish a system-wide committee if the registrant has more than one site.

(II) One or more registrant may form a cooperative RPC as long as each facility has a representative on the committee.

(III) If the registrant has already established a radiation safety committee, the requirements of this subsection may be delegated to that committee if the members meet the requirements of subparagraph (B) of this paragraph.

(IV) The committee shall meet as often as necessary to conduct business but no less than once every 14 months.

(V) Interim meetings may be conducted by electronic means.

(ii) The registrant shall make a record of each RPC meeting to include the date, names of individuals in attendance, minutes of the meeting, and any actions taken. The registrant shall maintain the record in accordance with subsection (s)(1) of this section for inspection by the agency.

(B) Members required for the RPC. Members shall include but not be limited to the following individuals:

(i) a licensed physician of the healing arts who meets the requirements in subparagraph (E) of this paragraph;

(ii) a licensed medical physicist;

(iii) the RSO; and

(iv) other individuals as deemed necessary by the registrant.

(C) Establish and implement FGI procedure protocols.

(i) The RPC shall establish and implement written protocols, or protocols documented in an electronic report system, that include but are not limited to the following.

(I) A restriction of the use of fluoroscopic systems for interventional purposes to radiologists, radiation oncologists, physicians, as well as individuals to whom a physician has delegated authority pursuant to the Occupations Code, Chapter 601, and the applicable rules of the Texas Medical Board, who have completed the radiation safety awareness training as required in subparagraph (E) of this paragraph.

(II) A method to be used to monitor the radiation exposure.

(III) A recommended reference level for FGI procedures performed.

(IV) Actions to be taken for cases when the reference level was exceeded which may include patient follow-up.

(V) A review of the established protocol at an interval not to exceed 14 months.

(ii) The registrant shall make and maintain a record of each RPC protocol in accordance with subsection (s)(1) of this section for inspection by the agency. If the RPC revises a protocol, the registrant shall maintain the previous documentation after the revision in accordance with subsection (s)(1) of this section for inspection by the agency.

(D) Procedures for maintaining records.

(i) The registrant shall make and maintain a record of radiation output information so the radiation dose to the skin may be estimated in accordance with established protocols. The record shall include the following:

(I) patient identification;

(II) type and date of examination;

(III) identification of the fluoroscopic system used; and

(IV) cumulative air kerma or dose area product used if the information is available on the fluoroscopic system.

(ii) If the cumulative air kerma or dose area product are not displayed on the fluoroscopic system, records shall include other information necessary to estimate the radiation dose to the skin in accordance with established protocol or the following as necessary:

(I) fluoroscopic mode, such as, high-level or pulsed mode of operation;

(II) cumulative fluoroscopic exposure time; and

(III) number of films or recorded exposures.

(iii) The registrant shall maintain records required by this subparagraph in accordance with record retention policies of the facility.

(E) Radiation safety awareness training. Physicians, other than radiologists and radiation oncologists, as well as individuals to whom a physician has delegated authority pursuant to the Occupations Code, Chapter 601, and the applicable rules of the Texas Medical Board, shall complete a minimum of 8 hours of Category 1 CMEU in radiation safety awareness training prior to performing FGI procedures.

(i) The radiation safety awareness training shall include, but not be limited to the following topics:

- (I) principles of radiation protection;
- (II) biological effects of x-ray radiation;
- (III) principles of fluoroscopic systems;
- (IV) operation of fluoroscopic systems used for interventional purposes;
- (V) fluoroscopic exposure (air kerma) outputs;
- (VI) high level control options;
- (VII) dose reduction techniques; and
- (VIII) procedures for recording pertinent data specified in subparagraph (D) of this paragraph.

(ii) In addition to the 8-hour Category 1 CMEU as required in this subparagraph, the radiation safety awareness training shall:

- (I) include a minimum of 1 hour fluoroscopic machine training demonstrating application of clause (i)(I), and (IV) - (VII) of this subparagraph; and
- (II) be provided by a radiologist, licensed medical physicist, or a physician that meets the requirements of this subparagraph.

(iii) The registrant shall ensure that radiation safety awareness training be completed within 2 years from the effective date of this rule for each physician, "as well as individuals to whom a physician has delegated authority pursuant to the Occupations Code, Chapter 601, and the applicable rules of the Texas Medical Board," performing FGI procedures.

(iv) Two years after the effective date of this rule, the registrant shall ensure that prior to performing FGI procedures each physician, "as well as individuals to whom a physician has delegated authority pursuant to the Occupations Code, Chapter 601, and the applicable rules of the Texas Medical Board," shall complete the radiation safety awareness training.

(v) The 8 hours of Category 1 CMEU in radiation safety awareness training required by this subsection may be obtained by web-based online training.

(vi) The registrant shall maintain radiation safety awareness training records for the 8 hours Category 1 CMEU and the 1 hour fluoroscopic machine training required in this subparagraph in accordance with subsection (s)(1) of this section for inspection by the agency.

(n) CT systems.

(1) CT system requirements shall include the following.

(A) Warning label. The warning label will meet the requirements of §289.231(z) of this title.

(B) Visual indication. The CT control panel shall provide visual indication of the production of x-rays.

(C) Indicated technique factors. The indicated technique factors shall be accurate to meet manufacturer's specifications. If these specifications are not available from the manufacturer, the factors shall be accurate to within plus or minus 10% of the indicated setting.

(D) Tomographic plane indication and alignment.

(i) For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

(ii) For any multiple slice tomogram system, means shall be provided to permit visual determination of the location of a reference plane. The reference plane can be offset from the location of the tomographic planes.

(iii) If a device using a light source is used to satisfy the requirements of clause (i) or (ii) of this subparagraph, the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.



(E) Indication of CT conditions of operation. The CT system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence are indicated prior to the initiation of a scan or a scan sequence. On CT systems having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

(F) Initiation of operation.

(i) The CT control panel and gantry shall provide visual indication whenever x rays are produced and, if applicable, whether the shutter is open or closed.

(ii) Means shall be provided to require operator initiation of each individual scan or series of scans.

(iii) All emergency buttons/switches shall be clearly labeled as to their functions.

(G) Termination of exposure.

(i) Means shall be provided to terminate the x-ray exposure automatically by either de-energizing the x-ray source or shuttering the x-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110% of its preset value through the use of either a backup timer or devices that monitor equipment function.

(ii) A signal visible to the operator shall indicate when the x-ray exposure has been terminated through the means required by clause (i) of this subparagraph.

(iii) The operator shall be able to terminate the x-ray exposure at any time during a scan or series of scans under CT system control, of greater than 0.5 seconds duration. Termination of the x-ray exposure shall necessitate resetting of the CT conditions of operation prior to initiation of another scan.

(H) Additional requirements applicable to CT systems. Additional requirements applicable to CT systems containing a gantry manufactured after September 3, 1985, are as follows.

(i) The total error in the indicated location of the tomographic plane or reference plane shall not exceed 5 mm.

(ii) If the x-ray production period is less than 0.5 seconds, the indication of x-ray production shall be actuated for at least 0.5 seconds. Indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.

(iii) The deviation of indicated scan increment versus actual increment shall not exceed plus or minus 1 mm with any mass from 0 to 100 kilograms (kg) resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 cm, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment can be taken anywhere along this travel.

(2) Facility design requirements shall include the following.

(A) Provision shall be made for two-way aural communication between the patient and the operator at the control panel.

(B) Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.

(i) Should the viewing system described in subparagraph (B) of this paragraph fail or be inoperative, treatment shall not be performed with the unit until the system is restored.

(ii) In a facility that has a primary viewing system by electronic means and an alternate viewing system, should the viewing system described in subparagraph (B) of this paragraph fail or be inoperative, treatment shall not be performed with the unit until one of the systems is restored.

(3) Measurements of the radiation output of the CT system, using the computed tomography dose index (CTDI) as recommended by the American Association of Physicists in Medicine (AAPM) and the International Council on Radiation Protection (ICRP), shall be performed by a licensed medical physicist.

(A) Performance of the radiation output measurements shall be:

(i) within 30 days after initial installation;

(ii) thereafter annually or at intervals not to exceed 14 months from the date of the prior radiation output measurements;

(iii) within 30 days of any major maintenance, that could affect radiation output; and

(iv) within 30 days of any major change in equipment operation for example, introduction of a new software package.

(B) The registrant shall ensure that radiation output measurements of a CT system are performed with a calibrated dosimetry system in accordance with subsection (i)(14) of this section.

(4) A maintenance schedule shall be developed and followed. This schedule shall be in writing or documented in an electronic reporting system and shall be included in the registrant's operating and safety procedures. The maintenance schedule shall include but not be limited to the following:

(A) radiation output measurements required by paragraph (3)(A) of this subsection;

(B) acquisition of images by a licensed medical physicist obtained with phantoms and using the same processing mode and CT conditions of operation as are used to perform radiation output measurements required by paragraph (3)(A) of this subsection; and

(C) acquisition of images by the registrant for quality control purposes obtained with phantoms and using protocol and intervals recommended by the manufacturer or the licensed medical physicist.

(5) The registrant shall maintain the images specified in paragraph (4)(B) and (C) of this subsection in accordance with subsection (s)(1) of this section for inspection by the agency. The images may be maintained by either of the following methods:

(A) photographic copies of the images obtained from the image display device; or

(B) images stored in digital form.

(6) Radiation protocol committee (RPC) for CT systems.

(A) Development of a RPC.

(i) Each registrant utilizing CT systems shall develop a RPC in accordance with the following:

(I) The registrant may establish a system-wide committee if the registrant has more than one site.

(II) One or more registrants may form a cooperative RPC as long as each facility has a representative on the committee.

(III) If the registrant has already established a radiation safety committee, the requirements of this subsection may be delegated to that committee if the members meet the requirements of subparagraph (B) of this paragraph.

(IV) The committee shall meet as often as necessary to conduct business but no less than once every 14 months.

(V) Interim meetings may be conducted by electronic means.

(ii) The registrant shall make a record of each RPC meeting to include the date, names of individuals in attendance, minutes of the meeting, and any action taken. The registrant shall maintain the record in accordance with subsection (s)(1) of this section for inspection by the agency.

(B) Members required for the RPC. Members shall include but not be limited to the following individuals:

(i) a radiologist or radiation oncologist;

(ii) a licensed medical physicist;

(iii) the RSO; and

(iv) other individuals as deemed necessary by the registrant.

(C) Establish and implement CT system protocols.

(i) The RPC shall establish and implement written protocols, or protocols documented in an electronic reporting system, that include but are not limited to the following.

(I) A method to be used to monitor the radiation output.

(II) A recommended reference level for CT procedures performed.

(III) Actions to be taken for cases when the reference level was exceeded which may include patient follow-up.

(IV) A review of the established protocols at an interval not to exceed 14 months.

(ii) The registrant shall make and maintain a record of each RPC protocol in accordance with subsection (s)(1) of this section for inspection by the agency. If the RPC revises a protocol, the registrant shall maintain the previous documentation after the revision in accordance with subsection (s)(1) of this section for inspection by the agency.

(D) Procedures for maintaining records.

(i) The registrant shall make and maintain a record of radiation output information so the radiation dose to the skin may be estimated in accordance with established protocols. The record shall include the following:

(I) patient identification;

(II) type and date of examination;

(III) identification of the CT system used; and

(IV) if the CT system is capable of calculating and displaying these values:

(-a-) CTDI<sub>vol</sub>;

(-b-) DLP; or

(-c-) recommendations as identified in "Comprehensive Methodology for the Evaluation of Radiation Dose in X-ray Computed Tomography. Report of American Association of Physicists in Medicine, Task Group 111; The Future of CT Dosimetry, February 2010," may be used to meet compliance with this subsection.

(ii) The registrant shall maintain records required by this subparagraph in accordance with record retention policies of the facility.

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(o) Equipment performance evaluation (EPE).

(1) Frequency of EPE. For x-ray, fluoroscopic, and CT systems, an EPE shall be performed at the frequency listed in the following table.

Type of Machine	Frequency
CT	Annually not to exceed 14 months from the date of prior EPE
Fluoroscopy	Annually not to exceed 14 months from the date of prior EPE
Radiographic Podiatric use only	4 years from the date of prior EPE
All other Radiographic	2 years from the date of prior EPE

(2) Performance of EPE. For all x-ray systems an EPE shall be performed by or under the supervision of a licensed medical physicist:

(A) within 30 days after initial installation of new machines;

(B) within 30 days after reinstallation of a machine; or

(C) within 30 days after repair of a machine component that would effect the radiation output that includes but is not limited to the timer, tube, and power supply.

(3) Records of EPE results. Records of the test results shall include:

(A) measurements and numerical readings;

(B) indicate a pass or fail for each test; and

(C) be reviewed and signed by the licensed medical physicist.

(4) Correction of EPE results.

(A) Any items not meeting the specifications of the EPE shall be corrected or repaired. The correction or repair shall begin within 30 days following the EPE and shall be performed according to a plan designated by the registrant. Correction or repair shall be completed no longer than 90 days from discovery unless authorized by the agency.

(B) The registrant shall make and maintain records of corrections or repairs in accordance with subsection (s)(1) of this section for inspection by the agency.

(5) Calibrated dosimetry system. The registrant shall ensure that measurements of the radiation output of an x-ray system are performed with a calibrated dosimetry system in accordance with subsection (i)(14) of this section.

(6) EPE for x-ray systems.

(A) Timer. The accuracy of the timer shall meet the manufacturer's specifications. If the manufacturer's specifications are not obtainable, the timer accuracy shall be plus or minus 10% of the indicated time with testing performed at 0.5 second.

(B) Exposure reproducibility. Exposure reproducibility shall meet the requirements of subsection (l)(4) of this section.

(C) Linearity. mR/mAs (mGy/mAs) stations shall meet the requirements of subsection (l)(5) of this section.

(D) kVp. If the registrant possesses documentation of the appropriate manufacturer's kVp specifications, the radiation machine shall meet those specifications. If the registrant does not possess documentation of the appropriate manufacturer's kVp specifications, the indicated kVp shall be accurate to within plus or minus 10% of the indicated setting at no less than 3 points over the usual operating range of the machine.

(E) Tube stability. The x-ray tube shall remain physically stable during exposures. In cases where tubes are designed to move during exposure, the registrant shall assure proper and free movement of the unit.

(F) Collimation. The following items shall meet the requirements of subsection (l)(1) of this section:

- (i) numerical indicators of x-ray field size;
- (ii) light field versus x-ray field congruence;
- (iii) automatic and semi-automatic collimators unless disabled; and
- (iv) center of x-ray field alignment with center of image

receptor.

(G) Entrance exposure (air kerma) limits. Entrance exposure (air kerma) limits shall meet the requirements specified in subsection (j) of this section and shall be determined for all examinations specified in Table I of subsection (j) of this section, that are performed by the registrant.

(7) EPE for fluoroscopic systems and spot film devices. Fluoroscopic systems shall meet the requirements of subsections (i)(14) and (m)(1)(C) and (3) of this section.

(8) EPE for CT systems. CT systems shall meet the requirements of subsections (i)(14) and (n)(1)(H) of this section.

(p) Automatic and manual film processing for facilities and mobile services.

(1) Films shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer. The specified developer temperature for automatic processing and the time-temperature chart for manual processing shall be posted near the film processing area. If the registrant determines an alternate time-temperature relationship is more appropriate for a specific facility, that time-temperature relationship shall be documented and posted.

(2) Chemicals shall be replaced according to the chemical manufacturer's or supplier's recommendations or at an interval not to exceed 3 months.

(3) Darkroom light leak tests shall be performed at intervals not to exceed 6 months.

(4) Lighting in the film processing/loading area shall be maintained with the filter, bulb wattage, and distances recommended by the film manufacturer for that film emulsion or with products that provide an equivalent level of protection against fogging.

(5) Corrections or repairs of the light leaks or other deficiencies in paragraphs (2)-(4) of this subsection shall be initiated within 72 hours of discovery and completed no longer than 15 days from detection of the deficiency unless a longer time is authorized by the agency. The registrant shall make a record of the correction or repairs to include the date and initials of the individual performing these functions. The records shall be maintained in accordance with subsection (s)(1) of this section for inspection by the agency.

(6) Documentation of the items in paragraphs (2), (3), and (5) of this subsection shall include the date and initials of the individual completing these items. The registrant shall maintain these records at the site where performed in accordance with subsection (s)(1) of this section for inspection by the agency.

(q) Alternative processing systems. Users of daylight processing systems, laser processors, self-processing film units, or other alternative processing systems shall follow manufacturer's recommendations for image processing. Documentation that the registrant is following manufacturer's recommendations shall include the date and initials of the individual completing the document and shall be maintained at the site where performed in accordance with subsection (s)(1) of this section for inspection by the agency.



(r) Digital imaging acquisition systems. Users of digital imaging acquisition systems shall follow quality assurance/quality control protocol for image processing established by the manufacturer or, if no manufacturer's protocol is available, by the registrant. The registrant shall include the protocols, whether established by the registrant or the manufacturer, in its operating and safety procedures. The registrant shall document the frequency at which the quality assurance/quality control protocol is performed. Documentation shall include the date and initials of the individual completing the document and shall be maintained at the site where performed in accordance with subsection (s)(1) of this section for inspection by the agency.

(s) Record/document requirements for mobile services and authorized use locations.

(1) Each registrant shall maintain the following records/documents at each site, including authorized records sites for mobile services at the time intervals specified, for inspection by the agency. The records may be maintained in electronic format.

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§289.227(s)(1)(A)

Name of Record/Document		Rule Cross Reference	Time Interval for Keeping Records
(A)	Current 25 TAC §§289.203, 289.204, 289.205, 289.226, 289.227, and 289.231	As listed on certificate of registration	Until termination of registration
(B)	Current certificate of registration	§289.203(b)(1)(B)	Until termination of registration
(C)	Notice of violation from last inspection, if applicable	§289.203(b)(1)(D)	Until next agency inspection
(D)	Documentation of correction of any violations	§289.203(b)(1)(D)	Until next inspection
(E)	Annual Radiation Machine Inventory	§289.226(m)(1)(B)	3 years
(F)	Receipt, transfer, and disposal	§289.226(m)(1)(D)	Until termination of registration
(G)	Records of training and experience	§289.226(m)(4)	Until termination of registration or 5 years after personnel leave the facility
(H)	FDA variances on x--ray systems	§289.227(h)	Until termination of registration
(I)	Current operating and safety procedures	§289.227(i)(2)	Until termination of registration
(J)	Protective devices annual check	§289.227(i)(4)(B)	3 years
(K)	Credentials of individuals operating radiation machines	§289.227(i)(5)	Until 2 years after the individual leaves that facility
(L)	Records of dosimetry system calibrations	§289.227(i)(14)	5 years
(M)	Records of maintenance and repairs of radiation machines	§289.227(l)(7) and (8) and (o)(4)	5 years
(N)	Entrance exposure rate (air kerma rate) /fluoroscopy	§289.227(m)(3)(D)	10 years
(O)	Records of Radiation Protocol Committee for FGI and CT procedures		
	(i) meeting minutes	§289.227(m)(9)(A)(ii)	5 years
	(ii) protocol revisions	§289.227(n)(6)(A)(ii) §289.227(m)(9)(C)(ii) §290.227(n)(6)(C)(ii)	5 years
(P)	Records of radiation safety awareness training for physicians	§289.227(m)(9)(E)(vi)	As long as the physician performs FGI procedures

§289.227(s)(1)(Q)

Name of Record/Document		Rule Cross Reference	Time Interval for Keeping Records
(Q)	CT films resulting from quality control tests	§289.227(n)(5)	10 years
(R)	Equipment performance evaluations and corrections	§289.227(o)(3) and (o)(4)(B)	10 years
(S)	Film processing records and corrections	§289.227 (p)(2), (3), (5), and (6)	3 years
(T)	Alternate processing system records	§289.227(q)	3 years
(U)	Digital imaging acquisition system records	§289.227(r)	3 years
(V)	Personnel monitoring records	§289.231(m)	Until termination of registration
(W)	Surveys (public dose evaluation)	§289.231(p)	Until termination of registration

(2) Records required in item F of the table in paragraph (1) of this subsection shall include the following:

- (A) manufacturer's name, model and serial number;
- (B) unique identification of the calibrated dosimetry system; and
- (C) name of the individual recording the information.

(3) Copies of the records/documents in items (A) - (D), (H), (J), and (N) - (Q) of the table in paragraph (1) of this subsection shall be kept with radiation machines authorized to be used for mobile services. Mobile services with on-board film processors shall maintain the records in items (O) - (Q) of the table in paragraph (1) of this subsection, as applicable, with the processor or system for a period of no less than 1 year.

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