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TITLE 216 – DEPARTMENT OF HEALTH

CHAPTER 40 – PROFESSIONAL LICENSING & FACILITIES REGULATION

SUBCHAPTER 20 - RADIATION

PART 4 – DIAGNOSTIC X-RAYS AND ASSOCIATED IMAGING SYSTEMS IN THE HEALING ARTS

4.1 Authority

A. This Part is promulgated pursuant to the authority conferred under R.I. Gen. Laws § 23-1.3-5(f), as amended.

B. This Part establishes requirements, for which a registrant is responsible, for use of diagnostic X-ray equipment and associated imaging systems in the healing arts or veterinary medicine. The provisions of this Part are in addition to, and not in substitution for, other applicable provisions of this Subchapter.

C. The use of diagnostic X-ray equipment and associated imaging systems for the intentional exposure of individuals for diagnosis shall be by or under the supervision of a licensed practitioner of the healing arts.

D. The use of diagnostic X-ray equipment and associated imaging systems in the practice of veterinary medicine shall be by or under the supervision of an individual authorized by and licensed in accordance with R.I. Gen. Laws Chapter 5-25 to practice veterinary medicine.

E. Any notifications, reports or correspondence required by this Part shall be directed to the Agency using contact information specified in § 1.4 of this Subchapter.

4.1.1 Incorporation by Reference

Except as provided in this Part, the requirements of 21 CFR Part 900 (2018) https://www.ecfr.gov/cgi-bin/text-idx?SID=8b1830a39d3795a4c126c839c31f99ae&mc=true&node=pt21.8.900&rgn=div5 are incorporated by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with this Part.

4.2 Definitions

Whenever used in this Part, the following terms shall be construed as follows:

"Accessible surface" means the external surface of the enclosure or housing of the radiation producing machine as provided by the manufacturer.

“Act” means Title 23, Chapter 1.3 of the General Laws of the State of Rhode Island entitled "Radiation Control".

“Agency” means Rhode Island Radiation Control Agency (RCA), Center for Health Facilities Regulation - Radiation Control Program, Rhode Island Department of Health.

"Air kerma" means kerma in air (see definition of Kerma).

"Air kerma rate (AKR)" means the air kerma per unit time.

"Alert value" means a dose index (e.g., of $CTDI_{vol}$(mGy) or DLP(mGy-cm)) that is set by the registrant to trigger an alert to the CT operator prior to scanning within an ongoing examination. The Alert value represents a universal dose index value well above the registrant's established range for the examination that warrants more stringent review and consideration before proceeding.

"Aluminum equivalent" means 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 is 99.00 percent minimum aluminum, 0.12 percent copper.]

"Articulated joint" means a joint between two separate sections of a tabletop which joint provides the capacity of one of the sections to pivot on the line segment along which the sections join.

"Attenuation block" means a block or stack of type 1100 aluminum alloy, or aluminum alloy having equivalent attenuation, with dimensions 20 centimeters (cm) or larger by 20 cm or larger by 3.8 cm, that is large enough to intercept the entire x-ray beam.

"Automatic exposure control (AEC)" means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation.

"Automatic exposure rate control (AERC)" means a device which automatically controls one or more technique factors in order to obtain, at a preselected location(s), a required quantity of radiation per unit time.

"Barrier" (See "Protective barrier").

"Beam axis" means a line from the source through the centers of the x-ray fields.

"Beam-limiting device" means a device which provides a means to restrict the dimensions of the x-ray field.

"Bone densitometry" means a noninvasive measurement of certain physical characteristics of bone that reflect bone strength. Test results are typically reported as bone mineral content or density and are used for diagnosing osteoporosis, estimating fracture risk, and monitoring changes in bone mineral content.

"Bone densitometer" means a device intended for medical purposes to measure bone density and mineral content by x-ray or gamma ray transmission measurements through the bone and adjacent tissues. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

"C-arm fluoroscope" means a fluoroscopic x-ray system in which the image receptor and the x-ray tube housing assembly are connected or coordinated to maintain a spatial relationship. Such a system allows a change in the direction of the beam axis with respect to the patient without moving the patient.

"Cantilevered tabletop" means a tabletop designed such that the unsupported portion can be extended at least 100 cm beyond the support.

"Cassette holder" means a device, other than a spot-film device, that supports and/or fixes the position of the image receptor during a radiographic exposure.

"Coefficient of variation (C)" means the ratio of the standard deviation to the

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

mean value of a population of observations. It is estimated using the following equation:

where

s = Estimated standard deviation of the population.

$\bar{x}$ = Mean value of observations in sample.

x_i = ith observation in sample.

n = Number of observations in sample.

"Computed radiography (CR; also see DR)" means a digital x-ray imaging method in which a photo-stimulable phosphor is used to capture and store a latent image. The latent image is read out by stimulating the phosphor with a laser. Computed radiography systems may use cassettes to house the phosphor, or it may be integrated into a digital radiography system.

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

"Computed tomography dose index" (CTDI) means the average absorbed dose, along the z-axis, from a series of contiguous irradiations. It is measured from one axial CT scan (one rotation of the x-ray tube), and is calculated by dividing the integrated absorbed dose by the nominal total beam collimation. The scattering media for CTDI consist of two (16 and 32 cm in diameter) polymethylmethacrylate (PMMA, e.g., acrylic or Lucite) cylinders of 14 cm length. The equation is:

$$CTDI = \frac{1}{NT}\int_{-\infty}^{\infty} D(z)dz \ ,$$

where:

D(z) = the radiation dose profile along the z-axis,

N = the number of tomographic sections imaged in a single axial scan. This is equal to the number of data channels used in a particular scan. The value of N may be less than or equal to the maximum number of data channels available on the system, and

T = the width of the tomographic section along the z-axis imaged by one data channel. In multiple-detector-row (multislice) CT scanners, several detector elements may be grouped together to form one data channel. In single-detector-row (single-slice) CT, the z-axis collimation (T) is the nominal scan width.

"$CTDI_{100}$" means the accumulated multiple scan dose at the center of a 100-mm scan and underestimates the accumulated dose for longer scan lengths. It is thus smaller than the equilibrium dose. The $CTDI_{100}$, requires integration of the radiation dose profile from a single axial scan over specific integration limits. In the case of $CTDI_{100}$, the integration limits are +50 mm, which corresponds to the 100-mm length of the commercially available “pencil” ionization chamber. $CTDI_{100}$ is acquired using a 100-mm long, 3-cc active volume CT “pencil” ionization chamber and one of the two standard CTDI acrylic phantoms (16 and 32 cm diameter) and a stationary patient table. The equation is:

$$CTDI_{100} = \frac{1}{NT}\int_{-50mm}^{50mm} D(z)dz$$

"$CTDI_{vol}$ "see "Volume Computed Tomography Dose Index ($CTDI_{vol}$) "

"$CTDI_w$" see "Weighted Computed Tomography Dose Index ($CTDI_w$) "

"Cone Beam Computed Tomography (CBCT)" is a volumetric imaging modality. Volumetric data are acquired using two dimensional digital detector arrays, and a

cone-shaped x-ray beam (instead of fan-shaped) that rotates around the patient. Reconstruction algorithms can be used to generate images of any desired plane.

"Control panel" means that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons, keypads, touchscreens, and other hardware necessary for manually setting the technique factors.

"Cradle" means:

(1) A removable device which supports and may restrain a patient above an x-ray table; or

(2) A device;

(i) Whose patient support structure is interposed between the patient and the image receptor during normal use;

(ii) Which is equipped with means for patient restraint; and

(iii) Which is capable of rotation about its long (longitudinal) axis.

"CT" (See "Computed tomography").

"CT conditions of operation" means all selectable parameters governing the operation of a CT x-ray system including nominal tomographic section thickness, filtration, and the technique factors as defined in § 4.2 of this Part.

"CT gantry" means tube housing assemblies, beam-limiting devices, detectors, and the supporting structures, frames, and covers which hold and/or enclose these components within a computed tomography system.

"CT number" means the number used to represent the x-ray attenuation associated with each elemental area of the CT image:

$$\overline{\mathrm{CTN}} = \frac{k(\mu_x - \mu_w)}{\mu_w}$$

where:

k = A constant, a normal value of 1,000 when the Houndsfield scale of CT number is used;

u_x = Linear attenuation coefficient of the material of interest;

u_w = Linear attenuation coefficient of water.

"Cumulative air kerma" means the total air kerma accrued from the beginning of an examination or procedure and includes all contributions from fluoroscopic and radiographic irradiation.

"Detector" (See "Radiation detector")

"Diagnostic reference level" (DRL) is an investigational level used to identify unusually high radiation doses or dose rates for common medical X-ray imaging procedures. DRLs are suggested action levels above which a facility should review its methods and determine if acceptable image quality can be achieved at lower doses. DRLs should not be applied to an individual patient.

"Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.

"Diagnostic x-ray system" means an x-ray system designed for irradiation of any part of the human [or animal] body for the purpose of diagnosis or visualization.

"Digital radiography (DR)" means an x-ray imaging method (or radiography) which produces a digital rather than analog image. DR includes both computed radiography and direct digital radiography.

"Direct digital radiography (DDR; also see CR and DR)" means an x-ray imaging method in which a digital sensor, usually incorporating a thin-film transistor, is used to capture an x-ray image. Some DDR systems use a scintillator to convert x-rays to light and a photodiode array to convert light to charge, while others use a photoconductor to convert x-rays directly to charge, which is stored on the thin-film transistor.

"Direct scattered radiation" means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (See "Scattered radiation").

"Direct supervision" means a qualified practitioner must exercise general supervision and be present in the facility and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the licensed practitioner must be present in the room when the procedure is being performed.

"Dose" means the absorbed dose as defined by the International Commission on Radiation Units and Measurements. The absorbed dose, D, is the quotient of de by dm, where de is the mean energy imparted to matter of mass dm; thus D=de/dm, in units of J/kg, where the special name of the unit of absorbed dose is gray (Gy).

"Dose area product (DAP) (aka kerma-area product (KAP))" means the product of the air kerma and the area of the irradiated field and is typically expressed in Gy-cm2, so it does not change with distance from the x-ray tube.

"Dose length product (DLP)" means the indicator of the integrated radiation dose from a complete CT examination. It addresses the total scan length by the formula:

$$\text{DLP (mGy-cm)} = \text{CTDI}_{vol}\text{ (mGy) x scan length (cm)}$$

"Dose profile" means the dose as a function of position along a line.

"Effective dose (E)" means the sum of the tissue-weighted equivalent doses for the radiosensitive tissues and organs of the body. It is given by the expression $E = \Sigma_T (w_T H_T)$, in which H_T is the equivalent dose in tissue or organ T and w_T is the tissue weighting factor for tissue or organ T. The unit of E and H_T is joule per kilogram (J·kg-1), with the special name sievert (Sv).

"Equipment" (See "X-ray equipment") means x-ray equipment.

"Exposure (X)" means the quotient of dQ by dm where dQ is the absolute value of the total charge of the ions of one sign produced in air when all the electrons and positrons liberated or created by photons in air of mass dm are completely stopped in air; thus X=dQ/dm, in units of C/kg. A second meaning of exposure is the process or condition during which the x-ray tube produces x-ray radiation.

"Field emission equipment" means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

"Filter" means material placed in the useful beam to preferentially absorb selected radiations.

"Fluoroscopic imaging assembly" means a subsystem in which x-ray photons produce a set of fluoroscopic images or radiographic images recorded from the fluoroscopic image receptor. It includes the image receptor(s), electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

"Fluoroscopic irradiation time" means the cumulative duration during an examination or procedure of operator-applied continuous pressure to the device, enabling x-ray tube activation in any fluoroscopic mode of operation.

"Fluoroscopically-Guided Interventional (FGI) Procedures" means 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.

"Fluoroscopy" means a technique for generating x-ray images and presenting them simultaneously and continuously as visible images. This term has the same meaning as the term “radioscopy” in the standards of the International Electrotechnical Commission.

"Focal spot (actual)" means 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.

"General purpose radiographic x-ray system" means any radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

"General supervision" means the procedure is performed under the overall direction and control of the qualified practitioner but who is not required to be physically present during the performance of the procedure.

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

"Hand-held x-ray equipment" means x-ray equipment that is designed to be hand-held during operation.

"Healing arts screening" means the testing of human beings using x-ray 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.

"Heat unit" means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds, i.e., kVp x mA x second.

"HVL" (See "Half-value layer").

"Image intensifier" means a device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher intensity.

"Image receptor" means any device, such as a fluorescent screen, radiographic film, x-ray image intensifier tube, solid-state detector, or gaseous detector which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations. In those cases where means are provided to preselect a portion of the image receptor, the term “image receptor” shall mean the preselected portion of the device.

"Irradiation" means the exposure of matter to ionizing radiation.

"Isocenter" means the center of the smallest sphere through which the beam axis passes when the equipment moves through a full range of rotations about its common center.

"Kerma" means the quantity defined by the International Commission on Radiation Units and Measurements. The kerma, K, is the quotient of dEtr by dm, where dEtr is the sum of the initial kinetic energies of all the charged particles

liberated by uncharged particles in a mass dm of material; thus K=dEtr/dm, in units of J/kg, where the special name for the unit of kerma is gray (Gy). When the material is air, the quantity is referred to as "air kerma."

"Kerma-area product (KAP) " (See "dose area product")

"Kilovolts peak" (See "Peak tube potential").

"kV" means kilovolts.

"kVp" (See "Peak tube potential").

"kWs" means kilowatt second.

"Last-image hold (LIH) radiograph" means an image obtained either by retaining one or more fluoroscopic images, which may be temporarily integrated, at the end of a fluoroscopic exposure or by initiating a separate and distinct radiographic exposure automatically and immediately in conjunction with termination of the fluoroscopic exposure.

"Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

"Leakage radiation" means radiation emanating from the diagnostic source assembly except for:

(1) The useful beam; and

(2) Radiation produced when the exposure switch or timer is not activated.

"Leakage technique factors" means the technique factors associated with the diagnostic source assembly which are used in measuring leakage radiation. They are defined as follows:

(1) 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 (or 10 mAs) or the minimum obtainable from the unit, whichever is larger;

(2) 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; and

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

"Light field" means that area of the intersection of the light beam from the beam-limiting device and 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 illumination is one-fourth of the maximum in the intersection.

"Line-voltage regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential; that is,

$$\text{Percent line-voltage regulation} = 100\ (V_n - V_l)/V_l$$

where:

V_n = No-load line potential; and

V_l = Load line potential.

"mA" means milliampere.

"mAs" means milliampere second.

"Mobile x-ray equipment" (See "X-ray equipment").

"Mode of operation" means, for fluoroscopic systems, a distinct method of fluoroscopy or radiography provided by the manufacturer and selected with a set of several technique factors or other control settings uniquely associated with the mode. The set of distinct technique factors and control settings for the mode may be selected by the operation of a single control. Examples of distinct modes of operation include normal fluoroscopy (analog or digital), high-level control fluoroscopy, cineradiography (analog and digital), digital subtraction angiography, electronic radiography using the fluoroscopic image receptor, and photospot recording. In a specific mode of operation, certain system variables affecting kerma, AKR, or image quality, such as image magnification, x-ray field size, pulse rate, pulse duration, number of pulses, source-image receptor distance (SID), or optical aperture, may be adjustable or may vary; their variation per se does not comprise a mode of operation different from the one that has been selected.

"Multiple tomogram system" means a computed tomography x-ray system which obtains x-ray transmission data simultaneously during a single scan to produce more than one tomogram.

“Noise” means the standard deviation of the fluctuations in CTN expressed as a percentage of the attenuation coefficient of water. Its estimate (S_n) is calculated using the following expression:

$$S_n = \frac{100 \cdot \mu_x \cdot s}{\mu_w}$$

where:

μ_x = Linear attenuation coefficient of the material of interest.

μ_w = Linear attenuation coefficient of water.

s = Estimated standard deviation of the CTN of picture elements in a specified area of the CT image.

"Nominal tomographic section thickness" means 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.

"Notification value" means a protocol-specific dose index (e.g. $CTDI_{vol}$(mGy) or of DLP(mGy-cm)) that is set by the registrant to trigger a notification to the CT operator prior to scanning when the dose index exceeds the established range for the examination.

"Patient" means an individual or animal subjected to healing arts examination, diagnosis or treatment.

"Picture element" means an elemental area of a tomogram.

"PBL" See "Positive beam limitation."

"Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.

"Personal supervision" means a qualified practitioner must exercise General Supervision and be present in the room or adjacent control area during the performance of the procedure.

"Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. This requires that both the atomic number (Z) and the density of the material be similar to that of tissue.

"Photostimulable storage phosphor (PSP)" means a material used to capture and store radiographic images in computed radiography systems.

"PID" (See "Position indicating device").

"Pitch" means the table incrementation, in CT, per x-ray tube rotation, divided by the nominal x-ray beam width at isocenter.

"Portable x-ray equipment" (See "X-ray equipment").

"Position indicating device (PID)" means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

"Positive beam limitation" means the automatic or semi-automatic adjustment of an x-ray beam to the size of the selected image receptor, whereby exposures cannot be made without such adjustment.

"Primary protective barrier" means the material, excluding filters, placed in the useful beam to reduce the radiation exposure [beyond the patient and cassette holder] for protection purposes.

"Protective apron" means an apron made of radiation absorbing materials used to reduce radiation exposure.

"Protocol" means a collection of settings and parameters that fully describe an examination.

"Pulsed mode" means operation of the x-ray system such that the x-ray tube current is pulsed by the x-ray control to produce one or more exposure intervals of duration less than one-half second.

"Quality Assurance" means a program providing for verification by written procedures such as testing, auditing, and inspection to ensure that deficiencies, deviations, defective equipment, or unsafe practices, or a combination thereof, relating to the use, disposal, management, or manufacture of radiation devices are identified, promptly corrected, and reported to the appropriate regulatory authorities as required.

“Qualified Medical Physicist” (for activities authorized pursuant to this Part) means an individual registered to provide Radiation Physics Services (Diagnostic X-ray Physics Services) in accordance with 3.6 of this Subchapter.

"Radiation detector" means a device which in the presence of radiation provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

“Radiation medical event” means an event that meets the criteria in § 4.4.14(A) of this Part.

"Radiation Protocol Committee (RPC)" means the representative group of qualified individuals in a CT or FGI facility responsible for the ongoing review and management of CT or FGI protocols to ensure that exams being performed achieve the desired diagnostic image quality at the lowest radiation dose possible while properly exploiting the capabilities of the equipment being used.

"Radiation therapy simulation system" means a radiographic or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

"Radiograph" means an image receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record.

"Radiography" means a technique for generating and recording an x-ray pattern for the purpose of providing the user with an image(s) after termination of the exposure.

"Recording" means producing a retrievable form of an image resulting from x-ray photons.

"Reference plane" means a plane which parallel to and which can be offset (as specified in manufacturer information provided to users) from the location of the tomographic plane(s).

“Registrant” means any person who is registered with the Agency and is legally obligated to register with the Agency pursuant to this Subchapter and the Act.

“Registration” means registration with the Agency pursuant to this Subchapter and the Act.

“R.I. Gen. Laws” means the General Laws of Rhode Island, as amended.

"Scan" means the complete process of collecting x-ray transmission data for the production of a tomogram. Data may be collected simultaneously during a single scan for the production of one or more tomograms.

"Scan increment" means the amount of relative displacement of the patient with respect to the CT x-ray system between successive scans measured along the direction of such displacement.

"Scan sequence" means a pre-selected set of two or more scans performed consecutively under pre-selected CT conditions of operation.

"Scan time" means the time elapsed during the accumlation of x-ray transmission data for a single scan.

"Scattered radiation" means radiation that, during passage through matter, has been deviated in direction (See "Direct scattered radiation").

"Sensitivity profile" means the relative response of the CT x-ray system as a function of position along a line perpendicular to the tomographic plane.

"Single tomogram system" means a CT x-ray system which obtains x-ray transmission data during a scan to produce a single tomogram.

"Shutter" means a device attached to the tube housing assembly which can intercept the entire cross sectional area of the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

"SID" (See "Source-image receptor distance").

"Size-specific dose estimate (SSDE)" means a patient dose estimate which takes into consideration corrections based on the size of the patient, using linear dimensions measured on the patient or patient images.

"Source" means the focal spot of the x-ray tube.

"Source-image receptor distance" means the distance from the source to the center of the input surface of the image receptor.

"Source-skin distance (SSD)" means the distance from the source to the center of the entrant x-ray field in the plane tangent to the patient skin surface.

"Spot-film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure. Digital image receptors used in place of film with spot-film devices should be considered "spot-film".

"Spot-film device" means 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 the fluoroscopic image receptor for the purpose of producing a radiograph.

"Stationary x-ray equipment" (See "X-ray equipment").

"Stray radiation" means the sum of leakage and scattered radiation.

"Substantial radiation dose level" (SRDL) means an appropriately-selected dose used to trigger additional dose-management actions during a procedure and medical follow-up for a radiation level that might produce a clinically-relevant injury in an average patient.

“Technique factors” means the following conditions of operation:

(1) For capacitor energy storage equipment, peak tube potential in kilovolts (kV) and quantity of charge in milliampere-seconds (mAs);

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

(3) For CT X-ray systems designed for pulsed operation, 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;

(4) For CT X-ray 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 and the scan time when the scan time and exposure time are equivalent; and

(5) For all other equipment, 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.

"Tomogram" means the depiction of the x-ray attenuation properties of a section through the body.

"Tomographic plane" means that geometric plane which the manufacturer identified as corresponding to the output tomogram.

"Tomographic section" means the volume of an object whose x-ray attenuation properties are imaged in a tomogram.

"Tube" means an x-ray tube, unless otherwise specified.

"Tube housing assembly" means 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.

"Unintended" radiation dose in diagnostic or interventional x-ray means a patient radiation dose resulting from a human error or equipment malfunction during the procedure.

"Useful beam" means the radiation which passes through the tube housing port and the aperture of the beam limiting device when the exposure switch or timer is activated.

"Visible area" means that portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

"Volume Computed Tomography Dose Index ($CTDI_{vol}$)" means a radiation dose parameter derived from the $CTDI_w$ (weighted or average CTDI given across the field of view). The formula is:

$CTDI_{vol} = (N)(T)(CTDI_w)/I$, where

N = number of simultaneous axial scans per x-ray source rotation,

T = thickness of one axial scan (mm), and

I = table increment per axial scan (mm).

Thus,

$CTDI_{vol} = CTDI_w$ / pitch

"Weighted Computed Tomography Dose Index ($CTDI_w$)" means the estimated average $CTDI_{100}$ across the field of view (FOV). The equation is:

Where 1/3 and 2/3 approximate the relative areas represented by the center and edge values derived using the 16 or 32 cm acrylic phantom. $CTDI_w$ uses $CTDI_{100}$ and an f-factor for air (0.87 rad/R or 1.0 mGy/mGy).

"X-ray control" means a device which 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, which control the technique factors of an x-ray exposure.

"X-ray exposure control" means a device, switch, button or other similar means by which an operator initiates and/or terminates the radiation exposure. The x-ray exposure control may include such associated equipment as timers and back-up timers.

"X-ray equipment" means an x-ray system, subsystem, or component thereof. Types of x-ray equipment are as follows:

(1) "Mobile x-ray equipment" means x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled;

(2) "Portable x-ray equipment" means x-ray equipment designed to be hand-carried; and

(3) "Stationary x-ray equipment" means x-ray equipment which is installed in a fixed location.

(4) "Hand-held x-ray equipment" means x-ray equipment that is designed to be hand-held during operation.

"X-ray field" means that area of the intersection of the useful beam and any one of a set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the AKR is one-fourth of the maximum in the intersection.

"X-ray high-voltage generator" means a device which 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 tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.

"X-ray system" means an assemblage of components for the controlled production of x-rays. 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 which function with the system are considered integral parts of the system

"X-ray table" means a patient support device with its patient support structure (tabletop) interposed between the patient and the image receptor during radiography and/or fluoroscopy. This includes, but is not limited to, any stretcher equipped with a radiolucent panel and any table equipped with a cassette tray (or bucky), cassette tunnel, fluoroscopic image receptor, or spot-film device beneath the tabletop.

"X-ray tube" means any electron tube which is designed for the conversion of electrical energy into x-ray energy.

4.3 General and Administrative Requirements

4.3.1 Administrative Controls

The registrant shall be responsible for directing the operation of the X-ray system(s) under their administrative control. The registrant or the registrant's agent shall assure that the requirements of this Subchapter are met in the operation of the X-ray system(s).

4.3.2 An X-ray system which does not meet the provisions of this Part shall not be operated for diagnostic purposes.

4.3.3 Individuals Operating X-ray Systems for Healing Arts Use

A. Individuals who will be operating the X-ray systems for healing arts use shall possess a current license in accordance with Licensure of Radiographers, Nuclear Medicine Technologists, Radiation Therapists and Radiologist Assistants [216-RICR-40-05-34], unless the individual is specifically exempted from licensure by said regulations. Individuals who will be operating the X-ray systems and who are not subject to licensure under 216-RICR-40-05-34 shall be adequately instructed in the safe operating procedures and be competent in the safe use of the equipment. As a minimum, such instruction shall consist of subjects outlined in § 4.12 of this Part.

B. The names and qualifications of all personnel operating X-ray equipment for healing arts use must be kept on file for Agency inspection at each facility location.

C. All individuals operating fluoroscopic X-ray systems shall have completed at least the following training before using fluoroscopy independently:

1. Biological effects of X-ray;
2. Principles of radiation protection;
3. Factors affecting fluoroscopic outputs;
4. Dose reduction techniques for fluoroscopic X-ray systems;
5. Principles and operation of the specific fluoroscopic X-ray system(s) to be used;
6. Fluoroscopic and fluorographic outputs of each mode of operation on the system(s) to be used clinically; and
7. Applicable requirements of this Subchapter.

D. The registrant shall either provide in-service training for all operators of fluoroscopic x-ray systems used for high dose, high risk procedures, as defined in § 4.5.13 of this Part, at intervals not to exceed twenty-four (24) months or require evidence of continuing medical education, in fluoroscopic radiation safety and patient dose management at intervals not to exceed twenty-four (24) months.

E. Documentation pertaining to the requirements of §§ 4.3.3(c) and (d) of this Part shall be maintained for review for three (3) years.

4.3.4 Written technique information shall be provided in the vicinity of the diagnostic X-ray system's control panel, which specifies, for all examinations performed with that system, the following information:

A. Patient's body part and anatomical size, or body part thickness, or age (for pediatrics), versus technique factors to be utilized;

B. Equivalent manual technique information if AEC is not available;

C. Type and size of the image receptor combination to be used, if any;

D. Source to image receptor distance to be used (except for dental intraoral radiography, which shall list cone length to be used);

E. Type and location of placement of patient shielding (e.g., gonad, thyroid, lap apron, etc.); and

F. For mammography, indication of kVp/target/filter combination and, if phototimed setting is used, the density setting.

4.3.5 The registrant of a facility shall create and make available to X-ray operators written safety procedures, including patient holding and any restrictions of the operating technique required for the safe operation of the particular X-ray system. The operator shall be able to demonstrate familiarity with these procedures.

4.3.6 Except for patients who cannot be moved out of the room, only the staff, ancillary personnel or other persons required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:

A. All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by not less than 0.5 millimeter lead equivalent material.

B. The X-ray operator, other staff, ancillary personnel and other persons required for the medical procedure shall be protected from the direct scatter radiation by

protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent material.

C. Human patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of not less than 0.25 millimeter lead equivalent or shall be so positioned that the nearest portion of the body is at least two (2) meters from both the tube head and the nearest edge of the image receptor.

D. Written safety procedures, as required by § 4.3.5 of this Part, shall describe how the requirements of this section will be met when using mobile or portable X-ray systems.

4.3.7 Gonadal shielding of not less than 0.5 millimeter lead equivalent material shall be used for patients who have not passed the reproductive age during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

4.3.8 Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been ordered in writing by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure of an individual for training, demonstration or other non-healing-arts purposes, and exposure of an individual for the purpose of healing arts screening except as authorized by § 4.3.12 of this Part.

4.3.9 **When a Patient or Image Receptor Must be Provided with Auxiliary Support During a Radiation Exposure**

A. Mechanical holding devices shall be used when the technique permits. The written safety procedures, required by § 4.3.5 of this Part, shall list individual projections where holding devices cannot be utilized;

B. Written safety procedures, as required by § 4.3.5 of this Part, shall indicate the requirements for selecting a holder and the procedure the holder shall follow;

C. The human holder shall be instructed in personal radiation safety and protected as required by § 4.3.6 of this Part;

D. No individual shall be used routinely to hold image receptor or patients;

E. In those cases where the patient must hold the image receptor, except during dental examinations covered in this Part, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material; and

F. Each facility shall have protective aprons and gloves available in sufficient numbers to provide protection for all personnel who are involved with X-ray operations and who are otherwise not shielded.

G. A record shall be made of the examination and shall include the name of the human holder; date of the examination, number of exposures and technique factors utilized for the exposure(s).

4.3.10 **Procedures and Auxiliary Equipment Designed to Minimize Patient and Personnel Exposure Commensurate with The Needed Diagnostic Information Shall Be Utilized**

A. The fastest imaging system consistent with the diagnostic objective of the examinations shall be used. Film cassettes without intensifying screens shall not be used for any diagnostic radiological imaging, with the exception of veterinary radiography and standard film packets for intraoral use in dental radiography.

B. The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.

C. Portable or mobile equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a stationary X-ray installation.

D. Facilities shall establish and implement a quality assurance program for X-ray film processing, whether processing is manual or automatic.

E. X-ray Film Processing Facilities and Practices. Each installation using a radiographic X-ray system and using analog image receptors (e.g., radiographic film) shall have available suitable equipment for handling and processing radiographic film in accordance with the following provisions.

1. Manual Processing of Films

a. Processing of film: The temperature of solutions in the tanks shall be maintained within the range of 60o F to 80o F (16o C to 27o C). Film shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer.

b. Devices shall be utilized which will:

1. Indicate the actual temperature of the developer; and

2. Give an audible or visible signal indicating the termination of a preset time.

c. Processing tanks shall be constructed of mechanically rigid, corrosion resistant material.

2. Automatic Processors and Other Closed Processing Systems

a. Films shall be processed in accordance with the time temperature relationships recommended by the film manufacturer; and

b. Processing deviations from the requirements of § 4.3.10(E)(2)(a) of this Part shall be documented by the registrant in such manner that the requirements are shown to be met or exceeded (e.g., extended processing, and special rapid chemistry).

F. If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast, the grid shall:

1. Be positioned properly (i.e., tube side facing the proper direction) and grid centered to the central ray.

2. If of the focused type, be of the proper focal distance for the SID being used.

G. Other Requirements

1. Pass boxes, if provided, shall be so constructed as to exclude light from the darkroom when cassettes are placed in or removed from the boxes, and shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film.

2. The darkroom shall be light-tight and use proper safelighting such that any film type in use exposed in a cassette to x-radiation sufficient to produce an optical density from 1 to 2 when processed shall not suffer an increase in density greater than 0.05 when exposed in the darkroom for two (2) minutes with all safelights on. If used, daylight film handling systems shall preclude fogging of the film.

3. Darkrooms typically used by more than one individual shall be provided a method to prevent accidental entry while undeveloped films are being handled or processed.

4. Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light-tight container.

5. Film cassettes and intensifying screens shall be inspected periodically and shall be cleaned and replaced as necessary to assure radiographs of good diagnostic quality.

6. Outdated x-ray film shall not be used for diagnostic radiographs, unless the film has been stored in accordance with the manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base plus fog and speed.

7. Film developing solutions shall be prepared in accordance with the directions given by the manufacturer, and shall be maintained in strength

by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.

H. The tube housing and the position indicating device (PID) for a permanently mounted intraoral dental system shall not be hand-held during an exposure. § 4.13 of this Part specifies requirements for the use of intraoral dental radiographic units designed to be hand-held during patient examination.

I. Dental fluoroscopy without image intensification shall not be used.

4.3.11 All individuals who are associated with the operation of an X-ray system are subject to the applicable requirements of Parts 1 and 2 of this Subchapter.

4.3.12 **Healing Arts Screening**

Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the Agency. When requesting such approval, that person shall submit the information outlined in § 4.11 of this Part. If any information submitted to the Agency becomes invalid or outdated, the Agency shall be immediately notified.

4.3.13 **Information and Maintenance Record and Associated Information.** The registrant shall maintain the following information in a separate file or package in chronological order for each X-ray system, for inspection by the Agency:

A. Maximum rating of technique factors;

B. Model and serial numbers of all major components, and user's manuals for those components;

C. Aluminum equivalent filtration in the useful beam, including any routine variation;

D. Tube rating charts and cooling curves;

E. Records of surveys, calibrations, maintenance, and modifications performed on the X-ray system(s) after 2 June 1978 with the names of persons who performed such services;

F. A scale drawing of the room in which a stationary X-ray system is located with such drawing indicating the current use of areas adjacent to the room and an estimate of the extent of occupancy by an individual in such areas. In addition, the drawing shall include the results of a survey for radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions; or the type and thickness of materials, or lead equivalency, of each protective barrier.

G. A copy of all correspondence with this Agency regarding that X-ray system.

4.3.14 **X-Ray Utilization Log**

A. Except for veterinary facilities, each facility shall maintain a record containing the patient's name, the type of examinations, and the dates the examinations were performed. The record shall also include the following information:

1. Name of the licensed practitioner of the healing arts ordering the examination.

2. Name(s) of individuals who performed the examination.

3. Any deviation from the standard procedure as specified on the technique chart, including all repeat exposures.

4. When applicable, the fluoro recordkeeping requirements of § 4.5.3(E) of this Part.

5. When applicable, the X-ray system used.

6. When the patient or image receptor must be provided with human auxiliary support, the name of the human holder.

B. X-ray utilization logs shall be maintained for a minimum of five (5) years following the examination or treatment of adult patients. Records of examination or treatment of minors shall be maintained for a minimum of five (5) years beyond the age of majority.

C. If X-ray utilization logs are stored electronically, records shall be maintained in a manner that will allow retrieval of records for any specified time period.

4.3.15 **Report and Notification of a Dose to an Embryo/Fetus**

A. A registrant shall report any dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent that is a result of an administration of radiation to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the referring physician.

B. The registrant shall notify the Agency by telephone no later than the next business day after discovery of a dose to the embryo/fetus that requires a report in § 4.3.15(A) of this Part.

C. The registrant shall submit a written report, prepared by a Qualified Medical Physicist, to the Agency within fifteen (15) business days after discovery of a dose to the embryo/fetus that requires a report in § 4.3.15(A) of this Part.

1. The written report shall include:

a. The registrant's name and registration number;

b. The name of the referring physician;

c. A brief description of the event;

d. Why the event occurred;

e. The effect, if any, on the embryo/fetus;

f. What actions, if any, have been taken or are planned to prevent recurrence; and

g. Certification that the registrant notified the pregnant individual (or the pregnant individual's responsible relative or guardian), and if not, why not.

2. The report must not contain the individual's name or any other information that could lead to identification of the individual.

D. The registrant shall provide notification of the event to the referring physician and also notify the pregnant individual, no later than twenty-four (24) hours after discovery of an event that would require reporting under § 4.3.15(A) of this Part, unless the referring physician personally informs the registrant either that he or she will inform the pregnant individual or that, based on medical judgment, telling the pregnant individual would be harmful. The registrant is not required to notify the pregnant individual without first consulting with the referring physician. If the referring physician or pregnant individual cannot be reached within twenty-four (24) hours, the registrant shall make the appropriate notifications as soon as possible thereafter. The registrant may not delay any appropriate medical care for the embryo/fetus, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this paragraph, the notification may be made to the pregnant individual's responsible relative or guardian instead of the pregnant individual. If a verbal notification is made, the registrant shall inform the pregnant individual, or the pregnant individual's responsible relative or guardian, that a written description of the event can be obtained from the registrant upon request. The registrant shall provide such a written description if requested.

E. A registrant shall:

1. Annotate a copy of the report provided to the Agency with the:

a. Name of the pregnant individual who is the subject of the event; and

b. Social security number or other identification number, if one has been assigned, of the pregnant individual who is the subject of the event; and

2. Provide a copy of the annotated report to the referring physician, if other than the registrant, no later than fifteen (15) days after the discovery of the event.

4.4 General Requirements for All Diagnostic X-Ray Systems

4.4.1 In addition to other requirements of this Part, all diagnostic X-ray systems shall meet the requirements of § 4.4 of this Part.

4.4.2 Maintaining Compliance

Diagnostic X-ray systems and their associated components used on humans and certified pursuant to the Federal X-ray Equipment Performance Standard (21 CFR Part 1020) shall be maintained in compliance with applicable requirements of that standard.

4.4.3 Warning Label

The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This X-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions and maintenance schedules are observed".

4.4.4 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.

4.4.5 Leakage Radiation from the Diagnostic Source Assembly

The leakage radiation from the diagnostic source assembly measured at a distance of one (1) meter in any direction from the source shall not exceed 0.88 milligray (mGy) air kerma [100 milliroentgen (mR) exposure] in one (1) hour when the X-ray tube is operated at its leakage technique factors. If the maximum rated peak tube potential of the tube housing assembly is greater than the maximum rated peak tube potential for the diagnostic source assembly, positive means shall be provided to limit the maximum X-ray tube potential to that of the diagnostic source assembly. Compliance shall be determined by measurements averaged over an area of one-hundred square centimeters (100 cm2) with no linear dimension greater than twenty (20) centimeters.

4.4.6 Radiation from Components Other Than the Diagnostic Source Assembly

The radiation emitted by a component other than the diagnostic source assembly shall not exceed an air kerma of eighteen (18) µgray [two (2) milliroentgens exposure] in one (1) hour at five (5) centimeters from any accessible surface of the component when it is operated in an assembled X-ray system under any

conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of one-hundred square centimeters (100 cm^2) with no linear dimension greater than twenty centimeters (20 cm).

4.4.7 **Beam Quality**

A. Half-Value Layer (HVL)

1. The HVL of the useful beam for a given X-ray tube potential shall not be less than the values shown in § 4.4.7(B) of this Part [Table 1] under the heading "Specified Dental Systems," for any dental X-ray system designed for use with intraoral image receptors and manufactured after 1 December 1980; under the heading," Other X-Ray Systems[2]" for any dental X-ray system designed for use with intraoral image receptors and manufactured before or on 1 December 1980, and all other X-ray systems subject to this section and manufactured before 10 June 2006; and under the heading, "Other X-Ray Systems[3]" for all X-ray systems, except dental X-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after 10 June 2006. If it is necessary to determine such half-value layer at an X-ray tube potential which is not listed in § 4.4.7(B) of this Part [Table 1], linear interpolation or extrapolation may be made. Positive means shall be provided to ensure that at least the minimum filtration needed to achieve beam quality requirements is in the useful beam during each exposure. In the case of a system, which is to be operated with more than one thickness of filtration, this requirement can be met by a filter interlocked with the kilovoltage selector which will prevent X-ray emissions if the minimum required filtration is not in place.

2. Optional Filtration. Fluoroscopic systems manufactured on or after 10 June 2006, incorporating an X-ray tube(s) with a continuous output of one (1) kilowatt or more and an anode heat storage capacity of one-million (1,000,000) heat units or more shall provide the option of adding X-ray filtration to the diagnostic source assembly in addition to the amount needed to meet the half-value layer provisions of § 4.4.7(A)(1) of this Part. The selection of this additional X-ray filtration shall be either at the option of the user or automatic as part of the selected mode of operation. A means of indicating which combination of additional filtration is in the X-ray beam shall be provided.

B. Table 1 - X-Ray Tube Voltage (kilovolt peak)

Design Operating Range	Measured Operating Potential	Minimum HVL (mm in Aluminum)		
		Specified Dental Systems[1]	Other X-Ray Systems[2]	Other X-Ray Systems[3]
Below 51	30	1.5	0.3	0.3

Design Operating Range	Measured Operating Potential	Minimum HVL (mm in Aluminum)		
		Specified Dental Systems[1]	Other X-Ray Systems[2]	Other X-Ray Systems[3]
	40	1.5	0.4	0.4
	50	1.5	0.5	0.5
51 to 70	51	1.5	1.2	1.3
	60	1.5	1.3	1.5
	70	1.5	1.5	1.8
	71	2.1	2.1	2.5
Above 70	80	2.3	2.3	2.9
	90	2.5	2.5	3.2
	100	2.7	2.7	3.6
	110	3.0	3.0	3.9
	120	3.2	3.2	4.3
	130	3.5	3.5	4.7
	140	3.8	3.8	5.0
	150	4.1	4.1	5.4

[1] Dental X-ray systems designed for use with intraoral image receptors and manufactured after 1 December 1980

[2] Dental X-ray systems designed for use with intraoral image receptors and manufactured before or on 1 December 1980, and all other X-ray systems subject to this section and manufactured before 10 June 2006

[3] All X-ray systems, except dental X-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after 10 June 2006.

C. Beryllium window tubes shall have a minimum of 0.5 millimeter aluminum equivalent filtration permanently installed in the useful beam.

D. Measuring Compliance. For capacitor energy storage equipment, compliance shall be determined with the maximum selectable quantity of charge per exposure.

E. Aluminum Equivalent of Material Between Patient and Image Receptor. Except when used in a CT X-ray system, the aluminum equivalent of each of the items listed in § 4.3.7(F) of this Part [Table 2], which are used between the patient and the image receptor, shall not exceed the indicated limits. Compliance shall be determined by X-ray measurements made at a potential of one-hundred (100) kilovolts peak and with an X-ray beam that has an HVL specified in § 4.3.7(B) of this Part [Table 1] for the potential. This requirement applies to front panel(s) of cassette holders and film changers provided by the manufacturer for patient support or for prevention of foreign object intrusions. It does not apply to screens and their associated mechanical support panels or grids.

F. Table 2 - Maximum Aluminum Equivalent (millimeters)

ITEM	Maximum Aluminum Equivalent (millimeters)
1. Front panel(s) of cassette holders (total of all)	1.2
2. Film panel(s) of film changer (total of all)	1.2
3. Cradle	2.3
4. Tabletop, stationary, without articulated joints	1.2
5. Tabletop, movable, without articulated joint(s) (including stationary subtop)	1.7
6. Tabletop, with radiolucent panel having one articulated joint	1.7
7. Tabletop, with radiolucent panel having two or more articulated joints	2.3
8. Tabletop, cantilevered	2.3
9. Tabletop, radiation therapy simulator	5.0

G. Modification of Certified Diagnostic X-ray Components and Systems

1. Diagnostic X-ray components and systems certified in accordance with 21 CFR Part 1020 shall not be modified such that the component or system fails to comply with any applicable provision of this Part unless a variance in accordance with 21 CFR 1010.4 or an exemption under §534(a)(5) or §538(b) of the Federal Food, Drug, and Cosmetic Act has been granted.

2. The owner of a diagnostic X-ray system who uses the system in a professional or commercial capacity may modify the system provided the modification does not result in the failure of the system or component to comply with the applicable requirements of his Part. The owner who causes such modification need not submit the reports required by this Subchapter, provided the owner records the date and the details of the modification in the system records and maintains this information, and provided the modification of the X-ray system does not result in a failure to comply with this Subchapter.

H. kVp Limitations. Dental X-ray machines with a nominal fixed kVp of less than fifty (50) kVp shall not be used to make diagnostic dental radiographs of humans.

4.4.8 **Multiple Tubes**

Where two (2) or more radiographic tubes are controlled by one (1) exposure switch, the tube or tubes which 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 which has been selected.

4.4.9 Mechanical Support of Tube Head

The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the X-ray system.

4.4.10 Technique Indicators

A. The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic EXPOSURE controls are used, the technique factors which are set prior to the exposure shall be indicated.

B. The requirement of § 4.4.10(A) of this Part may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films.

4.4.11 Structural Shielding

Structural shielding shall be provided whenever necessary to meet the requirements of §§ 1.7.1 and 1.8.1 of this Subchapter, in addition to specific requirements contained in other parts of this Subchapter.

4.4.12 Locks

All position locking, holding, and centering devices on x-ray system components and systems shall function as intended.

4.4.13 Use of Calibrated Dosimetry System

The measurement of the radiation output of an X-ray system shall be performed with a calibrated dosimetry system. The calibration of such a system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding two (2) years.

4.4.14 Reports and Notifications of Radiation Medical Events

A. Other than events that result from intervention by a patient or human research subject, a registrant shall report any event in which the administration of ionizing radiation from a diagnostic radiation machine meets one or more of the following criteria:

1. A patient or human research subject receives an unintended skin dose to the same area in a single procedure greater than two (2) Gy [two-hundred (200) rads].

2. A patient or human research subject receives an unintended dose other than skin dose in a single procedure greater than:

a. Five (5) times the facility's established protocol, and five-hundred (500) mGy [fifty (50) rads] to any organ; or

b. Five (5) times the facility's established protocol, and fifty (50) mSv [five (5) rem] total effective dose.

3. Wrong patient or wrong site for the entire procedure when the resultant dose:

a. Exceeds five-hundred (500) mGy [fifty (50) rads] to any organ; or

b. Total effective dose is greater than or equal to (≥) fifty (50) mSv [five (5) rem].

4. Equipment failure, personnel error, accident, mishap or other unusual occurrence with the administration of ionizing radiation that exceeds fifty (50) mGy [five (5) rads] total effective dose.

B. Any wrong patient or wrong site imaged regardless of dose received should be reported, documented and addressed internally within the facility.

C. The registrant shall notify the Agency by telephone no later than the next business day after discovery of the radiation medical event.

1. All required notifications shall use Agency contact information specified in § 1.4 of this Subchapter.

D. The registrant shall submit a written report, prepared by a Qualified Medical Physicist, to the Agency within fifteen (15) business days after discovery of the radiation medical event. The written report shall include:

1. The registrant's name;

2. Date of event and date discovered;

3. The total estimated dose received;

4. The imaging procedure(s) performed;

5. The type of equipment in use (e.g., CT, fluoroscopy, radiographic, other);

6. The manufacturer and model of the unit used:

7. Why the event occurred;

8. How the event was discovered;

9. The effect, if any, on the individuals(s) who is the subject of the radiation medical event;

10. Actions, if any, that have been taken, or are planned, to prevent recurrence;

11. Certification that the registrant notified the individual (or the individual's responsible relative or guardian), and if not, why not; and

12. If there was notification, what information was provided to the individual.

E. The registrant shall provide a clinical summary of the radiation medical event to the prescribing physician and patient within fifteen (15) business days.

4.4.15 **Records of Radiation Medical Events**

A registrant shall retain a record of a radiation medical event reported in accordance with § 4.4.14 of this Part as part of the patient's permanent medical record.

4.5 FLUOROSCOPIC EQUIPMENT

4.5.1 The provisions of § 4.5 of this Part apply to equipment for fluoroscopic imaging or for recording images from the fluoroscopic image receptor, except computed tomography X-ray systems manufactured on or after 29 November 1984.

4.5.2 **Primary Protective Barrier**

A. Limitation of Useful Beam. The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID. The X-ray tube used for fluoroscopy shall not produce X-rays unless the barrier is in position to intercept the entire useful beam. The air kerma (exposure) rate due to transmission through the barrier with the attenuation block in the useful beam combined with radiation from the fluoroscopic imaging receptor shall not exceed 3.34×10^{-3} percent of the entrance air kerma (exposure) rate, at a distance of ten (10) cm from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor.

B. Measuring Compliance. The air kerma (exposure) rate shall be measured in accordance with § 4.6 of this Part. The air kerma (exposure) rate due to transmission through the primary barrier combined with radiation from the fluoroscopic image receptor shall be determined by measurements averaged over an area of one-hundred square centimeters (100 cm^2) with no linear dimension greater than twenty (20) cm. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned thirty (30) cm above the tabletop. 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 thirty (30) cm. Movable grids and compression devices shall be removed from the useful beam during the

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

4.5.3 Equipment Operation

A. All imaging formed by the use of fluoroscopic x-ray systems shall be viewed, directly or indirectly, and interpreted by a licensed practitioner of the healing arts.

B. The operation of mobile or portable fluoroscopic x-ray systems, for positioning purposes only, by radiologic technologists shall be performed under the direct supervision of a licensed practitioner of the healing arts who meets the requirements of § 4.3.3(C) of this Part.

C. Radiologic technology students shall not be allowed to operate fluoroscopic x-ray systems unless in the physical presence of a licensed practitioner of the healing arts and a radiologic technologist, as specified in § 4.3.3(C) of this Part.

D. Overhead fluoroscopy shall not be used as a positioning tool for general purpose radiographic examinations.

E. Each registrant that uses fluoroscopic x-ray systems shall maintain a record of the cumulative fluoroscopic exposure time used and the number of images recorded from the fluoroscopic image receptor for each examination. This record shall include patient identification, type and date of examination, the fluoroscopic system used, and operator's name. The record shall be maintained for five (5) years.

4.5.4 Field Limitation

A. Angulation. For fluoroscopic equipment manufactured after 25 February 1978, when the angle between the image receptor and the beam axis of the X-ray beam is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor. Compliance with §§ 4.5.4(D) and (E) of this Part shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

B. Further Means for Limitation. Means shall be provided to permit further limitation of the X-ray field to sizes smaller than the limits of §§ 4.5.4(D) and (E) of this Part. Beam-limiting devices manufactured after 22 May 1979, and incorporated in equipment with a variable SID and/or capability of a visible area of greater than three-hundred square cm (300 cm^2), shall be provided with means for stepless adjustment of the X-ray field. Equipment with a fixed SID and the capability of a visible area of no greater than three-hundred square cm (300 cm^2) shall be provided with either stepless adjustment of the X-ray field or with a means to further limit the X-ray field size at the plane of the image receptor to one-hundred twenty five square cm (125 cm^2) or less. Stepless adjustment shall, at the

greatest SID, provide continuous field sizes from the maximum obtainable to a field size containable in a square of five (5) cm by five (5) cm. This paragraph does not apply to non-image-intensified fluoroscopy.

C. Non-Image-Intensified Fluoroscopy. The X-ray field produced by non-image-intensified fluoroscopic equipment shall not extend beyond the entire visible area of the image receptor. Means shall be provided for stepless adjustment of field size. The minimum field size, at the greatest SID, shall be containable in a square of five (5) cm by five (5) cm.

D. Fluoroscopy and Radiography Using the Fluoroscopic Imaging Assembly with Inherently Circular Image Receptors

1. For fluoroscopic equipment manufactured before 10 June 2006, other than radiation therapy simulation systems, the following applies:

a. Neither the length nor 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 three percent (3%) of the SID. The sum of the excess length and the excess width shall be no greater than four percent (4%) of the SID.

b. 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 which pass through the center of the visible area of the image receptor.

2. For fluoroscopic equipment manufactured on or after 10 June 2006, other than radiation therapy simulation systems, the maximum area of the X-ray field in the plane of the image receptor shall conform with one of the following requirements:

a. When any linear dimension of the visible area of the image receptor measured through the center of the visible area is less than or equal to thirty-four (34) cm in any direction, at least eighty percent (80%) of the area of the X-ray field overlaps the visible area of the image receptor, or

b. When any linear dimension of the visible area of the image receptor measured through the center of the visible area is greater than thirty-four (34) cm in any direction, the X-ray field measured along the direction of greatest misalignment with the visible area of the image receptor does not extend beyond the edge of the visible area of the image receptor by more than two (2) cm.

E. Fluoroscopy and Radiography Using Fluoroscopic Imaging Assembly With Inherently Rectangular Image Receptors. For X-ray systems manufactured on or after 10 June 2006, the following applies:

1. Neither the length nor 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 three percent (3%) of the SID. The sum of the excess length and the excess width shall be no greater than four percent (4%) of the SID.

2. The error in alignment shall be determined along the length and width dimensions of the X-ray field which pass through the center of the visible area of the image receptor.

F. Override Capability. If the fluoroscopic X-ray field size is adjusted automatically as the SID or image receptor size is changed, a capability may be provided for overriding the automatic adjustment in case of system failure. If it is so provided, a signal visible at the operator's position shall indicate whenever the automatic field adjustment is overridden. Each such system failure override switch shall be clearly labeled as follows:

FOR X-RAY FIELD LIMITATION SYSTEM FAILURE

4.5.5 **Activation of the Tube**

X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the operator for the entire time of any exposure. When recording serial fluoroscopic images from the fluoroscopic image receptor, the operator shall be able to terminate the X-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

4.5.6 **Air Kerma (Exposure) Rates**. For fluoroscopic equipment, the following requirements apply:

A. Fluoroscopic equipment manufactured before 19 May 1995.

1. Equipment provided with automatic exposure rate control (AERC) shall not be operable at any combination of tube potential and current that will result in an air kerma (exposure) rate in excess of 88 mGy per minute (10 R/min exposure rate) at the measurement point specified in § 4.5.6(C) of this Part, except as specified in § 4.5.6(A)(5) of this Part.

2. Equipment provided without AERC shall not be operable at any combination of tube potential and current that will result in an air kerma (exposure) rate in excess of 44 mGy per minute (5 R/min exposure rate) at the measurement point specified in § 4.5.6(C) of this Part, except as specified in § 4.5.6(A)(5) of this Part.

3. Equipment 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 air kerma (exposure) rate in excess of 88 mGy per minute (10

R/min exposure rate) in either mode at the measurement point specified in § 4.5.6(C) of this Part, except as specified in § 4.5.6(A)(5) of this Part.

4. Equipment may be modified in accordance with § 4.4.7(E)(1) of this Part to comply with § 4.5.6(B) of this Part. When the equipment is modified, it shall bear a label indicating the date of the modification and the statement:

MODIFIED TO COMPLY WITH 21 CFR 1020.32(H)(2)

5. Exceptions:

a. During recording of fluoroscopic images, or

b. When a mode of operation has an optional high-level control, in which case that mode shall not be operable at any combination of tube potential and current that will result in an air kerma (exposure) rate in excess of the rates specified in §§ 4.5.6(A)(1), (2) and (3) of this Part at the measurement point specified in § 4.5.6(C) of this Part, 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 operator shall indicate that the high-level control is being employed.

B. Fluoroscopic equipment manufactured on or after 19 May 1995.

1. Shall be equipped with AERC if operable at any combination of tube potential and current that results in an air kerma (exposure) rate greater than 44 mGy per minute (5 R/min exposure rate) at the measurement point specified in § 4.5.6(C) of this Part. Provision for manual selection of technique factors may be provided.

2. Shall not be operable at any combination of tube potential and current that will result in an air kerma (exposure) rate in excess of 88 mGy per minute (10 R/min exposure rate) at the measurement point specified in § 4.5.6(C) of this Part, except as specified in § 4.5.6(B)(3) of this Part.

3. Exceptions

a. For equipment manufactured prior to 10 June 2006, during the recording of images from a fluoroscopic image receptor using photographic film or a video camera when the X-ray source is operated in a pulsed mode.

b. For equipment manufactured on or after 10 June 2006, during the recording of images from the fluoroscopic image receptor for the purpose of providing 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.

c. When a mode of operation has an optional high-level control and the control is activated, in which case the equipment shall not be operable at any combination of tube potential and current that will result in an air kerma (exposure) rate in excess of 176 mGy per minute (20 R/min exposure rate) at the measurement point specified in § 4.5.6(C) of this Part. 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 operator shall indicate that the high-level control is employed.

4.5.7 **Measurement of Entrance Air Kerma (Exposure) Rate.** Measurement of entrance air kerma (exposure) rate shall be performed for both maximum and typical values and shall be made at intervals not to exceed twelve (12) months or after any maintenance of the system which might affect the air kerma (exposure) rate. Results of these measurements shall be posted where any fluoroscopist may have ready access to such results during the fluoroscopic procedure and in the record required in § 4.3.13(E) of this Part. Results of the measurements shall include the mGy per minute (R/min exposure rate), as well as the technique factors used to determine such results. The name of the Qualified Medical Physicist performing the measurements and the date the measurements were performed shall be included in the results.

A. Conditions of measurement of maximum entrance air kerma (exposure) rate are as follows:

1. The measurements shall be made under conditions that satisfy the requirements of §§ 4.5.6(A) & (B) of this Part;

2. The kVp, mA and/or other selectable parameters shall be adjusted to those settings which give the maximum air kerma (exposure) rate; and

3. An X-ray system that incorporates automatic exposure rate control (AERC) shall have sufficient material placed in the useful beam to produce the maximum output of that system.

B. Conditions of measurement of typical air kerma (exposure) rate are as follows:

1. The measurements shall be made under conditions that satisfy the requirements of § 4.5.7(C) of this Part and are typical of clinical use of the X-ray system;

2. The kVp shall be that typical of clinical use of the X-ray system;

3. An X-ray system(s) that incorporates AERC shall have sufficient material placed in the useful beam to produce operating parameters typical of the use of the X-ray system; and

4. An X-ray system(s) that does not incorporate an AERC shall utilize a milliamperage typical of the clinical use of the X-ray system.

   a. Material should be placed in the useful beam when conducting these periodic measurements to protect the imaging system.

C. Measuring Compliance. Compliance with this subsection shall be determined as follows:

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

2. If the source is above the X-ray table, the air kerma (exposure) rate shall be measured at thirty (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.

3. In a C-arm type of fluoroscope, the air kerma (exposure) rate shall be measured at thirty (30) cm from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than thirty (30) cm from the input surface of the fluoroscopic imaging assembly.

4. In a C-arm type of fluoroscope having an SID less than forty-five (45) cm, the air kerma (exposure) rate shall be measured at the minimum SSD.

5. In a lateral type of fluoroscope, the air kerma (exposure) rate shall be measured at a point fifteen (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 tabletop 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 fifteen (15) cm to the centerline of the X-ray table.

4.5.8 Indication of Potential and Current

During fluoroscopy and cinefluorography, the X-ray tube potential and current shall be continuously indicated. Deviation of X-ray tube potential and current from the indicated value shall not exceed the maximum deviation as stated by the manufacturer.

4.5.9 Source-Skin Distance

A. Means shall be provided to limit the source-skin distance to not less than thirty-eight (38) cm on stationary fluoroscopes and to not less than thirty (30) cm on mobile and portable fluoroscopes. In addition, for fluoroscopes intended for specific surgical application that would be prohibited at the source-skin distances specified in this paragraph, provisions may be made for operating at shorter source-skin distances but in no case less than twenty (20) cm.

B. For stationary, mobile, or portable C-arm fluoroscopic systems manufactured on or after 10 June 2006, having a maximum source-image receptor distance of less than forty-five (45) cm, means shall be provided to limit the source-skin distance to not less than nineteen (19) cm. Such systems shall be labeled for extremity use only. In addition, for those systems intended for specific surgical application that would be prohibited at the source-skin distance specified in this paragraph, provisions may be made for operation at shorter source-skin distances but in no case less than ten (10) cm.

4.5.10 **Fluoroscopic Irradiation Time, Display and Signal**

A. Fluoroscopic equipment manufactured before 10 June 2006

1. Shall be provided with means to preset the cumulative irradiation time of the fluoroscopic tube. The maximum cumulative time of the timing device shall not exceed five (5) minutes without resetting. A signal audible to the operator shall indicate the completion of any preset cumulative irradiation time. Such signal shall continue to sound while X-rays are produced until the timing device is reset. Fluoroscopic equipment may be modified in accordance with 21 CFR 1020.30(q) to comply with the requirements of § 4.5.10 of this Part. When the equipment is modified, it shall bear a label indicating the statement:

   MODIFIED TO COMPLY WITH 21 CFR 1020.32(H)(2)

B. For X-ray controls manufactured on or after 10 June 2006, there shall be provided for each fluoroscopic tube:

1. A display of the fluoroscopic irradiation time at the operator's working position. This display shall function independently of the audible signal described § 4.5.10(B)(2) of this Part. The following requirements apply:

   a. 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 once every six (6) seconds.

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

c. Means shall be provided to reset the display to zero prior to the beginning of a new examination or procedure.

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

4.5.11 **Mobile and Portable Fluoroscopes.**

In addition to the other requirements of § 4.5 of this Part, mobile and portable fluoroscopes shall provide an image receptor incorporating more than a simple fluorescent screen.

4.5.12 **Control of Scattered Radiation**

A. Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be not less than 0.25 millimeter lead equivalent.

B. Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:

1. Is at least one-hundred twenty (120) centimeters from the center of the useful beam, or

2. The radiation has passed through not less than 0.25 millimeter lead equivalent material (e.g., drapes, Bucky-slot cover-sliding or folding panel, or self supporting curtains) in addition to any lead equivalency provided by the protective apron referred to in § 4.3.6 of this Part.

C. The Agency may grant exemptions to § 4.5.12(B) of this Part where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the Agency shall not permit such exception.

4.5.13 **Patient Dose Evaluation**

A. Each registrant performing fluoroscopically-guided interventional procedures shall develop written policies and procedures to:

1. Identify those procedures which have a potential to result in patient doses exceeding the threshold for injury;

2. Reduce the probability of such exposures; and

3. Ensure that appropriate action occurs for patients receiving doses that warrant follow-up.

B. The registrant shall have a patient dose monitoring procedures in place and shall document (in the patient's medical record) an estimate of the absorbed dose to the skin. When the fluoroscopy unit is equipped with an Air-Kerma dose readout, the recording of this value shall suffice as a patient dose record.

C. The registrant shall conduct patient dose evaluation for any procedure that has a reasonable probability of resulting in a deterministic injury (i.e., a cumulative absorbed dose to the skin equal to or greater than 1 Gy (100 rads)). This evaluation shall be noted in the patient's medical record and reviewed by the Radiation Safety Committee. If the registrant does not have a Radiation Safety Committee, the review shall be conducted by the Radiation Safety Officer and the registrant's medical physicist.

4.5.14 **Radiation Therapy Simulation Systems**

A. Radiation therapy simulation systems shall be exempt from the requirements of § 4.5.2(A), provided such systems are intended only for remote control operation.

B. Radiation therapy simulation systems shall be exempt from all the requirements of §§ 4.5.4(D), 4.5.6 and 4.6.12(B)(2) of this Part when used for therapy simulation purposes.

C. As an alternative to the requirements of §4.5.10 of this Part, radiation therapy simulation systems may be provided with a means to indicate the total cumulative exposure time during which X-rays were produced, and which is capable of being reset between X-ray examinations.

4.5.15 **Display of Last-Image-Hold (LIH).** Fluoroscopic equipment manufactured on or after 10 June 2006, shall be equipped with means to display LIH image following termination of the fluoroscopic exposure.

A. For an LIH image obtained by retaining pretermination fluoroscopic images, if the number of images and method of combining images are selectable by the user, the selection shall be indicated prior to initiation of the fluoroscopic exposure.

B. For an LIH image obtained by initiating a separate radiographic-like exposure at the termination of fluoroscopic imaging, the technique factors for the LIH image shall be selectable prior to the fluoroscopic exposure, and the combination selected shall be indicated prior to initiation of the fluoroscopic exposure.

C. Means shall be provided to clearly indicate to the user whether a displayed image is the LIH radiograph or fluoroscopy. Display of the LIH radiograph shall be replaced by the fluoroscopic image concurrently with re-initiation of

fluoroscopic exposure, unless separate displays are provided for the LIH radiograph and fluoroscopic images.

4.5.16 **Displays of Values of Air Kerma (Exposure) Rate and Cumulative Air Kerma.** Fluoroscopic equipment manufactured on or after 10 June 2006, shall display at the operator's working position the air kerma (exposure) rate and cumulative air kerma. The following requirements apply for each X-ray tube used during an examination or procedure:

A. When the X-ray tube is activated and the number of images produced per unit time is greater than six (6) images per second, the air kerma (exposure) rate in mGy/min shall be continuously displayed and updated at least once every second.

B. The cumulative air kerma in units of mGy shall be displayed either within five (5) seconds of termination of an exposure or displayed continuously and updated at least once every five (5) seconds.

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

D. The air kerma (exposure) rate and cumulative air kerma shall represent the value for conditions of free-in-air irradiation at one of the following reference locations specified according to the type of fluoroscope.

1. For fluoroscopes with X-ray source below the X-ray table, X-ray source above the table, or of lateral type, the reference location shall be the respective locations specified in §§ 4.5.7(C)(1), (C)(2) or (C)(5) of this Part.

2. For C-arm fluoroscopes, the reference location shall be fifteen (15) cm from the isocenter toward the X-ray source along the beam axis. Alternatively, the reference location shall be at a point specified by the manufacturer to represent the location of the intersection of the X-ray beam with the patient's skin.

E. Means shall be provided to reset to zero the display of cumulative air kerma prior to the commencement of a new examination or procedure.

F. The displayed air kerma (exposure) rate and cumulative air kerma shall not deviate from the actual values by more than ± thirty-five percent (± 35%) over the range of 6 mGy/min and 100 mGy to the maximum indication of air kerma (exposure) rate and cumulative air kerma, respectively. Compliance shall be determined with an irradiation time greater than three (3) seconds.

4.6 RADIOGRAPHIC EQUIPMENT

4.6.1 **Beam Limitation, Except Mammographic Systems**. The useful beam shall be limited to the area of clinical interest. This shall be deemed to have been met if a positive beam limiting device meeting manufacturer's specifications and the requirements of § 4.4.2 of this part has been properly used or if evidence of collimation is shown on at least three sides or three corners of the film (for example, projections from the shutters of the collimator, cone cutting at the corners, or borders at the film's edge).

4.6.2 **Radiation Exposure Control**

A. Exposure Initiation. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action. In addition, it shall not be possible to initiate an exposure when the timer is set to a "zero" or "off" position if either position is provided.

B. Exposure Indication. Means shall be provided for visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

C. Operator Protection, Except Veterinary Systems.

1. Stationary Systems. Stationary X-ray systems shall be required to have the X-ray control permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure.

2. Mobile and Portable Systems. Mobile and portable X-ray systems which are:

a. Used continuously for greater than one (1) week in the same location (i.e., a room or suite) shall meet the requirements of § 4.6.2(C)(1) of this Part;

b. Used for less than one (1) week at the same location shall be provided with either a protective barrier at least two (2) meters (6.5 feet) high for operator protection during exposures, or means shall be provided to allow the operator to be at least 2.7 meters (9 feet) from the tube housing assembly during the exposure.

D. Operator Protection for Veterinary Systems.

1. All stationary, mobile or portable X-ray systems used for veterinary work shall be provided with either a two (2) meter (6.5 feet) high protective barrier for operator protection during exposures, or shall be provided with

means to allow the operator to be at least 2.7 meters (9 feet) from the tube housing assembly during exposures. No individual other than the operator shall be in the X-ray room while exposures are being made unless such individual's assistance is required. Refer to § 4.13 of this Part for hand-held intraoral dental radiographic units used in veterinary practice.

2. When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used. If necessary, general anesthesia, sedation or tranquilization should be used. If the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, such as protective gloves and apron, and shall be so positioned that no part of their body will be struck by the useful beam. No individual shall be used routinely to hold animals or film during radiation exposures. The exposure of any individual used for this purpose shall be monitored, and a record shall be made of the examination, including the name of the human holder, date of the examination, number of exposures and technique factors utilized for the exposure(s).

4.6.3 Control and Indication of Technique Factors

A. Visual Indication. 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 which are set prior to the exposure shall be indicated. On equipment having fixed technique factors, this requirement may be met by permanent markings. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the operator.

B. 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.

1. Except during serial radiography, the operator shall be able to terminate the exposure at any time during an exposure of greater than one-half (0.5) second. Except during panoramic dental radiography, termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero. 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.

2. During serial radiography, the operator shall be able to terminate the X-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

C. Automatic Exposure Controls. When an automatic exposure control is provided:

1. Indication shall be made on the control panel when this mode of operation is selected;

2. When the X-ray tube potential is equal to or greater than fifty-one (51) kilovolts peak (kVp), the minimum exposure time for field emission equipment rated for pulse operation shall be equal to or less than a time interval equivalent to two pulses and the minimum exposure time for all other equipment shall be equal to or less than 1/60 second or a time interval required to deliver five (5) milliampere-seconds (mAs), whichever is greater;

3. Either the product of peak X-ray tube potential, current, and exposure time shall be limited to not more than sixty (60) kilowatt-seconds (kWs) per exposure or the product of X-ray tube current and exposure time shall be limited to not more than six-hundred (600) mAs per exposure, except when the X-ray tube potential is less than fifty-one (51) kVp, in which case the product of X-ray tube current and exposure time shall be limited to not more than two-thousand (2,000) mAs per exposure; and

4. A visible signal shall indicate when an exposure has been terminated at the limits described in § 4.6.3(A)(3) of this Part, and manual resetting shall be required before further automatically timed exposures can be made.

D. Accuracy. Deviation of technique factors from indicated values shall not exceed the limits given by the manufacturer.

4.6.4 **Positive Beam Limitation (PBL).** The requirements of § 4.6.4 of this Part shall apply to radiographic systems which contain PBL.

A. Field Size. When a PBL system is provided, it shall prevent X-ray production when:

1. Either the length or width of the X-ray field in the plane of the image receptor differs from the corresponding image receptor dimension by more than three percent (3%) of the SID; or

2. The sum of the length and width differences stated in F.5.4(a)(1) without regard to sign exceeds four percent (4%) of the SID.

3. The beam-limiting device is at an SID for which PBL is not designed for sizing.

B. Conditions For PBL. When provided, the PBL system shall function as described in § 4.6.4(A) of this Part whenever all the following conditions are met:

1. The image receptor is inserted into a permanently mounted cassette holder;

2. The image receptor length and width are less than fifty (50) cm;

3. The X-ray beam axis is within ± three degrees (±3°) of vertical and the SID is ninety (90) cm to one-hundred thirty (130) cm inclusive; or the X-ray beam axis is within ± three degrees (±3°)of horizontal and the SID is ninety (90) cm to two-hundred five (205) cm inclusive;

4. The X-ray beam axis is perpendicular to the plane of the image receptor to within ± three degrees (±3°); and

5. Neither tomographic nor stereoscopic radiography is being performed.

C. Measuring Compliance. Compliance with the requirements of § 4.6.4(A) of this Part shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of § 4.6.4(B) of this Part are met. Compliance shall be determined no sooner than five (5) seconds after insertion of the image receptor.

D. Operator Initiated Undersizing. The PBL system shall be capable of operating such that, at the discretion of the operator, the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. Each dimension of the minimum field size at an SID of one-hundred (100) cm shall be equal to or less than five (5) cm. Return to PBL function as described in § 4.6.4(A) of this Part shall occur automatically upon any change of image receptor size or SID.

E. Override of PBL. A capability may be provided for overriding PBL in case of system failure and for servicing the system. This override may be for all SIDs and image receptor sizes. A key shall be required for any override capability that is accessible to the operator. It shall not be possible to remove the key while PBL is overridden. Each such key switch or key shall be clearly and durably labeled as follows:

FOR X-RAY FIELD LIMITATION SYSTEM FAILURE

1. The override capability is considered accessible to the operator if it is referenced in the operator's manual or in other material intended for the operator or if its location is such that the operator would consider it part of the operational controls.

4.6.5 **Source-to-Skin Distance**

A. X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit the source-skin distance to not less than:

1. Eighteen (18) cm if operable above fifty (50) kVp; or

2. Ten (10) cm if not operable above fifty (50) kVp.

B. Mobile and portable X-ray systems other than dental shall be provided with means to limit the source-skin distance to not less than thirty (30) cm.

4.6.6 **Air Kerma (Exposure) Reproducibility**. The following requirements shall apply when the equipment is operated on an adequate power supply as specified by the manufacturer:

A. For any specific combination of selected technique factors, the coefficient of variation of the air kerma (exposure) shall not exceed 0.10 when all technique factors are held constant. This requirement shall be deemed to have been met if, when four EXPOSURES are made at identical technique factors, the value of the average EXPOSURE (E) is greater than or equal to 5 times the maximum EXPOSURE (E_{max}) minus the minimum EXPOSURE (E_{min}); i.e., $E \geq 5 (E_{max} - E_{min})$.

B. For equipment having automatic exposure controls, compliance shall be determined with a sufficient thickness of attenuating material in the useful beam such that the technique factors can be adjusted to provide individual exposures of a minimum of twelve (12) pulses on field emission equipment rated for pulsed operation or no less than one-tenth (0.1) second per exposure on all other equipment.

4.4.7 **Radiation from Capacitor Energy Storage Equipment**. Radiation emitted from the X-ray tube shall not exceed:

A. An air kerma of 0.26 µGy (0.03 mR exposure) in one (1) minute at five (5) cm from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open, the system fully charged, and the exposure switch, timer, or any discharge mechanism not activated. Compliance shall be determined by measurements averaged over an area of one-hundred square cm (100 cm^2), with no linear dimensions greater than twenty (20) cm: and

B. An air kerma of 0.88 mGy (100 mR exposure) in one (1) hour at one-hundred (100) cm from the X-ray source, with beam-limiting device fully open, when the system is discharged through the X-ray tube either manually or automatically by use of a discharge switch or deactivation of the input power. Compliance shall be determined by measurements of the maximum air kerma per discharge multiplied by the total projected number of discharges in one (1) hour. The measurements shall be averaged over an area of one-hundred square cm (100 cm^2) with no linear dimension greater than twenty (20) cm.

4.6.8 **Tube Stands for Portable X-Ray Systems**. A tube stand or other mechanical support shall be used for portable X-ray systems, so that the X-ray tube housing assembly need not be hand-held during exposures.

4.6.9 **Measurement of Radiation Output**.

A. Measurement of the radiation output shall be performed at a specified distance and over a range of clinical kVp values, and shall be made at intervals not to exceed twelve (12) months or after any maintenance of the system which might affect the radiation output. These measurements shall be performed in-air with minimum scatter conditions. Results of the measurements shall include the µGy/mAs (mR/mAs), as well as the technique factors used to determine such results.

B. The name and signature of the Qualified Medical Physicist performing the measurements, and the date the measurements were performed, shall be included in the results.

C. These measurements may be used to estimate entrance skin exposure (ESE) for the average adult patient for selected routine radiographic procedures. These values should be compared with available national reference values.

4.6.10 **Beam-on Indicators.** The X-ray control shall provide visual indication whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

4.6.11 **Primary Protective Barrier for Mammography X-ray Systems**

A. For X-ray systems manufactured after 5 September 1978, and before 30 September 1999, which are designed only for mammography, the transmission of the primary beam through any image receptor support provided with the system shall be limited such that the air kerma five (5) cm from any accessible surface beyond the plane of the image receptor supporting device does not exceed 0.88 µGy (0.1 mR exposure) for each activation of the tube.

B. For mammographic X-ray systems manufactured on or after 30 September 1999:

1. At any SID where exposures can be made, the image receptor support device shall provide a primary protective barrier that intercepts the cross section of the useful beam along every direction except at the chest wall edge.

2. The X-ray system shall not permit exposure unless the appropriate barrier is in place to intercept the useful beam as required in § 4.6.11(B)(1) of this Part.

3. The transmission of the useful beam through the primary protective barrier shall be limited such that the air kerma five (5) cm from any accessible surface beyond the plane of the primary protective barrier does not exceed 0.88 µGy (0.1 mR exposure) for each activation of the tube.

C. Compliance with the requirements of §§ 4.6.11(A) and (B)(3) of this Part. for transmission shall be determined with the X-ray system operated at the minimum SID for which it is designed, at maximum rated peak tube potential, at the

maximum rated product of X-ray tube current and exposure time (mAs) for the maximum rated peak tube potential, and by measurements averaged over an area of one-hundred square cm (100 cm^2) with no linear dimension greater than twenty (20) cm. The sensitive volume of the radiation measuring instrument shall not be positioned beyond the edge of the primary protective barrier along the chest wall side.

4.6.12 **Field Limitation and Alignment for Mobile, Portable and Stationary General Purpose X-ray Systems**. Except when spot-film devices are in service, mobile, portable and stationary general purpose radiographic X-ray systems shall meet the following requirements:

A. Variable X-ray Field Limitation. A means for stepless adjustment of the size of the X-ray field shall be provided. Each dimension of the minimum field size at an SID of one-hundred (100) cm shall be equal to or less than five (5) cm.

B. Visual Definition.

1. Means for visually defining the perimeter of the X-ray field shall be provided. The total misalignment of the edges of the visually defined field with the respective edges of the X-ray field along either the length or width of the visually defined field shall not exceed two percent (2%) of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the X-ray beam.

2. When a light localizer is used to define the X-ray field, it shall provide an average illuminance of not less than 160 lux (15 footcandles) at one-hundred (100) cm or at the maximum SID, whichever is less. The average illuminance shall be based on measurements made in the approximate center of each quadrant of the light field.

3. The edge of the light field at one-hundred (100) cm or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than four (4) in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than three (3) in the case of beam-limiting devices designed for use on mobile and portable equipment. The contrast ratio is defined as I_1/I_2, where I_1 is the illuminance three (3) mm from the edge of the light field toward the center of the field; and I_2 is the illuminance three (3) mm from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring aperture of one (1) mm.

C. 1. Portable X-ray systems shall have an evaluation of light field vs. X-ray field alignment performed at least every six (6) months to determine compliance with both § 4.6.12(B)(1) and § 4.6.13(C) of this Part.

2. Portable X-ray systems shall have an evaluation of centering alignment performed at least every six (6) months to determine compliance with § 4.6.13(A) of this Part.

4.6.13 **Field Indication and Alignment on Stationary General Purpose X-ray Equipment**. Except when spot-film devices are in service, stationary general purpose X-ray systems shall meet the following requirements in addition to those prescribed in § 4.6.12 of this Part:

A. Means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor, to align the center of the X-ray field with respect to the center of the image receptor to within two percent (2%) of the SID, and to indicate the SID to within two percent (2%);

B. The beam-limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted;

C. Indication of field size dimensions and SIDs shall be specified in centimeters and/or inches and shall be such that aperture adjustments result in X-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within two percent (2%) of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor; and

D. Compliance measurements will be made at discrete SIDs and image receptor dimensions in common clinical use (such as SIDs of 100, 150, and 200 cm and/or 36, 40, 48, 72 inches and nominal image receptor dimensions of 13, 18, 24, 30, 35, 40, and 43 cm and/or 5, 7, 8, 9, 10, 11, 12, 14, and 17 inches) or at any other specific dimensions at which the beam-limiting device or its associated diagnostic X-ray system is uniquely designed to operate.

4.6.14 **Linearity**. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer in accordance with 21 CFR Part 1020 for any fixed X-ray tube potential within the range of forty percent (40%) to one-hundred percent (100%) of the maximum rated:

A. Equipment Having Independent Selection of X-Ray Tube Current (mA). The average ratios (X_i) of air kerma (exposure) to the indicated milliampere-seconds product (mGy/mAs or mR/mAs) obtained at any two (2) consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 \leq 0.10\,(X_1 + X_2)$$

where X_1 and X_2 are the average mGy/mAs (mR/mAs) values obtained at each of two (2) consecutive tube current settings, or at two (2) settings differing by no more than a factor of two (2) where the mA selector provides continuous selection.

B. Equipment Having Selection of X-Ray Tube Current-Exposure Time Product (mAs). For equipment manufactured after 3 May 1994, the average ratios of air kerma (exposure) to the indicated milliampere-seconds product (mGy/mAs or mR/mAs) obtained at any two (2) consecutive mAs selector settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 \leq 0.10\ (X_1 + X_2)$$

where X_1 and X_2 are the average mGy/mAs values obtained at any two (2) consecutive mAs selector settings, or at two (2) settings differing by no more than a factor of two (2) where the mAs selector provides continuous selection.

C. Measuring Compliance. Determination of compliance will be based on consecutive exposures, made within one (1) hour. These settings may include any two (2) focal spot sizes except where one is equal to or less than 0.45 mm and the other is greater than 0.45 mm. For purposes of this requirement, focal spot size is the focal spot size specified by the X-ray tube manufacturer.

4.6.15 Field Limitation on Radiographic X-ray Equipment Other Than General Purpose Radiographic Systems

A. Equipment for Use With Intraoral Image Receptors. Radiographic equipment designed for use with an intraoral image receptor shall be provided with means to limit the X-ray beam such that:

1. If the minimum source-to-skin distance (SSD) is eighteen (18) cm or more, the X-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than seven (7) cm; and

2. If the minimum SSD is less than eighteen (18) cm, the X-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than six (6) cm.

B. X-ray Systems Designed for One Image Receptor Size. Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the X-ray field with the center of image receptor to within two percent (2%) of the SID, or shall be provided with means to both size and align the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond the edge of the image receptor.

C. Systems Designed for Mammography.

1. Radiographic systems designed only for mammography and general purpose radiography systems, when special attachments for mammography are in service, manufactured on or after 1 November 1977, and before 30 September 1999, shall be provided with means to limit the

useful beam such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated SID except the edge of the image receptor designed to be adjacent to the chest wall where the X-ray field may not extend beyond this edge by more than two percent (2%) of the SID. This requirement can be met with a system that performs as prescribed in §§ 4.6.15(D)(1), (2) and (3) of this Part. When the beam-limiting device and image receptor support device are designed to be used to immobilize the breast during a mammographic procedure and the SID may vary, the SID indication specified in §§ 4.6.15(D) (2) and (3) of this Part shall be the maximum SID for which the beam-limiting device or aperture is designed.

2. Mammographic beam-limiting devices manufactured on or after 30 September 1999, shall be provided with a means to limit the useful beam such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor by more than two percent (2%) of the SID. This requirement can be met with a system that performs as prescribed in §§ 4.6.15(D)(1), (2) and (3) of this Part. For systems that allow changes in SID, the SID indication specified in §§ 4.6.15(D)(2) and (3) of this Part shall be the maximum SID for which the beam-limiting device or aperture is designed.

3. Each image receptor support device manufactured on or after 1 November 1977, intended for installation on a system designed for mammography shall have clear and permanent markings to indicate the maximum image receptor size for which it is designed.

D. Other X-ray Systems. Radiographic systems not specifically covered in §§ 4.6.12, 4.6.13, 4.6.15(B), 4.6.15(C), and systems covered in § 4.6.15(A) of this Part, which are also designed for use with extraoral image receptors and when used with an extraoral image receptor, shall be provided with means to limit the X-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than two percent (2%) of the SID, when the axis of the X-ray beam is perpendicular to the plane of the image receptor. In addition, means shall be provided to align the center of the X-ray field with the center of the image receptor to within two percent (2%) of the SID, or means shall be provided to both size and alignment the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. These requirements may be met with:

1. A system which performs in accordance with §§ 4.6.12 and 4.6.13 of this Part; or when alignment means are also provided, may be met with either;

2. 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. Each such device shall have

clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

3. 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 unit 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.

4.6.16 **Field Limitation and Alignment for Spot-Film Devices**. The following requirements shall apply to spot-film devices, except when the spot-film device is provided for use with a radiation therapy simulation system:

A. Means shall be provided between the source and the patient for adjustment of the X-ray field size in the plane of the image receptor to the size of that portion of the image receptor which has been selected on the spot-film selector. Such adjustment shall be accomplished automatically when the X-ray field size in the plane of the image receptor is greater than the selected portion of the image receptor. If the X-ray field size is less than the size of the selected portion of the image receptor, the field size shall not open automatically to the size of the selected portion of the image receptor unless the operator has selected that mode of operation.

B. Neither the length nor width of the X-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than three percent (3%) of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences shall not exceed four percent (4%) of the SID. On spot film devices manufactured after 25 February 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

C. The center of the X-ray field in the plane of the image receptor shall be aligned with the center of the selected portion of the image receptor to within two percent (2%) of the SID.

D. Means shall be provided to reduce the X-ray field size in the plane of the image receptor to a size smaller than the selected portion of the image receptor such that:

1. For spot-film devices used on fixed-SID fluoroscopic systems which are not required to, and do not provide stepless adjustment of the X-ray field, the minimum field size, at the greatest SID, does not exceed one-hundred twenty-five square cm (125 cm^2); or

2. For spot-film devices used on fluoroscopic systems that have a variable SID and/or stepless adjustment of the field size, the minimum field size, at the greatest SID, shall be containable in a square of five (5) cm by five (5) cm.

E. A capability may be provided for overriding the automatic X-ray field size adjustment in case of system failure. If it is so provided, a signal visible at the operator's position shall indicate whenever the automatic X-ray field size adjustment override is engaged. Each such system failure override switch shall be clearly labeled as follows:

FOR X-RAY FIELD LIMITATION SYSTEM FAILURE

4.7 COMPUTED TOMOGRAPHY SYSTEMS

4.7.1 Requirements for Equipment

A. Applicability. Unless otherwise specified, the requirements for equipment contained in § 4.7.1 of this Part are applicable to CT X-ray systems manufactured or remanufactured on or after 3 September 1985.

B. Termination of Exposure.

1. 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 one hundred ten percent (110%) of its preset value through the use of either a backup timer or devices which monitor equipment function.

2. A visible signal shall indicate when the X-ray exposure has been terminated through the means required by § 4.7.1(B) of this Part.

3. 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 one-half (0.5) second duration.

C. Tomographic Plane Indication and Alignment.

1. 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.

2. For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic planes.

3. If a device using a light source is used to satisfy §§ 4.7.1(C)(1) or (2) of this part, 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 five hundred (500) lux.

D. Beam-On and Shutter Status Indicators and Control Switches.

1. The CT X-ray control and gantry shall provide visual indication whenever X-rays are produced and, if applicable, whether the shutter is open or closed.

2. Each emergency button or switch shall be clearly labeled as to its function.

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 shall be indicated prior to the initiation of a scan or scan sequence. On equipment 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. Extraneous Radiation. When data are being collected for image production, the radiation adjacent to the tube port shall not exceed that permitted by § 4.4.5 of this Part.

G. Maximum Surface CTDI Identification. The angular position where the maximum surface CTDI occurs shall be identified to allow for reproducible positioning of a CT dosimetry phantom.

H. Additional Requirements Applicable to CT X-Ray Systems Containing a Gantry.

1. The total error in the indicated location of the tomographic plane or reference plane shall not exceed five (5) millimeters.

2. If the X-ray production period is less than one-half (0.5) second, the indication of X-ray production shall be actuated for at least one-half (0.5) second. 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.

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

4. Premature termination of the X-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.

4.7.2 **Facility Design Requirements**.

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

B. Viewing Systems.

1. 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.

2. When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of the primary viewing system.

4.7.3 Radiation Output Measurements, Spot Checks, and Operating Procedures

A. Output Measurements.

1. The measurement of the radiation output of the CT X-ray system shall be performed by, or under the direction of, a Qualified Medical Physicist.

2. The measurement of the radiation output of a CT X-ray system shall be performed:

a. Before the first medical use following installation or reinstallation of the CT X-ray system; and

b. At intervals not to exceed twelve (12) months; and

c. After any change or replacement of components which, in the opinion of the Qualified Medical Physicist, could cause a change in the radiation output.

3. CT dosimetry phantom(s) shall be used in determining the radiation output of a CT X-ray system. Such phantom(s) shall meet the following specifications and conditions of use:

a. CT dosimetry phantoms shall be right circular cylinders of polymethyl methacrylate of density 1.19 plus or minus 0.01 grams per cubic centimeter (g/cm^3). The phantoms shall be at least fourteen (14) centimeters in length and shall have diameters of thirty-two (32.0) centimeters for testing CT X-ray systems designed

to image any section of the body and sixteen (16.0) centimeters for systems designed to image the head or for whole body scanners operated in the head scanning mode.

b. CT dosimetry phantom(s) shall provide means for the placement of a dosimeter(s) along the axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. Means for the placement of dosimeters or alignment devices at other locations may be provided.

c. Any effects on the doses measured due to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom.

d. All dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.

4. These radiation output measurements shall be required for a representative type of head and body scans performed at the facility.

5. The CTDI along the two (2) axes specified in § 4.7.3(B)(4)(b) of this Part shall be measured. The CT dosimetry phantom shall be oriented so that the measurement point 1.0 centimeter from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface CTDI identified. The CT conditions of operation shall correspond to typical values used by the registrant.

a. For the purpose of determining the CTDI, the manufacturer's statement as to the nominal tomographic section thickness for that particular system may be utilized.

6. Procedures for measurement of radiation output shall be in writing. Records of radiation measurements performed shall be maintained for inspection by the Agency.

7. The dose profile along the center axis of the CT dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the registrant shall be readily available.

B. Spot-checks

1. The spot-check procedures shall be in writing and shall have been developed by a Qualified Medical Physicist.

2. The spot-check procedures shall incorporate the use of a CT imaging phantom which has the capability of providing an indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the system for low and high contrast objects, and measuring the mean CTN for water or other reference material.

3. Spot-checks shall be evaluated for compliance with tolerance limits specified pursuant to § 4.7.3(C)(1) of this Part at the time the radiation measurements required by § 4.7.3(B) of this Part are performed.

4. Spot-checks shall include acquisition of images obtained with the CT imaging phantoms. The images shall be retained, until a new set of radiation measurements is performed as follows:

   a. If applicable, photographic copies of the images obtained from the image display device;

   b. Images stored in digital form on a storage medium compatible with the CT X-ray system; and

   c. Acceptance criteria for image validation shall be documented.

5. The registrant shall maintain a record of each spot check required by § 4.7.3(C) of this Part for three (3) years.

C. Operating Procedures

1. The CT X-ray system shall not be operated except by an individual who has been specifically trained in its operation.

2. Information shall be readily available regarding the operation of the system. Such information shall include the following:

   a. The latest set of radiation measurements and spot-checks;

   b. Instructions on the use of the CT imaging phantom, including a schedule of spot-checks appropriate for the system, and allowable variations for the indicated parameters;

   c. The distance in millimeters between the tomographic plane and the reference plane if a reference plane is utilized; and

   d. Current imaging protocols shall be available at the control panel which specify the CT conditions of operation and the number of scans for each routine examination.

3. If the measurement of radiation output or spot-check of the CT X-ray system identifies that a system operating parameter has exceeded a

tolerance established by a Qualified Medical Physicist, report the problem to the service engineer and notify the Qualified Medical Physicist. The registrant shall maintain a record of all such notifications for three (3) years.

4.7.4 CT X-ray System Used for Radiation Therapy Simulation

A. A CT X-ray system used solely for radiation therapy simulation is exempt from the specific requirements of §§ 4.7.1, 4.7.2 and 4.7.3 of this Part, and is only subject to the requirements of § 5.10 of this Subchapter.

B. A CT X-ray system used for both diagnostic X-ray and radiation therapy simulation is subject to the requirements of both § 4.7 of this Part and § 5.10 of this Subchapter.

4.8 MAMMOGRAPHY

4.8.1 Applicability

The provisions of this section are in addition to, and not in substitution for, other applicable provisions of this Subchapter.

4.8.2 Certification Requirements

A. Only X-ray systems in compliance with the requirements of the Mammography Quality Standards Reauthorization Act of 1998, Public Law 105-248, and 21 CFR. Part 900 shall be used for screening and diagnostic mammography.

B. A facility performing mammography shall have a valid certificate issued by the U.S. Department of Health and Human Services, pursuant to the Mammography Quality Standards Reauthorization Act of 1998, Public Law 105-248, and 21 CFR. Part 900.

C. A facility performing mammography shall ensure that the additional mammography activities of processing the x-ray film, interpreting the image, and maintaining viewing conditions, wherever performed, meet all quality standards pursuant to the Mammography Quality Standards Reauthorization Act of 1998, Public Law 105-248, and 21 CFR. Part 900.

4.8.3 Retention of Mammography X-rays.

Pursuant to RI Gen. Laws § 23-4.9-1, each mammographic imaging facility that takes a mammography x-ray of any individual within Rhode Island shall keep and maintain that mammography x-ray for the life of the individual. However, any mammography x-ray may be destroyed if the individual has had no contact with the mammographic imaging facility for a period exceeding fifteen (15) years.

4.9 BONE DENSITOMETRY

4.9.1 Bone densitometry systems shall be:

A. Certified by the manufacturer pursuant to the Medical Device Act and Subchapter C - Electronic Product Radiation Control (EPRC) of Chapter V of the Federal Food, Drug and Cosmetic Act.;

B. Registered in accordance with Part 3 of this Subchapter; and

C. Maintained and operated in accordance with the manufacturer's specification and recommendations.

4.9.2 Equipment Requirements

Systems with stepless collimators shall be provided with means to both size and align the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond two percent (2%) of the SID.

4.9.3 Operators of bone densitometry systems shall be:

A. Licensed as a practitioner of the healing arts; or

B. Individuals who possess a current license in accordance with Licensure of Radiographers, Nuclear Medicine Technologists, Radiation Therapists and Radiologist Assistants [216-RICR-40-05-34], unless the individual is specifically exempted from licensure by said regulations; or

C. Individuals who are not subject to licensure under 216-RICR-40-05-34 and have been instructed in the proper use of the bone densitometry system. As a minimum, such instruction shall include:

1. Basic radiation protection;

2. Operating procedures for bone densitometry systems, to include use of various system functions, safety, and maintenance; and

3. Patient positioning for the types of examinations performed.

4.9.4 During the operation of any bone densitometry system:

A. The operator, ancillary personnel, and members of the general public shall be positioned at least one meter from the patient and bone densitometry system during the examination.

B. The operator shall advise the patient that the bone densitometry examination is a type of X-ray procedure.

4.9.5 The registrant shall keep maintenance records for bone densitometry systems as prescribed by § 4.9(C) of this Part. These records shall be maintained for inspection by the Agency for five (5) years from the date the maintenance action was completed.

4.9.6 Bone densitometry on human patients shall be conducted only:

A. Under a prescription of a licensed practitioner of the healing arts; or

B. Under a screening program approved by the Agency.

4.9.7 Any person proposing to conduct a bone densitometry screening program shall submit the information outlined in § 4.11 of this Part, and include the name and address of the licensed practitioner of the healing arts who will interpret the screening results.

4.10 QUALITY ASSURANCE PROGRAM.

4.10.1 Except where otherwise specified by the provisions of § 4.10.1(G) of this Part, all registrants of diagnostic X-ray imaging equipment shall establish and maintain a quality assurance program consisting of quality control assessments addressing at least the following items:

A. Administration:

1. Written standard operating procedures on radiation protection are reviewed and updated by management at intervals not to exceed twelve (12) months;

2. Employee review and written acknowledgement of standard operating procedures and policies on radiation protection;

3. Credentialing of practitioners, medical physicists, and X-ray equipment operators; and

4. Record retention in accordance with applicable Rhode Island statutes and regulations, but in no case less than three (3) years.

B. Image Processing Equipment: Compliance with § 4.3.10 of this Part;

C. Radiographic Equipment:

1. Compliance with performance standards in §§ 4.4 and 4.6 of this Part, as specified by a Qualified Medical Physicist;

2. Estimated entrance skin exposures for selected patient examinations;

3. Image printing and viewing equipment;

4. Evaluation of image quality; and

5. Radiation protection.

D. Fluoroscopic Equipment:

1. Compliance with performance standards in §§ 4.4 and 4.5 of this Part, as specified by a Qualified Medical Physicist;

2. Low and high contrast resolution; and

3. Radiation protection.

E. Computerized Tomography Equipment:

1. Compliance with performance standards in § 4.7 of this Part, as specified by a Qualified Medical Physicist;

2. CT number;

3. Low and high contrast resolution;

4. Dosimetry of selected patient examinations to include pediatric patients if applicable;

5. Image printing and viewing equipment; and

6. Radiation protection.

F. Bone Densitometry Equipment:

1. Compliance with requirements in § 4.9 of this Part.

G. Clarification of required quality assurance program elements for certain mammography and dental X-ray facilities.

1. The requirements in § 4.10 of this Part do not pertain to diagnostic X-ray imaging equipment subject to the Mammography Quality Standards Reauthorization Act of 1998, Public Law 105-248, and 21 C.F.R. Part 900.

2. Registrants performing diagnostic radiography limited to intra-oral dental procedures and/or panoramic procedures and cephalometric procedures which do not utilize an open beam configuration are only required to comply with §§ 4.10.1(A)(1), (A)(2) (A)(4) and (B) of this Part.

4.10.2 The quality assurance program shall be in written form and available for review by the Agency.

4.10.3 Implementation of Quality Assurance Program

A. The registrant shall assign qualified personnel to fully implement the quality assurance program. Quality control assessments for §§ 4.10.1(B), (C), (D) and (E) of this Part shall be conducted by, or under the direction of, a Qualified Medical Physicist.

B. A Qualified Medical Physicist shall determine the frequency and nature of quality control tests, except when the frequency for a specific quality control test is defined by this Subchapter.

C. A Qualified Medical Physicist shall perform a review of the Quality Assurance Program at an interval not to exceed twelve (12) months, and shall provide a written report which documents the results of this review.

4.11 INFORMATION TO BE SUBMITTED BY PERSONS PROPOSING TO CONDUCT HEALING ARTS SCREENING

A. Persons requesting that the Agency approve a healing arts screening program shall submit the following information and evaluation:

1. Name and address of the applicant and where applicable, the names and addresses of agents within Rhode Island.

2. Diseases or conditions for which the X-ray examinations are to be used in diagnoses.

3. A description of the X-ray examinations proposed in the screening program (i.e., type and number of views).

4. Description of the population to be examined in the screening program, i.e., age range, gender, physical condition, and other appropriate information.

5. An evaluation of any known alternate methods not involving ionizing radiation that could achieve the goals of the screening program and why these methods are not used in preference to the X-ray examinations.

6. An evaluation conducted by a Qualified Medical Physicist, of the X-ray system(s) to be used in the screening program. The evaluation shall include the following:

    a. Documentation that such system(s) satisfy all requirements of this Subchapter; and

    b. Estimation of patient entrance skin exposures from the X-ray examinations to be performed;

7. A description of the diagnostic X-ray quality control program.

8. Documentation of the techniques for the X-ray examination procedures to be used.

9. The name and RI license number of each radiologic technologist who will be operating the X-ray system(s).

10. 1The name and RI license number of each health care provider who will be supervising the operators of the X-ray system(s). The extent of supervision and the method of work performance evaluation shall be specified.

11. The name and address of the Rhode Island-licensed practitioner of the healing arts who will interpret the images.

12. Procedures to be used in advising the individuals screened and their health care provider(s) of the results of the screening procedure and any further medical needs indicated.

13. Procedures for the retention or disposition of the images and other records pertaining to the X-ray examinations.

14. Frequency of screening of individuals.

15. The duration of the screening program.

4.12 INSTRUCTION OF USERS OF X-RAY EQUIPMENT IN THE HEALING ARTS

A. Fundamentals of Radiation Safety

1. Characteristics of x-radiation

2. Units of radiation dose

3. Hazards of excessive exposure to radiation

4. Levels of radiation from sources of radiation

5. Methods of controlling radiation dose

   a. Working time

   b. Working distances

   c. Shielding

B. Radiation Detection Instrumentation to be Used

1. Radiation survey instruments

a. Operation

b. Calibration

c. Limitations

2. Survey, monitoring and spot-check techniques

3. Personnel monitoring devices

4. Interpretation of personnel monitoring reports

C. Operation and Control of X-ray Equipment

1. Collimation and Filtration

2. Exposure techniques for the equipment used

3. Image processing techniques

D. Anatomy and positioning

1. Relevant human anatomy

2. Relevant human physiology

3. Radiographic positioning

E. The requirements of pertinent federal and state regulations

F. The licensee's or registrant's written operating and emergency procedures

4.13 REQUIREMENTS FOR USE OF HAND-HELD INTRAORAL DENTAL RADIOGRAPHIC UNIT -

A. The following requirements are applicable to intraoral dental radiographic units designed to be operated as a hand-held unit:

1. For All Uses:

a. Operators of hand-held intraoral dental radiographic units shall be specifically trained to operate such equipment.

b. When operating a hand-held intraoral dental radiographic unit, operators shall wear a protective apron and thyroid collar, unless otherwise authorized by the Agency or recommended by a Qualified Medical Physicist.

c. A hand-held intraoral dental radiographic unit shall be held with minimal motion during a patient examination. A tube stand may be utilized to immobilize a hand-held intraoral dental radiographic unit during patient examination.

d. Unless otherwise authorized by the Agency, a hand-held intraoral dental radiographic unit shall be used with a secondary radiation block to shield the operator.

e. The operator shall ensure there are no bystanders within a radius of six (6) feet from the patient being examined with a hand-held intraoral radiographic unit.

f. Hand-held intraoral dental radiographic units shall not be used for patient examinations in hallways and waiting rooms.

g. The registrant shall comply with any facility-specific requirements established by the Agency

2. Additional Requirements for Operatories in Permanent Facilities:

When hand-held intraoral dental radiographic units are used for patient examinations in dental operatories, that facility shall meet the structural shielding requirements specified by the Agency or by a health physicist or Qualified Medical Physicist.