

PART F

MEDICAL DIAGNOSTIC AND INTERVENTIONAL X-RAY AND IMAGING SYSTEMS

Sec. F.1 - Purpose and Scope. This Part establishes requirements, for which a registrant [licensee] is responsible, for use of diagnostic and interventional x-ray equipment and imaging systems by, or under the supervision of, an individual authorized by and registrant licensed in accordance with State statutes to engage 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 Parts A, B, D, G, J, I, X, and Z of these regulations.

Sec. F.2 - Definitions. As used in this Part, the following definitions apply:

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

“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)) threshold that is set by the registrant [licensee] to trigger an alert to the CT operator when a planned scan would result in a cumulative dose index value above this threshold. The user must review and acknowledge to proceed with the exam. One purpose of alerting the user is to avoid tissue reactions such as erythema or epilation, prior to scanning within an ongoing examination. The Alert value represents a universal dose index value well above the registrant [licensee]’s established range for the examination that warrants more stringent review and consideration before proceeding.

~~“Aluminum equivalent” means the thickness of type 1100 aluminum alloy¹¹ affording the same attenuation, under specified conditions, as the material in question.¹²~~

~~“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.¹³~~

“Attenuation block” means a block or stack of type 1100 aluminum alloy, or aluminum alloy with having equivalent attenuation, and 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.¹⁴

“Automatic exposure control (AEC)” means a device that which automatically controls one or more technique factors in order to obtain a at a preselected location(s) a required quantity of radiation.¹⁵

¹¹The nominal chemical composition of type 1100 aluminum is 99.00 percent minimum aluminum, 0.12 percent copper.

¹²Based on Current FDA standards.

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“Automatic exposure rate control (AERC)” means a device ~~that 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 ~~that 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 mean value of a population of observations. It is estimated using the following equation:

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

where:

s = Estimated standard deviation of the population.

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

x_i = i_{th} observation in sample;

n = Number of observations sampled.[⚡]

[⚡]Based on Current FDA standards.

“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.

“CTDI₁₀₀” 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 CTDI₁₀₀, requires integration of the radiation dose profile from a single axial scan over specific integration limits. In the case of CTDI₁₀₀, the integration limits are +50 mm, which corresponds to the 100-mm length of the commercially available “pencil” ionization chamber. CTDI₁₀₀ 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})”

[≠]Based on Current FDA standards.

“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 ~~the~~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 F.2.[≠]

“CT gantry” means tube housing assemblies, beam-limiting devices, detectors, associated components, 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

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

elemental area of the CT image:

where:

- k = A constant, a normal value of 1,000 when the Hounsfield scale of CT number is used;
- μ_x = Linear attenuation coefficient of the material of interest;
- μ_w = Linear attenuation coefficient of water.

[≠]Based on Current FDA standards.

“Cumulative air kerma” means the total air kerma accrued ~~during a single~~~~from the beginning of an~~ examination or procedure and includes all contributions from fluoroscopic and radiographic irradiation.

“Detector” (See "Radiation detector")

~~“Deviation Index (DI)” means a scaled representation of the difference between the actual exposure index and the target exposure index for a given body part and view.~~

“Diagnostic reference level” (DRL) is an investigation~~al~~ level used ~~for optimizing radiation protection in the healing arts to identify unusually high radiation doses or dose rates for common medical X-ray imaging procedures.~~ DRL values are suggested action levels ~~that above which~~ a facility should use to review its methods and determine if acceptable image quality can be achieved at lower doses. ~~DRLs values are not regulatory limits. These values~~ 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” (see “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).[±]

[±]-Based on Current FDA standards.

“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:

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

“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 $E = \sum_T (w_T H_T)$, 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 Indicator (EI)” in digital radiography means a value that reflects the amount of radiation exposure reaching the detector after a radiographic image is taken. It’s a vendor-specific value used by radiographers to assess the adequacy of exposure settings for a particular image. EIs are used to ensure optimal image quality and patient radiation dose.

“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

[≠]Based on Current FDA standards.

to localize or characterize a lesion, diagnostic site, or treatment site, to monitor the procedure, and to control and document therapy.

“Fluoroscopy” means a dose-rate limited technique used in x-ray equipment and x-ray systems for obtaining a temporal sequence of x-ray patterns with a single activation of the x-ray controls and presenting them as images for clinical use at the time and location of image acquisition. These images may also be recorded. ~~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.~~²

“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.²

“General supervision” ~~(see “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 ~~that~~which attenuates the beam of radiation to an extent such that the AKR is reduced by one-half of its original value. ~~The~~ ~~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.²

“Hand-held x-ray equipment” ~~(See x-ray equipment), means x-ray equipment that is designed to be hand-held during operation.~~

“Healing arts screening” means the imaging testing of humans ~~beings~~ using x-ray machines for the ~~detection or~~ evaluation of health status 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 imaging 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.²

“Image receptor” means any device, ~~such as a fluorescent screen, radiographic film, x-ray image intensifier tube, solid state detector, or gaseous detector which~~ that transforms incident x-ray photons either into a visible image or into another form ~~which~~ that can be made into a visible image

²-Based on Current FDA standards.

by further transformations. In ~~those~~ cases where means are provided to preselect a portion of the image receptor, the term “image receptor” ~~shall~~ mean² the preselected portion of the device.²

“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.²

“Kerma” means the quantity defined by the International Commission on Radiation Units and Measurements. The kerma, K , is the quotient of dE_{tr} by dm , where dE_{tr} is the sum of the initial kinetic energies of all the charged particles liberated by uncharged particles in a mass dm of material; thus $K=dE_{tr}/dm$, 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.”²

“Kerma-area product (KAP)” (See “dose area product”)

“Kilovolts peak” (See “Peak tube potential”).

“kV” means kilovolts.

“kVp” (See “Peak tube potential”).

“kW” 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.²

“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.²

“Leakage technique factors” means the technique factors associated with the diagnostic source assembly ~~that~~^{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;

²Based on Current FDA standards.

- (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:

$$\begin{aligned} V_n &= \text{No-load line potential; and} \\ V_l &= \text{Load line potential.}^{\#} \end{aligned}$$

“mA” means milliamperes.

“mAs” means milliamperes second.

“Medical event” means administration of radiation to the wrong patient or wrong site, the wrong procedure, or any unintended dose:

1. “Non-reportable medical event” means a medical event that does not meet any of the criteria for a reportable medical event or an event resulting from patient intervention.

2. “Reportable medical event” means one or more of the following criteria have occurred:

- a. Unintended skin dose to the same area in a single procedure greater than 2 Gy (200 rad);
- b. Unintended dose other than skin dose in a single procedure greater than:
 - i. 5 times the facility’s established protocol, and > 0.5 Gy (50 rad) to any organ, or
 - ii. 5 times the facility’s established protocol, and > 0.05 Sv (5 rem) effective dose;
- c. Wrong patient or wrong site for the entire procedure, or wrong procedure.

when the resultant dose is:

- i. Dose > 0.5 Gy (50 rad) to any organ or,
- ii Effective dose \geq 0.05 Sv (5 rem).

“Mini C-arm” means stationary, mobile, or portable fluoroscopic systems manufactured on or after June 10, 2006 that have a maximum source-image receptor distance of less than 45 cm.

“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 ~~CT~~computed tomography x-ray system which obtains x-ray transmission data simultaneously during a single scan to produce more than one tomogram.[§]

“Nationally recognized organization” means a national or international professional body with expertise in the use of radiation in the healing arts. Recognition can stem from various factors, including accreditation, reputation, or a significant impact within radiation protection.

“Nationally recognized standard or guideline” means a widely acknowledged and accepted document that is valid or significant within the United States. The term implies that the document has achieved a high level of credibility, reliability, and use.

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

$$S_n = \frac{100 \cdot \overline{CS} \cdot s}{\mu_w}$$

where:

~~\overline{CS} = Linear attenuation coefficient of the material of interest.~~

~~μ_w = Linear attenuation coefficient of water.~~

~~s = Estimated [S] standard deviation of the CT numbers of picture elements in a specified area of the CT image.[§]~~

[§] Based on Current FDA standards.

Commented [JH1]: Feels incomplete. Suggest “within the radiation protection industry.”

“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 scan-specific dose index (e.g. CTDI_{vol}(mGy) or of DLP(mGy-cm)) that the registrant sets [licensee] to trigger a notification to the CT operator prior to scanning when the dose index exceeds the established range for the acquisition, means a protocol-specific dose index (e.g. CTDI_{vol}(mGy) or of DLP(mGy-cm)) that is set by the registrant [licensee] to trigger a notification to the CT operator prior to scanning when the dose index exceeds the established range for the examination.~~

“Notification level” ~~means a dose index value (e.g., cumulative air kerma (mGy)) that, when reached during a fluoroscopically-guided intervention, triggers a procedural pause and review of dose management practice.~~

“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” ~~(See “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 ~~apparel for~~” means ~~apparel~~ ~~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.[≠]

“Qualified Expert (QE)” means an individual who is granted professional privileges based on education and experience to provide clinical services in diagnostic medical physics by the Agency.

“Quality Assurance program (QA)” 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 ~~function~~ ~~manufacture~~ of radiation devices are identified, promptly corrected, and reported to the appropriate regulatory authorities as required.

“Qualified medical physicist (QMP)” means an individual who meets each of the following credentials:

1. Has earned a master's ~~and~~ or doctoral degree in physics, medical physics, biophysics, radiological physics, medical health physics, or equivalent disciplines from an accredited college or university; and
2. Has been granted certification in the specific subfield(s) of medical physics with its associated medical health physics aspects by an appropriate national certifying body and abides by the certifying body's requirements for continuing education;

“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 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.[≠]

[≠]Based on Current FDA standards.

“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 obtaining, recording, and optionally processing directly or after transfer, information contained in a single X-ray pattern at an image reception area. There is no dose limit, 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 that is which parallel to and which can be offset (as specified in manufacturer information provided to users) from the location of the tomographic plane(s).

“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 accumulation-accumulation 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.[‡]

“Serial radiography” means a radiographic mode of operation of fluoroscopy equipment for obtaining and recording a temporal sequence of x-ray patterns with a single activation of the x-ray controls where neither the tube nor the image receptor is moving. Examples of serial radiography include digital angiography (DA) and digital subtraction radiography (DSA).

“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 an attenuation -a lead equivalency not less than that of the tube housing assembly.

“SID” (See “Source-image receptor distance”).

[‡]-Based on Current FDA standards.

“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.²

“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.²

“Spot-film”² means a radiograph which is made during a fluoroscopic examination to permanently record conditions ~~that which~~ exist during that fluoroscopic procedure.²

“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.²

“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 index value 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.~~

“Supervision” types of supervision are as follows:

- (1) “Direct Supervision” means a qualified practitioner must exercise general supervision and be physically present in the facility, immediately available to furnish assistance, and direction throughout the performance of the procedure. It does not mean the licensed practitioner must be present in the room when the procedure is performed.
- (2) “General Supervision” means procedures are performed under the overall direction and control of a qualified practitioner who is not required to be physically present during the performance of the procedures.
- (3) “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.

“Technique factors” means the following conditions of operation:

² Digital image receptors used in place of film with spot-film devices should be considered "spot-film".

- (1) For capacitor energy storage equipment, peak tube potential in kilovolts (kV) and quantity of charge in milliamperere-seconds (mAs);
- (2) For field emission equipment rated for pulsed operation, peak tube potential in kV, tube current in milliamperes (mA), x-ray pulse width in seconds, and the number of x-ray pulses and number of x-ray pulses;
- (3) For CT equipment designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in milliamperes (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 equipment 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 ~~that 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 the tube installed, ~~including~~—It includes high-voltage ~~transformers 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 ~~that 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 ~~the 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:

[±]-Based on Current FDA standards.

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

$$CTDI_{vol} = CTDI_w / \text{pitch}$$

“Weighted Computed Tomography Dose Index (CTDI_w)” means the estimated average CTDI₁₀₀ across the field of view (FOV). The equation is:

$$CTDI_w = 1/3 CTDI_{100,center} + 2/3 CTDI_{100,edge}$$

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 CTDI₁₀₀ and an f-factor for air (0.87 rad/R or 1.0 mGy/mGy).

“X-ray control” means a device ~~that~~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 ~~that~~which is installed in a fixed location; ~~and~~
- (4) "Hand-held x-ray equipment" means x-ray equipment ~~that is~~ designed to be physically supported by the operator ~~hand-held~~ during operation.

“X-ray field” means ~~the~~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 ~~that~~^{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.^z

“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 ~~that~~^{which} function with the system are considered integral parts of the system.^z

“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 ~~that~~^{which} is designed for the conversion of electrical energy into x-ray energy.^z

Sec. F.3 - General and Administrative Requirements.

a. Radiation Safety Requirements. The registrant [licensee] shall be responsible for directing the operation of the x-ray system(s) under ~~their~~^{his or her} administrative control and shall assure that the requirements of these regulations are met in the operation of the x-ray system(s).

i. Remote operation of a radiation machine on humans is prohibited. Specifically, exposure of a human patient to ionizing radiation must be initiated by an operator meeting the requirements of Part Z and applicable training requirements specific to the imaging modality in use. The operator must be physically present at the installed radiation-producing machine.

ii. The registrant [licensee] shall have a radiation safety program. The radiation safety program shall include but not be limited to the following:

- (1) The use of ionizing radiation within its purview is performed in accordance with existing laws and regulations.
- (2) All persons are protected as required by Part D, Standards for Protection Against Radiation, of these regulations.
- (3) A process for evaluating reportable and non-reportable medical events:

^zBased on Current FDA standards.

- ~~(i)~~ Medical events shall be internally reported, investigated, documented, and addressed within the facility. Each registrant shall retain a record of these occurrences for five years.
- ~~(ii)~~ Additionally, upon~~Upon~~ discovery of a reportable medical event, the registrant [licensee] shall:

 - (i) Contact the Agency regarding the medical event within one business day;
 - (ii) Provide a written report, including the analysis of the medical event, by a QMP [QE] to the Agency within 15 business days;
 - (iii) Provide a clinical summary to the prescribing physician and patient within 15 business days; and
 - ~~(iv)~~ Maintain record of the medical event as part of the patient's permanent medical record.
- iii. An x-ray system which does not meet the provisions of these regulations shall not be operated for diagnostic purposes unless the Agency or a QMP [QE] determines that the non-compliance shall not pose a significant radiation risk or significantly affect image quality, and arrangements have been made to correct the non-compliance within 30 days.
- ~~iv.~~ iv. The QMP [QE], if required in this Part, shall complete initial and routine compliance evaluations following nationally recognized procedures or those recognized by the Agency. These evaluations shall include a review of the required QC tests.
- ~~v.~~ v. All x-ray equipment shall be installed and used in accordance with the equipment manufacturer's specifications.
- ~~vi.~~ vi. Individuals operating the x-ray systems shall meet the qualifications required by the Agency.
- ~~vii.~~ vii. A sufficient number of protective apparel (~~e.g., aprons, gloves, collars~~) and shields shall be available to provide the necessary radiation protection for all patients and personnel who are involved with x-ray operations.
- ~~viii.~~ viii. All protective apparel and auxiliary shields shall be evaluated annually for integrity and clearly labeled with their lead equivalence.
- ~~viii.~~ Each registrant [licensee] shall have a mechanism in place for the referring physician to access information on selecting the most appropriate diagnostic procedure to answer the clinical question.
- ~~ix.~~ ix. The registrant [licensee] shall follow a process for the collection, review, and analysis of clinical radiation dose indices, including comparison to external benchmarks when available. This process shall be documented, including the frequency of review (at

least annually, or at intervals not to exceed 14 months) benchmarks used for comparison, and any practice changes made based on the results of the review, analysis, and comparison process. When available, national diagnostic reference level (DRL) values shall be used as external benchmarks. Nationally recognized diagnostic reference levels (DRLs) shall be utilized when applicable.

- x. The registrant [licensee] shall use auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information.
- xii. Neither the x-ray tube housing nor the collimating device shall be held during an exposure. Exceptions are allowed for [Agency ~~approved~~cleared] devices specifically designed to be hand-held.
- xiii. The useful x-ray beam shall be limited to the area of clinical interest.
- xiv. Consideration shall be given to selecting the appropriate technique and employing available dose reduction methods and technologies across all patient sizes and clinical indications.
- xv. A facility shall have a documented procedure in place for verification of patient identity and exam to be performed, including identification of the appropriate body part.
- xvi. For general radiographic systems not equipped with an operational anatomic programming option, protocols shall be documented and readily available to the operator. At a minimum, these protocols shall include:
 - (1) Patient's (adult and pediatric, if appropriate) body part and anatomical size
 - (2) Technique factors
 - (3) Type of image receptor used
 - (4) Source to image receptor distance used (except for dental intraoral radiography)
 - (5) Type of anti-scatter grid, if any.
- xvii. The registrant [licensee] shall create and make available to x-ray operators written safety procedures, including instructions for 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.
- xviii. The registrant [licensee] shall restrict the presence of individuals in the immediate area of the patient being examined to those required or in training for the medical

procedure, or the parent or guardian of ~~the~~ patient while the x-ray tube is energized. The following applies to all individuals, other than the patient being examined:

- (1) All persons 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 (~~mm~~) lead equivalent material;
 - (2) All persons shall be protected from the secondary radiation by protective ~~apparel garments~~ or whole body protective barriers of not less than 0.25 ~~mm~~ millimeter lead equivalent material;
 - (3) Instances may warrant having human patients other than the one being examined in the room during the exam. If the procedure results in scatter radiation in excess of 0.02 mSv (2 mR) in any one hour at the position of these patients, they shall be protected from the direct scatter radiation by whole body protective barriers of not less than 0.25 ~~mm~~ millimeter lead equivalent material or shall be positioned so that the 0.02 mSv (2 mR) in any one hour limit is met.
- xix. Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed practitioner of the healing arts or approved by an Institutional Review Board as defined in Part B of these regulations. This provision specifically prohibits deliberate exposure for the following purposes:
- (1) Exposure of an individual for training, demonstration, or other non-healing arts purposes; ~~or and~~
 - (2) Exposure of an individual for the purpose of healing arts screening except as authorized by the Agency.
- xx. In cases where a patient or image receptor must be provided with auxiliary support, mechanical support devices shall be used whenever possible. If a patient or image receptor must be provided with auxiliary support during a radiation exposure:
- (1) Written safety procedures, as required by F.3a.xv., shall indicate the requirements for selecting a holder and the procedure the holder shall follow;
 - (2) The human holder shall be instructed in personal radiation safety and protected as required by F.3a.xvi.;
 - (3) No individual shall be used routinely to hold the image receptor or patient during a radiation exposure;
 - (4) In those cases where the patient must hold the image receptor, except during intraoral examinations, 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 ~~mm~~ millimeter lead equivalent material.

- xxi. All individuals who are associated with the operation of an x-ray system are subject to the requirements of Part D of these regulations.
 - xxii. 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 Appendix A of this Part. If any information submitted to the Agency becomes invalid or outdated, the Agency shall be immediately notified. FDA/MQSA-certified facilities are registered with the Agency for the use of dedicated mammographic equipment to conduct mammography screening.
 - xxiii. Maintenance of Records. The registrant [licensee] shall maintain the following information on each x-ray system for inspection by the Agency for a minimum of 5 years or as noted below:
 - (1) Model and serial numbers of all major components, and user's manuals for those components, including software, shall be maintained for the life of the system.
 - (2) Records of surveys, calibrations, maintenance, and modifications (e.g., major software and hardware upgrades) performed on the x-ray system(s); and
 - (3) A copy of all correspondence with the Agency regarding the x-ray system.
 - xiv. X-Ray Utilization Record. Each facility shall maintain a record containing the patient's name, the type of examinations, and the dates the examinations were performed.
- b. Quality Assurance.
- i. The registrant [licensee] shall establish and maintain a quality assurance (QA) program. ~~In addition to the standards in the modality specific sections, the registrant [licensee] shall:~~
 - (1) Maintain documentation of minimum qualifications for practitioners, medical physicists, and x-ray equipment operators.
 - (2) Designate an appropriately trained individual to manage the QA program.
 - (3) Establish and maintain written QA and quality control (QC) procedures, including evaluation frequencies and tolerances.
 - (4) Check each study for artifacts. If an artifact is present, the source shall be identified and appropriate action taken.
 - (5) Perform ~~rejected image-repeat/reject~~ analysis of radiographic images at least quarterly following specifications of a nationally recognized organization.

- (6) Complete preventative maintenance on the x-ray systems in accordance with manufacturer specifications or annually or at intervals not to exceed 142 months.
- ~~(7) Inspect the tube housing and tube housing assembly annually or at intervals not to exceed 14 months. If visual inspection indicates possible damage or defects, the tube housing shall be evaluated for leakage according to the manufacturer's specifications. If the tube housing fails the evaluation, the unit shall be repaired or replaced.~~
- ~~(87) Maintain documentation showing that the testing instruments used in determining compliance with the provisions of this section are properly calibrated and maintained. The calibration of such system shall be traceable to a nationally recognized standard. The dosimetry system shall have been calibrated within the preceding 24 months, at twenty-four month intervals or in accordance with the Agency minimum standard or accepted professional standards when no Agency minimum is defined.~~
- ~~(89) Complete and document an annual review of the QA program.~~
- ~~(910) Retain QA/QC records for 36thirty-six months or of evaluations and reviews in accordance with state statutes and regulations, but in no case less than three years.~~
- ii. X-Ray Film Processing Facilities. A registrant [licensee] 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) Manually developed film:
 - (a) Processing tanks shall be constructed of mechanically rigid, corrosion resistant material; and
 - (b) Developing solutions shall be prepared, replenished, and replaced following manufacturer recommendations.
 - (c) The temperature of solutions in the tanks shall be maintained within the range of 60° F to 80° F (16° C to 27° C). Film shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer, or, in the absence of such recommendations, with the following time-temperature chart:

Manual Film Developing Technique Chart			
Developer	Developing	Developer	Developing

Temperature °C / °F	Time (Minutes)		Temperature °C / °F	Time (Minutes)
26.7 / 80	2.0		20.6 / 69	4.5
26.1 / 79	2.0		20.0 / 68	5.0
25.6 / 78	2.5		19.4 / 67	5.5
25.0 / 77	2.5		18.9 / 66	5.5
24.4 / 76	3.0		18.3 / 65	6.0
23.9 / 75	3.0		17.8 / 64	6.5
23.3 / 74	3.5		17.2 / 63	7.0
22.8 / 73	3.5		16.7 / 62	8.0
22.2 / 72	4.0		16.1 / 61	8.5
21.7 / 71	4.0		15.6 / 60	9.5
21.1 / 70	4.5			

- (d) Devices shall be utilized which will indicate the actual temperature of the developer solution and signal the passage of a preset time.
- (2) Automatic processors and other closed processing systems:
- (a) Automatic processors shall be operated and maintained following manufacturer specifications.
- (b) Films shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer; in the absence of such recommendations, the film shall be developed using the following chart:

Developer Temperature		Minimum Immersion Time ^{a/}
°C	°F	Seconds
35.5	96	19
35	95	20
34.5	94	21
34	93	22
33.5	92	23
33	91	24
32	90	25
31.5	89	26

31	88	27
30.5	87	28
30	86	29
29.5	85	30
^{a/} Immersion time only, no crossover time included.		

- (3) Processing deviations from the requirements of F.3b.ii. shall be documented by the registrant [licensee] in such manner that the requirements are shown to be met or exceeded (e.g., extended processing, and special rapid chemistry).
- iii. Additional Requirements for Facilities using X-ray Film.
- (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) 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.
- (3) 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.
- (4) Film cassettes and intensifying screens shall be inspected periodically and shall be cleaned and replaced as necessary.
- (5) Outdated x-ray film shall not be used for diagnostic radiographs.
- (6) The film and intensifying screen shall be spectrally compatible.
- (7) Facilities shall maintain a light-tight darkroom, use proper safelighting and safeguards, and evaluate darkroom integrity and daylight loading systems for film fog every six months and after a change that may impact film fog.
- (8) Facilities other than dental, podiatry, and veterinary shall:
- (a) Have a continuous and documented sensitometric quality control program, including quality control tests for speed, contrast and fog, These tests shall be performed according to specifications of the manufacturer, a QMP [QE], or a nationally recognized organization.
- (b) Maintain a light-tight darkroom and use proper safelighting and safeguards 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 optical density greater than 0.1 when exposed in the darkroom for 2 minutes with all safelights on. If used, daylight film handling boxes shall preclude fogging of the film.

- (c) Limit the base plus fog of unexposed film to an optical density less than 0.25 when developed by the routine procedure used by the facility.

iv. Facilities Using Computed Radiography (CR) or ~~Direct~~ Digital Radiography (DDR).

- (1) Facilities shall establish and follow an image quality control program in accordance with the recommendations of a QMP [QE], the system manufacturer, or a nationally recognized organization.
- (1) When exposure indicators are available, the facility shall establish and document an acceptable range for the exposure values for examinations routinely performed at the facility. The ~~exposure indicators indicated~~ exposure values for each image shall be compared to the established range. ~~Consistent Deviations exceeding limits and frequencies established by a QMP [QE] from established ranges~~ shall be investigated, corrective actions taken as necessary, and results documented.
- ~~(2) Facilities shall establish and follow an image quality control program in accordance with the recommendations of a QMP [QE], the system manufacturer, or a nationally recognized organization.~~
- (3) Facilities other than ~~dental, podiatric and~~ veterinary, shall annually, or at intervals not to exceed 14 months, quarterly complete phantom image evaluation using a phantom or other means on acquisition displays or workstation monitors as approved by a QMP [QE], system manufacturer, or the Agency. A~~The analysis at a minimum, the analysis~~ shall include: artifacts, spatial resolution, contrast/noise, ~~workstation monitors~~, and exposure indicator constancy.
- (4) In addition to F.3b.iv.(1) through (3), CR facilities shall perform erasure of all CR cassettes, at least on a weekly basis.

c. Exemptions.

- i. Dental facilities. Dental facilities performing only intra-oral, panoramic, or cephalometric ~~or volumetric dental~~ imaging are exempt from the following provisions of ~~this Section F.3b.iv.(3) (annual phantom image evaluation), Sec.F.3a.viii (information available to referring physician)~~ and Sec.F.3b.i.(5) (repeat analysis).

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- ii. Podiatry facilities. Podiatry facilities not using CBCT imaging equipment are exempt from the following provisions of ~~this Section: Sec.F.3a.vii. (information available to referring physician) and~~ Sec.F.3b.i.(5) (repeat analysis).
- iii. Veterinary facilities. Veterinary facilities are exempt from the following provisions of this Section: Sec.F.3a.viii. (information available to referring physician), Sec.F.3a. ix. (use of reference levels), Sec.F.3a.xii. (use of dose reduction techniques), Sec.F.3a.xiii. (patient identification), ~~Sec.F.3a.xiv. (protocol control),~~ Sec.F.3a.xviii.(3) (routine holding of patient), Sec.F.3a.xx. (healing arts screening), Sec.F.3b.i.(5) (~~reject image repeat~~ analysis), and Sec.F.3b.iii.(8)(a) through (c) (use of sensitometric equipment).

Sec. F.4 - General Requirements for All Diagnostic and Interventional X-Ray Systems. In addition to other requirements of this Part, all diagnostic and interventional x-ray systems shall meet the following requirements. Requirements specific to dental intra-oral, panoramic, cephalometric, volumetric dental imaging equipment are included in Sec.F.7.

- a. Warning Label.
 - i. On systems manufactured on or before June 10, 2006, the control panel containing the main power switch shall bear the warning statement, or the warning statement in F.4a.ii., legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions are observed."
 - ii. On systems manufactured after June 10, 2006, 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, operating instructions and maintenance schedules are observed."
- b. Leakage Radiation from the Diagnostic Source Assembly. The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source shall not exceed 0.88 milligray (mGy) air kerma (vice 100 milliroentgen (mR) exposure) in 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 100 square centimeters with no linear dimension greater than 20 centimeters (~~21CFR1020.30(d)~~).
- c. 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 18 microgray (vice 2 mR ~~milliroentgens~~ exposure) in 1 hour at 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 100 square centimeters with no linear dimension greater than 20 centimeters. (~~21CFR1020.30(d)~~)
- d. Technique Indicators.

- i. Technique factors must be displayed and visible from operator's position before exposure. ~~For x-ray equipment capable of displaying technique factors, 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. (21CFR1020.31(a)(1))~~
- ii. The requirement of F.4d.i. may be met by permanent markings on equipment with having fixed technique factors. ~~Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist. (21CFR1020.31(a)(1))~~
- iii. The accuracy of the indicated kilovoltage peak (kVp) shall meet manufacturer specifications. In the absence of a manufacturer specification, kVp accuracy shall be within ± 10 percent.

e. Beam Quality.

- i. The half value layer (HVL) of the useful beam for a given x-ray tube potential shall not be less than the values shown in Table 1. If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in Table 1 of this section, 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. ~~(21CFR1020.30(m))~~ 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. ~~(21CFR 1020.30)~~

TABLE 1
~~(21CFR1020.30(m))~~

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
	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
Above 70	71	2.1	2.1	2.5
	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 December 1, 1980. \2\ Dental x-ray systems designed for use with intraoral image receptors and manufactured before or on December 1, 1980, and all other x-ray systems subject to this section and manufactured before June 10, 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 June 10, 2006.				

- ii. Optional filtration on fluoroscopic systems. Fluoroscopic systems manufactured on or after June 10, 2006, ~~with incorporating~~ an x-ray tube(s) ~~with that has~~ a continuous output of 1 kilowatt or more and an anode heat storage capacity of 1 million 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 this subsection. 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. ~~(21CFR1020.30(m)(2))~~
- iii. Measuring compliance. For capacitor energy storage equipment, compliance shall be determined with the maximum selectable quantity of charge per exposure.

~~f. 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 Table 2 in this paragraph, which are used between the patient and the image receptor, may not exceed the indicated limits. Compliance shall be determined by x ray measurements made at a potential of 100 kilovolts peak and with an x ray beam that has an HVL specified in Table 1 of this section for the potential. This requirement applies to front panel(s) of image receptors 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.~~

TABLE 2

Item	Maximum Aluminum Equivalent (millimeters)
1. Front panel(s) of image receptor (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. Battery charge indicator. On battery-powered 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.
- h. Modification of certified diagnostic x-ray components and systems. 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.
- ~~ii. 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 this Part. The owner who causes such modification need not submit the reports required by this Part, 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 Part.~~
- i. Multiple Tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube which has been selected shall be clearly indicated prior to initiation of the exposure. Only the selected tube can be energized. This indication shall be both on the x-ray control panel and at or near the tube housing assembly which has been selected.
- j. Mechanical Support of Tube Head. The tube housing assembly ~~supports shall be adjusted such that the tube housing assembly will shall~~ remain stable during an exposure unless tube housing movement is a designed function of the x-ray system.
- k. Locks. All position locking, holding, and centering devices on x-ray system components and systems shall function as intended.
- l. 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.

Sec. F.5 - Fluoroscopic Equipment. The provisions of this Part apply to equipment for fluoroscopic imaging or for recording images from the fluoroscopic image receptor. ~~All fluoroscopic equipment shall be used per the equipment manufacturer's specifications, documented procedures established by the QMP [QE], or nationally recognized guidelines. (21CFR1020.32)~~

- a. Only image-intensified or ~~direct~~-digital receptor fluoroscopic equipment shall be used for fluoroscopy. Hand-held use of fluoroscopy equipment is prohibited.
- b. Primary Protective Barrier.
 - i. Limitation of useful beam. The fluoroscopic imaging assembly shall be provided with a primary protective barrier ~~that 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 AKR 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 AKR, at a distance of 10 cm from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor. Radiation therapy simulation systems shall be exempt from this requirement provided the systems are intended only for remote control operation. ~~(21CFR 1020.32(a)(1))~~
 - ii. Measuring compliance. The AKR shall be measured in accordance with F.5e. The AKR 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 100 square cm with no linear dimension greater than 20 cm. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 cm above the tabletop. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 cm. 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 10 cm from the point of measurement of entrance AKR and between this point and the input surface of the fluoroscopic imaging assembly. ~~(21CFR 1020.32(a)(2))~~
- c. Field Limitation.
 - i. Angulation. For fluoroscopic equipment manufactured after February 25, 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 F.5c.v. and F.5c.vi. shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor. ~~(21CFR 1020.32(b)(1))~~
 - ii. Further means for limitation. Means shall be provided to permit further limitation of the x-ray field to sizes smaller than the limits of F.5c.v. and F.5c.vi. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID and/or capability of a visible area of greater than 300 cm², 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 300 cm² 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 125 cm² 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 5 cm by 5 cm. ~~(21CFR 1020.32(b)(2))~~

iii. Spot-film devices. In addition to applicable regulations in F.6 (Radiographic Equipment), 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: ~~(21CFR 1020.31(h))~~

- (1) 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. ~~(21CFR 1020.31(h)(1))~~
- (2) 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 3 percent 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 4 percent of the SID. On spot-film devices manufactured after February 25, 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. ~~(21CFR 1020.31(h)(2))~~
- (3) 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 2 percent of the SID. ~~(21CFR 1020.31(h)(3))~~
- (4) 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: ~~(21CFR 1020.31(h)(4))~~
 - (a) 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 125 square cm; or ~~(21CFR 1020.31(h)(4)(i))~~
 - (b) 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 5 cm by 5 cm. ~~(21CFR 1020.31(h)(4)(ii))~~

- iv. 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 fluoroscopist'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

~~(21CFR 1020.31(h)(5))~~

- v. Fluoroscopy and radiography using the fluoroscopic imaging assembly with inherently circular image receptors.
- (1) For fluoroscopic equipment manufactured before June 10, 2006, other than radiation therapy simulation systems, the following applies: ~~(21CFR 1020.32(b)(4)(i))~~
- (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 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID.
~~(21CFR 1020.32(b)(4)(i)(A))~~
- (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. ~~(21CFR 1020.32(b)(4)(i)(B))~~
- (2) For fluoroscopic equipment manufactured on or after June 10, 2006, other than radiation 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: ~~(21CFR 1020.32(b)(4)(ii))~~
- (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 34 cm in any direction, at least 80 percent of the area of the x-ray field overlaps the visible area of the image receptor, or ~~(21CFR 1020.32(b)(4)(ii)(A))~~
- (b) When any linear dimension of the visible area of the image receptor measured through the center of the visible area is greater than 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 2 cm. ~~(21CFR 1020.32(b)(4)(ii)(B))~~
- vi. Fluoroscopy and radiography using fluoroscopic imaging assembly with inherently rectangular image receptors. For x-ray systems manufactured on or after June 10, 2006, the following applies: ~~(21CFR 1020.32(b)(5))~~

- (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 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID. ~~(21CFR1020.32(b)(5)(i))~~
 - (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. ~~(21CFR1020.32(b)(5)(ii))~~
- vii. 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 fluoroscopist'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
(21CFR 1020.32(b)(6))

- d. Activation of 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 radiographic 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. ~~(21CFR 1020.32(e))~~
- e. Air Kerma Rates. For fluoroscopic equipment, the following requirements apply:
- i. Fluoroscopic equipment manufactured before May 19, 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 AKR in excess of 88 mGy per minute (vice 10 R/min exposure rate) at the measurement point specified in F.5e.iv., except as specified in F.5e.i.(5). ~~(21CFR 1020.32(d)(1)(i))~~
 - (2) Equipment provided without AERC shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 44 mGy per minute (vice 5 R/min exposure rate) at the measurement point specified in F.5e.iv., except as specified in F.5e.i.(5). ~~(21CFR 1020.32(d)(1)(ii))~~
 - (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 AKR in excess of 88 mGy per minute (vice 10 R/min exposure rate) in

either mode at the measurement point specified in F.5e.iv., except as specified in F.5e.i.(5). ~~(21CFR 1020.32(d)(1)(iii))~~

- (4) Equipment may be modified in accordance with this Part to comply with F.5e.ii. 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)
(21CFR 1020.32(d)(1)(iv))

- (5) Exceptions: During recording of fluoroscopic images.

ii. Fluoroscopic equipment manufactured on or after May 19, 1995.

- (1) Shall be equipped with AERC if operable at any combination of tube potential and current that results in an AKR greater than 44 mGy per minute (vice 5 R/min exposure rate) at the measurement point specified in F.5e.iv. Provision for manual selection of technique factors may be provided. ~~(21CFR 1020.32(d)(2)(i))~~
- (2) Shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (vice 10 R/min exposure rate) at the measurement point specified in F.5e.iv., except as specified in F.5e.ii.(3). ~~(21CFR 1020.32(d)(2)(ii))~~
- (3) Exceptions:
 - (a) For equipment manufactured prior to June 10, 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. ~~(21CFR 1020.32(d)(2)(iii)(A))~~
 - (b) For equipment manufactured on or after June 10, 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. ~~(21CFR 1020.32(d)(2)(iii)(B))~~

iii. Fluoroscopy equipment with optional high-level control

- (1) When high-level control is selected 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 AKR in excess of 176 mGy per minute (vice 20 R/min exposure rate) at the measurement point specified in F.5e.iv. Special means of activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is employed.

- iv. Measuring compliance. Compliance with this subsection shall be determined as follows:
- (1) If the source is below the x-ray table, the AKR shall be measured at 1 cm above the tabletop ~~or cradle.~~ ~~(21CFR 1020.32(d)(3)(i))~~
 - (2) If the source is above the x-ray table, the AKR shall be measured at 30 cm above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. ~~(21CFR 1020.32(d)(3)(ii))~~
 - (3) In a C-arm type of fluoroscope, the AKR shall be measured at 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 30 cm from the input surface of the fluoroscopic imaging assembly. ~~(21CFR 1020.32(d)(3)(iii))~~
 - (4) In a C-arm type of fluoroscope having an SID less than 45 cm, the AKR shall be measured at the minimum SSD. ~~(21CFR 1020.32(d)(3)(iv))~~
 - (5) In a lateral type of fluoroscope, the air kerma rate shall be measured at a point 15 cm from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the 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 15 cm to the centerline of the x-ray table. ~~(21CFR 1020.32(d)(3)(v))~~
- v. Exemptions. Fluoroscopic radiation therapy simulation systems are exempt from the requirements set forth in F.5e. when used for therapy simulation purposes. ~~(21CFR 1020.32(d)(4))~~
- f. Indication of potential and current. During fluoroscopy and cinefluorography, 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. ~~(21CFR 1020.32(f))~~
- g. Source-skin distance.
- i. Means shall be provided to limit the source-skin distance to not less than 38 cm on stationary fluoroscopes and to not less than 30 cm on mobile and portable fluoroscopes. In addition, for fluoroscopes intended for specific surgical or interventional applications 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 20 cm.

- ii. ~~For mini C-arms, For stationary, mobile, or portable C-arm fluoroscopic systems manufactured on or after June 10, 2006, having a maximum source-image receptor distance of less than 45 cm,~~ means shall be provided to limit the source-skin distance to not less than 19 cm. ~~Such systems shall be labeled for extremity use only.~~ In addition, for those systems intended for specific surgical 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 10 cm.

- h. Fluoroscopic irradiation time, display, and signal.
 - i. Fluoroscopic equipment manufactured before June 10, 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 5 minutes without resetting. A signal audible to the fluoroscopist 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 this paragraph. When the equipment is modified, it shall bear a label indicating the statement:

Modified to comply with 21 CFR 1020.32(h)(2)
~~(21CFR 1020.32(h)(1)(i))~~
 - (2) As an alternative to the requirements of this paragraph, 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. ~~(21CFR 1020.32(h)(1)(ii))~~
 - ii. For x-ray controls manufactured on or after June 10, 2006, there shall be provided for each fluoroscopic tube:
 - (1) A display of the fluoroscopic irradiation time at the fluoroscopist's working position. This display shall function independently of the audible signal described in this subsection. The following requirements apply: ~~(variation of 21CFR 1020.32(h)(2)(i))~~
 - (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 6 seconds. ~~(21CFR 1020.32(h)(2)(i)(A))~~
 - (b) The fluoroscopic irradiation time shall also be displayed within 6 seconds of termination of an exposure and remain displayed until reset. ~~(21CFR 1020.32(h)(2)(i)(B))~~
 - (c) Means shall be provided to reset the display to zero prior to the beginning of a new examination or procedure. ~~(21CFR 1020.32(h)(2)(i)(C))~~

- (2) A signal audible to the fluoroscopist shall sound for each passage of 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 2 seconds. ~~(21CFR 1020.32(h)(2)(ii))~~
- i. Display of last-image-hold (LIH). Fluoroscopic equipment manufactured on or after June 10, 2006, shall be equipped with means to display LIH image following termination of the fluoroscopic exposure. ~~(21CFR 1020.32(j))~~
- i. 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. ~~(21CFR 1020.32(j)(1))~~
- ii. 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. ~~(21CFR 1020.32(j)(2))~~
- iii. 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. ~~(21CFR 1020.32(j)(3))~~
- j. Displays of values of AKR and cumulative air kerma. Fluoroscopic equipment manufactured on or after June 10, 2006, shall display at the fluoroscopist's working position the AKR and cumulative air kerma. The following requirements apply for each x-ray tube used during an examination or procedure: ~~(21CFR 1020.32(k))~~
- i. When the x-ray tube is activated and the number of images produced per unit time is greater than six images per second, the AKR in mGy/min shall be continuously displayed and updated at least once every second. ~~(21CFR 1020.32(k)(1))~~
- ii. The cumulative air kerma in units of mGy shall be displayed either within 5 seconds of termination of an exposure or displayed continuously and updated at least once every 5 seconds. ~~(21CFR 1020.32(k)(2))~~
- iii. The display of the AKR shall be clearly distinguishable from the display of the cumulative air kerma. ~~(21CFR 1020.32(k)(3))~~
- iv. The AKR 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. ~~(21CFR 1020.32(k)(4))~~

- (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 F.5e.iv(1), F.5e.iv(2) or F.5e.iv(5) ~~(21CFR 1020.32(k)(4)(i))~~
 - (2) For C-arm fluoroscopes, the reference location shall be 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. ~~(21CFR 1020.32(k)(4)(ii))~~
- v. Means shall be provided to reset to zero the display of cumulative air kerma prior to the commencement of a new examination or procedure. ~~(21CFR 1020.32(k)(5))~~
- vi. The displayed AKR and cumulative air kerma shall not deviate from the actual values by more than ± 35 percent over the range of 6 mGy/min and 100 mGy to the maximum indication of AKR and cumulative air kerma, respectively. Compliance shall be determined with an irradiation time greater than 3 seconds. ~~(21CFR 1020.32(k)(6))~~
- k. Protection From Scatter Radiation.
- i. For stationary fluoroscopic systems, ~~ancillary~~ shielding, such as drapes, self-supporting curtains, or viewing shields, shall be available and used as primary or supplemental protection for all individuals other than the patient in the room during a fluoroscopy procedure. Such shielding shall provide radiation protection of at least 0.25 mm lead equivalence.
 - ii. When the shielding provided by the devices in F5.k.i does not provide protection of at least 0.25 mm lead equivalence to all persons in the room, except the patient, all unshielded or inadequately shielded persons shall wear protective apparel that provides radiation protection of at least 0.25 mm lead equivalence. ~~Additionally, Where sterile fields or special procedures prohibit the use of normal protective barriers or drapes, all of the following conditions shall be met.~~
 - ~~(1) — Shielding required under F5.k.i shall be maintained to the degree possible under the clinical conditions.~~
 - ~~(2) — All persons, except the patient, in the room where fluoroscopy is performed shall wear protective aprons that provide a lead equivalent shielding of at least 0.25 mm.~~
- ~~(iii)3.~~ The fluoroscopic field size shall be reduced to the minimum required for the procedure being performed (area of clinical interest).
- ~~(iv)4.~~ Operating and safety procedures shall reflect the above conditions, and fluoroscopy personnel shall exhibit awareness of appropriate radiation protection strategies ~~situations requiring the use and/or non-use of the protective drapes.~~

1. Operator Qualifications.

- i. In addition to the applicable sections of these regulations, the operation of a fluoroscopic x-ray system for clinical purposes shall be limited to:
 - (1) A licensed practitioner working within his or her scope of practice;
 - (2) A Radiologist Assistant (RA) (if recognized by the Agency) working within ~~their~~ ~~his~~ ~~or~~ ~~her~~ scope of practice and under the direct supervision of a licensed practitioner meeting the conditions of F.51.i.(1);
 - (3) An individual who passed the American Registry of Radiologic Technologists (ARRT) Fluoroscopy Exam (or equivalent) and holds a valid certification, and only under the personal supervision of the licensed practitioner meeting the conditions of F.51.i.(1);
 - (4) A medical resident or radiologic technology student, in training, and only under the personal supervision of the licensed practitioner meeting the conditions of F.51.i.(1).
- ii. All persons operating, or supervising the operation of, fluoroscopy systems shall have completed a minimum of 4 hours training that includes but is not limited to the following:
 - (1) Basic properties of radiation;
 - (2) Biological effects of x-ray;
 - (3) Radiation protection methods for patients and staff;
 - (4) Units of measurement and dose, including DAP (dose-area product) values & air kerma;
 - (5) Factors affecting fluoroscopic outputs;
 - (6) High level control options;
 - (7) Dose management including dose reduction techniques, monitoring, and recording;
 - (8) Principles and operation of the specific fluoroscopic x-ray system(s) to be used;
 - (9) Fluoroscopic and fluorographic outputs of each mode of operation on the system(s) to be used clinically; and
 - (10) Applicable requirements of these regulations.

- iii. All persons operating, or supervising the operation of, fluoroscopy systems during FGI procedures shall have completed a minimum of 8 hours of training approved by the Agency. The topics shall include:
 - (1) The topics provided in F.5l.ii.;
 - (2) Methods to reduce patient dose using advanced imaging and recording features;
 - (3) Procedures for recording pertinent data specified in F.5o.
 - (4) Minimum of one hour of hands-on fluoroscopic machine training demonstrating application of topics required in this subsection.
- iv. The training required in this subsection shall be provided by a QMP [QE] or another individual approved by the Agency.
- v. Two years after the effective date of this rule, the registrant [licensee] shall ensure that prior to performing fluoroscopy procedures each person operating, or supervising the operation of, fluoroscopy systems completed the training required in this subsection.
- vi. The registrant [licensee] shall either provide a minimum of 2 hours in-service training every 2 years for all individuals operating or supervising the operation of fluoroscopy systems used or require evidence of continuing medical education meeting the conditions of this subsection.
- vii. Documentation pertaining to the requirements of F.5 shall be maintained for review for three years.
- m. Equipment Operation.
 - i. All fluoroscopic images shall be viewed, directly or indirectly, and interpreted by a licensed practitioner of the healing arts.
 - ii. Overhead fluoroscopy shall not be used as a positioning tool for general purpose radiographic examinations.
 - iii. Operators shall be competent in the standard operating procedures of the unit in use, including the use of available dose-saving features, and the relative radiation output rates of the various modes of operation.
 - iv. Procedure planning for fluoroscopic procedures on pregnant patients shall include feasible modifications to minimize the dose to the conceptus.
 - v. Procedure planning for fluoroscopic procedures on pediatric patients shall include feasible modifications to minimize dose.

- vi. The registrant [licensee] shall use all methods available on the fluoroscopy system to monitor dose during a fluoroscopic procedure.
- vii. The facility shall establish a written policy regarding patient dose management in fluoroscopically guided procedures in conformance with the *ACR-AAPM Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures* (ACR Resolution 44 – 2013), NCRP Report 168, or equivalent.

n. System Performance Qualified Medical Physicist Evaluations.

i. Testing of the fluoroscopy equipment shall be performed annually, or at intervals not to exceed 14 months, by, or under the personal supervision of, a QMP [QE] who assumes the responsibility and signs the final performance evaluation report.

ii. Evaluation standards and tolerances shall be established by the QMP [QE] and maintained by the facility. These standards and tolerances should meet nationally recognized standards and tolerances for the fluoroscopy equipment.

~~iii.~~ Fluoroscopic equipment shall be evaluated by a QMP [QE] within 30 days of installation and ~~of any maintenance of the system that may affect the exposure rate~~ Thereafter, the measurements shall be made annually or at intervals not to exceed ~~14~~ 12 months from the date of the prior measurement, ~~by or under the direction of a QMP [QE].~~ At a minimum these evaluations shall include:

- (1) A measurement of entrance exposure rates that covers the full range of patient thicknesses, including those that are expected to drive the system to maximum output in all modes clinically used, including fluoroscopy, high-level control, acquisition, digital subtraction and CINE, when available. These measurements shall:
 - (a) For systems without automatic exposure control, be made utilizing a milliamperage and kVp typical of the clinical use of the fluoroscopic system;
 - (b) For systems with automatic exposure control, be made utilizing sufficient attenuating material in the useful beam to produce a milliamperage and kVp typical of the clinical use of the fluoroscopic system;
- (2) A measurement and verification of compliance of maximum AKR for fluoroscopy and high-level control, if available. Measurements shall be made in accordance with Sec F.5e.iv.
- (3) An evaluation of high contrast resolution and low contrast resolution in both fluoroscopic and spot-film modes

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- (4) An evaluation of the operation of the 5-minute timer, warning lights, interlocks, and collision sensors.
 - (5) An evaluation of the beam quality and collimation in the fluoroscopy and spot-film modes.
 - (6) An evaluation of the availability and accuracy of technique indicators and integrated radiation dose displays.
 - (7) An evaluation of any changes that may impact patient and personnel protection devices.
- ~~ii.iv. The QMP [QE] shall complete an evaluation of the fluoroscopy equipment within 30 days after any change or replacement of any component that, in the opinion of the QMP [QE], could cause a change in the radiation output, exposure rate, or image quality. This evaluation may be limited to the relevant performance aspects of the fluoroscopic equipment, as determined by the QMP [QE].~~
- ~~ivi. The measurement of the radiation output of fluoroscopic equipment shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding 24 months. Measurements required in Sec F.5n.i. shall be performed with a calibrated dosimetry system per manufacturer recommendations not to exceed 2 years and records maintained for 5 years for inspection by the Agency.~~
- o. Additional requirements for facilities performing fluoroscopically-guided interventional (FGI) procedures.
- i. A registrant [licensee] utilizing FGI procedures shall establish a Radiation Protocol Committee (RPC) in accordance with the following.
 - (1) The registrant [licensee] may establish a system-wide committee if the registrant has more than one site.
 - (2) Two or more registrants [licensees] may form a cooperative RPC as long as each facility has a representative on the committee.
 - (3) If the registrant [licensee] has already established a radiation safety committee, the requirements of this subsection may be delegated to that committee if the members meet the requirements of F.5o.iv.
 - ii. A quorum of the RPC shall meet as often as necessary, but at intervals not to exceed 12 months.
 - iii. Record of RPC. A record of each RPC meeting shall include the date, names of individuals in attendance, minutes of the meeting, and any actions taken. The registrant [licensee] shall maintain the record for inspection by the Agency.

- iv. Provide an annual report to the radiation safety committee or radiation safety officer, in the absence of a radiation safety committee,
- v. RPC Members. Members shall include but not be limited to the following individuals:
 - (1) A supervising physician of the healing arts who meets the requirements in Sec. F.51.;
 - (2) A QMP [QE];
 - (3) The lead technologist; and
 - (4) Other individuals as deemed necessary by the registrant [licensee].
- vi. Establish and implement FGI procedure protocols.
 - (1) The RPC shall establish and implement written protocols, or protocols documented in an electronic report system, that include but are not limited to the following.
 - (a) Identification of individuals who are authorized to use fluoroscopic systems for interventional purposes.
 - (b) A method to be used to monitor patient radiation dose during FGI.
 - (c) Dose notification levels, as appropriate, at which the physician is notified and appropriate actions are taken for patient safety.
 - (d) SRDL values following nationally recognized standards,
 - (e) Actions to be taken for cases when a SRDL is exceeded which may include patient follow-up.
 - (f) A review of the established protocols at an interval not to exceed 12 months.
 - (2) A record of each RPC protocol shall be maintained for inspection by the Agency. If the RPC revises a protocol, documentation shall be maintained that includes the justification for the revision and the previous protocol for inspection by the Agency.
- vii. Procedures for maintaining records.
 - (1) Except for a mini c-arm, aA record of radiation output information shall be maintained so the radiation dose to the skin may be estimated in accordance with established protocols. The record shall include the following:

- (a) Patient identification;
 - (b) Type and date of examination;
 - (c) Identification of the fluoroscopic system used; and
 - (d) Peak skin dose, cumulative air kerma or dose area product used if the information is available on the fluoroscopic system.
 - (e) If the peak skin dose, cumulative air kerma or dose area product are not displayed on the fluoroscopic system, records shall include other information necessary to estimate the radiation dose to the skin in accordance with established protocol or the following as necessary:
 - (i) Fluoroscopic mode, such as, high-level or pulsed mode of operation;
 - (ii) Cumulative fluoroscopic exposure time; and
 - (iii) Number of films or recorded exposures.
- (2) The registrant [licensee] shall maintain records required by this subparagraph for inspection by the Agency.

Sec. F.6 - Radiographic Equipment. The following regulations apply to all non-dental registrants [licensees] using diagnostic x-ray equipment. Requirements specific to using dental intra-oral, hand held, panoramic, and cephalometric equipment are in Sec.F.7. Facilities using cone beam computed tomography (CBCT) technology shall follow applicable provisions of Sec. F.11h.

- a. Digital radiographic systems shall be evaluated by a QMP [QE] within 30 days of first clinical use and by or under the direction of a QMP [QE] and annually, at intervals not to exceed 142 months unless otherwise determined by the Agency. ~~The evaluation shall follow nationally recognized procedures or those recognized by the Agency. Unless otherwise specified in this Part, dental, podiatric, and veterinary systems are exempt from this requirement.~~
- b. Control and indication of technique factors.
 - i. 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. ~~(21CFR1020.31(a)(2))~~
 - (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 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. ~~(21CFR1020.31(a)(2)(i))~~

- (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. ~~(21CFR1020.31(a)(2)(iii))~~
- ii. 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; ~~(21CFR1020.31(a)(3)(i))~~
 - (2) When the x-ray tube potential is equal to or greater than 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 5 milliamperere-seconds (mAs), whichever is greater; ~~(21CFR1020.31(a)(3)(ii))~~
 - (3) Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kilowatt-seconds (kWs) per exposure or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure, except when the x-ray tube potential is less than 51 kVp, in which case the product of x-ray tube current and exposure time shall be limited to not more than 2,000 mAs per exposure; and ~~(21CFR1020.31(a)(3)(iii))~~
 - (4) A visible signal shall indicate when an exposure has been terminated at the limits described in F.6b.ii.(3), and manual resetting shall be required before further automatically timed exposures can be made. ~~(21CFR1020.31(a)(3)(iv))~~
- iii. Accuracy. Deviation of technique factors under Sec.F.6b. from indicated values shall not exceed the limits given by the manufacturer. ~~(variation of 21CFR1020.31(a)(4))~~
- c. Reproducibility.
 - i. Coefficient of variation. ~~When all technique factors are held constant, including control panel selections associated with AEC systems, the coefficient of variation of exposure for both manual and AEC systems shall not exceed 0.05. This requirement applies to clinically used techniques. For any specific combination of selected technique factors, the estimated coefficient of variation of the air kerma shall be no greater than 0.05.~~ ~~(21CFR1020.31(b)(1))~~
 - j.
 - ii. Measuring compliance. ~~The measurement method shall be documented and follow nationally recognized guidelines, manufacturer specifications, protocols recognized by the Agency, or protocols developed by the QMP [QE]. Determination of compliance In lieu of these options, the following method may be used.~~ Reproducibility may ~~shall~~ be based on 10 consecutive measurements taken within a time period of 1 hour. Equipment manufactured after September 5, 1978, shall be subject to the additional requirement that all variable controls for technique factors

shall be adjusted to alternate settings and reset to the test setting after each measurement. The percent line-voltage regulation shall be within ± 1 of the mean value for all measurements. 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 12 pulses on field emission equipment rated for pulsed operation or no less than one-tenth second per exposure on all other equipment.

~~(21CFR1020.31(b)(2))~~

- d. Linearity. The following requirements apply for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rated. ~~(variation of 21CFR1020.31(e))~~
- i. Equipment having independent selection of x-ray tube current (mA). The average ratios of air kerma to the indicated milliamperere-seconds product (mGy/mAs) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum. This is: $|X_1 - X_2| \leq 0.10(X_1 + X_2)$; where X_1 and X_2 are the average mGy/mAs values obtained at each of two consecutive mAs selector settings or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection. ~~(21CFR1020.31(e)(1))~~
- ii. Equipment having selection of x-ray tube current-exposure time product (mAs). For equipment manufactured after May 3, 1994, the average ratios of air kerma to the indicated milliamperere-seconds product (mGy/mAs) obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum. This is: $|X_1 - X_2| \leq 0.10(X_1 + X_2)$; where X_1 and X_2 are the average mGy/mAs values obtained at each of two consecutive mAs selector settings or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection. ~~(21CFR1020.31(e)(2))~~
- iii. Measuring compliance. ~~The measurement method shall be documented and follow nationally recognized guidelines, manufacturer specifications, protocols recognized by the Agency, or protocols developed by the QMP [QE]. In lieu of these options, the following method may be used. Linearity may~~ Determination of compliance will be based on 10 exposures, made within 1 hour, at each of the two settings. These two settings may include any two 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. The percent line-voltage regulation shall be determined for each measurement. All values for percent line-voltage regulation at any one combination of technique factors shall be within ± 1 of the mean value for all measurements at these technique factors. ~~(21CFR1020.31(e)(3))~~
- e. 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: ~~(21CFR1020.31(d))~~

- i. 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 100 cm shall be equal to or less than 5 cm. ~~(21CFR1020.31(d)(1))~~
- ii. 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 2 percent 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. ~~(21CFR1020.31(d)(2)(i))~~
 - (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 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. Radiation therapy simulation systems are exempt from this requirement. ~~(21CFR1020.31(d)(2)(ii))~~
 - (3) The edge of the light field at 100 cm or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than 4 in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than 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 3 mm from the edge of the light field toward the center of the field; and I_2 is the illuminance 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 1 mm. ~~(21CFR1020.31(d)(2)(iii))~~
- f. 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 F.6e.: ~~(21CFR1020.31(e))~~
 - i. 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 2 percent of the SID, and to indicate the SID to within 2 percent; ~~(21CFR1020.31(e)(1))~~
 - ii. The beam-limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted; ~~(21CFR1020.31(e)(2))~~
 - iii. 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 2 percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor; and ~~(21CFR1020.31(e)(3))~~

- iv. 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. ~~(21CFR1020.31(e)(4))~~

g. Field limitation on x-ray equipment other than general purpose radiographic systems.

- i. 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 2 percent 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.

- ii. Other x-ray systems. Radiographic systems not specifically covered in F.6e., F.6f., F.6g.ii., F.6g.iii., and systems covered in F.6g.i., 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 2 percent 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 2 percent 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: ~~(21CFR1020.31(f)(4))~~

- (1) A system which performs in accordance with F.6e. and F.6f.; or when alignment means are also provided, may be met with either; ~~(21CFR1020.31(f)(4)(i))~~
- (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 ~~(21CFR1020.31(f)(4)(ii))~~
- (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. ~~(21CFR1020.31(f)(4)(iii))~~

- h. Positive beam limitation (PBL). The requirements of this subsection shall apply to radiographic systems which contain PBL. ~~(21CFR1020.31(g))~~
- i. Field size. When a PBL system is provided, it shall prevent x-ray production when: ~~(21CFR1020.31(g)(1))~~
- (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 3 percent of the SID; or ~~(21CFR1020.31(g)(1)(i))~~
 - (2) The sum of the length and width differences stated in F.6h.i.(1) without regard to sign exceeds 4 percent of the SID. ~~(21CFR1020.31(g)(1)(ii))~~
 - (3) The beam-limiting device is at an SID for which PBL is not designed for sizing. ~~(21CFR1020.31(g)(1)(iii))~~
- ii. Conditions for PBL. When provided, the PBL system shall function as described in F.6h.i. whenever all the following conditions are met: ~~(21CFR1020.31(g)(2))~~
- (1) The image receptor is inserted into a permanently mounted cassette holder; ~~(21CFR1020.31(g)(2)(i))~~
 - (2) The image receptor length and width are less than 50 cm; ~~(21CFR1020.31(g)(2)(ii))~~
 - (3) The x-ray beam axis is within ± 3 degrees of vertical and the SID is 90 cm to 130 cm inclusive; or the x-ray beam axis is within ± 3 degrees of horizontal and the SID is 90 cm to 205 cm inclusive; ~~(21CFR1020.31(g)(2)(iii))~~
 - (4) The x-ray beam axis is perpendicular to the plane of the image receptor to within ± 3 degrees; and ~~(21CFR1020.31(g)(2)(iv))~~
 - (5) Neither tomographic nor stereoscopic radiography is being performed. ~~(21CFR1020.31(g)(2)(v))~~
- iii. Measuring compliance. Compliance with the requirements of F.6h.i. shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of F.6h.ii. are met. Compliance shall be determined no sooner than 5 second after insertion of the image receptor. ~~(21CFR1020.31(g)(3))~~
- iv. 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 100 cm shall be equal to or less than 5 cm. Return to PBL function as described in F.6h.i. shall occur automatically upon any change of image receptor size or SID. ~~(21CFR1020.31(g)(4))~~

- v. 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

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.
~~(21CFR1020.31(e)(5))~~

- vi. Disabling of PBL. A facility has the option to permanently functionally disable a PBL system. When this option is chosen, the standards for manual collimation apply.
- i. Source-skin distance. The minimum source-skin distance shall not be less than 30 cm, except podiatric specific equipment, intraoral dental equipment covered under F.6i.ii., and veterinary equipment.
- j. Radiation from capacitor energy storage equipment. Radiation emitted from the x-ray tube shall not exceed: ~~(21CFR1020.31(1))~~
 - i. An air kerma of 0.26 microGy (vice 0.03 mR exposure) in 1 minute at 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 100 square cm, with no linear dimensions greater than 20 cm; and ~~(21CFR1020.31(1)(1))~~
 - ii. An air kerma of 0.88 mGy (vice 100 mR exposure) in one hour at 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 number of discharges in 1 hour (duty cycle). The measurements shall be averaged over an area of 100 square cm with no linear dimension greater than 20 cm. ~~(21CFR1020.31(1)(2))~~
- k. Radiation Exposure Control.
 - i. Exposure Initiation. ~~Means shall be provided~~ A deliberate action on the part of the operator, such as the depression of a switch, is required 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 ~~possible~~ 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.

- ii. Exposure Indication. ~~Means shall be provided for visual indication observable- An observable indication is required~~ 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.
 - iii. Operator Protection, Except Veterinary Systems.
 - (1) Stationary Radiographic Systems. Stationary radiographic systems shall ~~be required to~~ have the x-ray control, including the exposure switch, 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 more~~ than one week in the same location, i.e., a room or suite are considered stationary radiographic systems and shall meet the requirements of F.6k.iii.(1);
 - (b) Used for less than one week at the same location shall be provided with ~~either~~ a protective barrier at least 2 meters (6.5 feet) high for operator protection during exposures, or ~~means shall be provided to allow~~ the operator ~~shall to~~ be at least 2 meters (6.5 feet) from the tube housing assembly during the exposure, or the operators shall wear personal protective apparel of at least 0.25 mm lead equivalent.
 - (3) Podiatry Systems. Podiatry facilities shall meet the protection requirements in F.6k.iii.(2)(b).
 - iv. Operator and Ancillary Personnel Protection for Veterinary Systems.

All operators and ancillary personnel using stationary, mobile or portable x-ray systems ~~used~~ for veterinary work shall be provided with a protective barrier at least 2 meters (6.5 feet) high for operator protection during exposures, or the operator shall be at least 2 meters (6.5 feet) from the tube housing assembly during the exposure, or the operators shall wear personal protective apparel of at least 0.25 mm lead equivalent. ~~shall be provided with either a 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 meters (6.5 feet) from the tube housing assembly during exposures. Otherwise, i~~In cases where animals are held, the operator and ancillary personnel shall be protected by a minimum of 0.25 mm lead equivalent from scatter radiation and 0.5 mm from the useful beam. Refer to F.7 for hand-held intraoral dental x-ray units used in veterinary practice.
1. Tube Stands for Additional Requirements for Portable and Mobile X-Ray Systems. ~~Except during veterinary field operations where it is impractical to do so, 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 an exposure.~~

xi. —

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- i. Portable or mobile x-ray equipment shall be used only for examinations when the medical status of the patient prohibits transfer of the patient to a stationary x-ray installation. In cases where patients are ambulatory, such as walk-in clinics and medical offices, a permanently installed stationary imaging system shall be used. ~~In cases where patient transport to a stationary system is possible.~~
 - ii. Except during veterinary field operations where it is impractical to do so, a tube stand or other mechanical support shall be used for portable x-ray systems, so that the x-ray tube housing assembly is not hand-held during an exposure.
 - iii. Hand-held use of serial radiography equipment is prohibited.
- m. Systems designed for mammography. All systems designed for mammography shall comply with the Mammography Quality Standards Act of 1998, as amended.
- ~~n. Prohibitions. Capacity energy storage equipment shall not be used to image humans 2 years after the effective date of this Part.~~

Sec.F.7 - Dental Facilities. In addition to the applicable provisions of Sec.F.3, the requirements of Sec.F.7 apply to dental facilities using intraoral, panoramic, and cephalometric x-ray equipment. Dental facilities using cone beam computed tomography (CBCT) technology shall follow the applicable provisions of Sec.F.11h.

- a. Quality Assurance. In addition to the general quality assurance provisions in Sec.F.3, the following requirements apply to a dental facility:
- i. If using film, maintain a light-tight darkroom, use proper safelighting and safeguards, and evaluate darkroom integrity and daylight loading systems for film fog every six months and after a change that may impact film fog.
 - ii. If using a filmless system, maintain and operate PSP and ~~D~~DR systems according to manufacturer specifications.
 - iii. Registrant [licensee] shall provide initial training and annual evaluations of x-ray operators ~~to include~~ including but not limited to: positioning of the x-ray tube, image processing, operator location during x-ray exposure, source to skin distance, radiation protection, appropriate radiographic protocol, and applicable regulatory requirements. Records of training and annual evaluations shall be maintained for inspection by the Agency.
- b. Warning Label.
- i. On systems manufactured on or before June 10, 2006, the control panel containing the main power switch shall bear the warning statement or the warning statement in F.7b.ii, legible and accessible to view: "WARNING: This x-ray unit may be

dangerous to patient and operator unless safe exposure factors, operating instructions are observed."

- ii. On systems manufactured after June 10, 2006, 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, operating instructions and maintenance schedules are observed."
- c. Radiation Exposure Control. ~~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 is required to initiate the radiation exposure. ~~Radiation exposure shall not be initiated without such an action.~~
- d. Exposure Control Location and Operator Protection. Except for units designed to be hand-held, the exposure control shall allow the operator to be:
 - i. Behind a protective barrier at least 2 meters (6.5 feet) tall or
 - ii. At least 2 meters (6.5 feet) from the tube housing assembly, outside the path of the useful x-ray beam, while making exposures.
- e. Administrative Controls.
 - i. Patient and image receptor holding devices shall be used when the techniques permit.
 - ii. Except for units designed to be hand-held, the tube housing and position indicating device (PID) shall not be hand-held during an exposure.
 - iii. Dental fluoroscopy without image intensification shall not be used.
- f. Hand-Held Intraoral Equipment. In addition to the standards in this chapter, the following applies specifically to hand-held devices:
 - i. The hand-held x-ray system shall be used ~~equipped~~ with a backscatter shield of not less than 0.25 mm lead equivalent and 15.2 cm (6 inches) in diameter that is positioned as close as practical ~~practicable~~ to the distal end of the position indication device.
 - ii. The facility shall maintain documentation that each operator has completed training as specified by the manufacturer, and approved by the Agency.
 - iii. The facility shall adopt and follow protocols provided by the manufacturer, and approved by the agency, regarding the safe operation of the device.
 - iv. When operating a hand-held intraoral dental radiographic unit, operators shall wear a 0.25 mm lead equivalent protective apparel ~~apron~~, unless otherwise authorized by the Agency or a certified health or qualified medical physicist.

- v. If the operator has difficulty ~~in~~ holding the device stationary during the exposure, the operator shall use a stand to immobilize the device.
- vi. The registrant [licensee] shall secure the hand-held device from unauthorized removal or use.
 - vii. If the tube housing or tube housing assembly becomes damaged, the unit shall be removed from service and evaluated for integrity according to the manufacturer's specifications. If the unit fails testing, it shall be repaired or replaced.
- g. 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. ~~(21CFR1020.31(j))~~
- h. Multiple Tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube which has been selected shall be clearly indicated prior to initiation of the exposure. Only the selected tube can be energized. This indication shall be both on the x-ray control panel and at or near the tube housing assembly which has been selected. ~~(21CFR1020.31(k))~~
- i. 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.
- j. Battery charge indicator. On battery-powered 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. ~~(21CFR1020.30(e))~~
- k. Locks. All position locking, holding, and centering devices on x-ray system components and systems shall function as intended.
- l. Technique Indicators.
 - i. For x-ray equipment capable of displaying technique factors, 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. ~~(21CFR1020.31(a)(1))~~
 - ii. The requirement of F.7l.i. may be met by permanent markings on equipment having fixed technique factors. ~~(21CFR1020.31(a)(1))~~
- m. Exposure Reproducibility. For any specific combination of selected technique factors, the estimated coefficient of variation of the air kerma shall be no greater than 0.05. ~~(21CFR1020.31(b)(1))~~
- n. 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. ~~(21CFR1020.31(a)(2))~~

- o. Kilovolt Peak. Deviation of technique factors from indicated values shall not exceed the limits provided by the manufacturer. ~~(variation of 21CFR1020.31(a)(4))~~ At a minimum, the kVp on variable kVp units shall be accurate to within 10 percent and within 20 percent on fixed kVp units.
- p. X-ray Beam Alignment.
- i. The useful x-ray beam shall be limited to the area of clinical interest.
 - ii. Intraoral Dental Units
 - (1) X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit the source-to-skin distance (SSD) to not less than 18 cm. ~~(21CFR1020.31(i)(1))~~
 - (2) The x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 7 cm. ~~(21CFR1020.31(f)(1)(i))~~
 - iii. Extraoral, Panoramic and Cephalometric Units
 - (1) X-ray systems 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 2 percent 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 2 percent 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: ~~(21CFR1020.31(f)(4))~~
 - (a) 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 ~~(21CFR1020.31(f)(4)(ii))~~
 - (b) 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. ~~(21CFR1020.31(f)(4)(iii))~~

- q. **Beam Quality.** The Half Value Layer (HVL) of the useful beam for a given x-ray tube potential shall not be less than the values shown in Table 1. If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in Table 1 of this section, 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. ~~-(21 CFR 1020.30)~~

Table 1
~~(21CFR1020.30(m))~~

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
	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
Above 70	71	2.1	2.1	2.5
	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 December 1, 1980.
\2\ Dental x-ray systems designed for use with intraoral image receptors and manufactured before or on December 1, 1980, and all other x-ray systems subject to this section and manufactured before June 10, 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 June 10, 2006.

- r. Intraoral dental x-ray machines shall not be operated at less than a measured 51 kVp effective 2 years after the publication of this rule.
- s. Modification of certified diagnostic x-ray components and systems.
- i. 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. ~~(21CFR1020.30(q) but doesn't mention variance option)~~

- ii. 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 this Part. The owner who causes such modification need not submit the reports required by this Part, 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 Part. ~~(21CFR1020.30(q)(2))~~
- t. Leakage Radiation from the Diagnostic Source Assembly. The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source shall not exceed 0.88 milligray (mGy) air kerma (vice 100 milliroentgen (mR) exposure) in 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 100 square centimeters with no linear dimension greater than 20 centimeters. ~~(21CFR1020.30(k))~~
- u. 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 18 microgray (vice 2 milliroentgens exposure) in 1 hour at 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 100 square centimeters with no linear dimension greater than 20 centimeters. ~~(21CFR1020.30(l))~~
- v. 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.

Sec. F.11 - Computed Tomography Equipment.

- a. Requirements for CT Equipment.
 - i. Accreditation. All diagnostic CT x-ray systems for human use shall be accredited by an accrediting organization recognized by the Agency unless otherwise authorized by the Agency.
 - ii. Technical and Safety Information. The technical and safety information relating to the conditions of operation, dose information and imaging performance provided by the CT manufacturer shall be maintained by the facility.
 - iii. 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 110 percent of its preset value through the use of either a backup timer or devices which monitor equipment function. ~~(21efr1020.33(f)(2)(i))~~
- (2) A visible signal shall indicate when the x-ray exposure has been terminated through the means required by Subsection F.11a.iii.(1). ~~(21efr1020.33(f)(2)(i))~~
- (3) The operator shall be able to terminate the x-ray exposure at any time during a scan, or series of scans under CT x-ray system control, of greater than one-half second duration. ~~(first part of 21efr1020.33(f)(2)(ii))~~

iv. 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. ~~(21efr1020.33(g)(1))~~
- (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. ~~(version of 21efr1020.33(g)(2))~~
- (3) If a mechanism using a light source is used to satisfy the requirements of Subsections F.11a.iv.(1) or F.11a.iv.(2), the light source shall allow visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux. ~~(21efr1020.33(g)(5))~~

v. 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. ~~(First part of 21efr1020.33(h)(1))~~
- (2) Each emergency button or switch shall be clearly labeled as to its function.

vi. Indication of CT Conditions of Operation.

- (1) The CT x-ray 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 a 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. ~~(21efr1020.33(f))~~

vii. Additional Requirements Applicable to CT X-Ray Systems Containing a Gantry Manufactured After September 3, 1985.

- (1) The total error in the indicated location of the tomographic plane or reference plane shall not exceed 5 millimeters. ~~(21cfr1020.33(g)(3))~~
- (2) If the x-ray production period is less than one-half second, the indication of x-ray production shall be actuated for at least one-half 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. ~~(second part of 21cfr1020.33(h)(1))~~
- (3) The deviation of indicated scan increment versus actual increment shall not exceed plus or minus 1 millimeter with any mass from 0 to 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. ~~(21cfr1020.33(i))~~
- (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. ~~(second part of 21cfr1020.33(f)(2)(ii))~~

b. CT Facility Design Requirements.

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

c. CT Surveys, Performance Evaluations, Routine QC, and Operating Procedures.

- i. Radiation Protection Surveys.
 - (1) All CT x-ray systems installed after [insert the effective date of the regulations] shall have a radiation protection survey completed by, or under the direct supervision of, the QMP [QE] within 30 days of installation. Existing systems not previously surveyed shall have a surveying made by, or

under the direct supervision of, a QMP [QE] within 12 months of the effective date. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

- (2) The registrant [licensee] shall obtain a written report of the survey from the QMP [QE], and a copy of the report shall be made available to the Agency upon request.

ii. System Performance Evaluations.

- (1) The annual testing of the CT x-ray system shall be performed by, or under the personal supervision of, a QMP [QE] who assumes the responsibility and signs the final performance evaluation report.
- (2) Evaluation standards and tolerances shall be established by the QMP [QE] and maintained by the facility. These standards and tolerances shall meet nationally recognized standards and tolerances for the CT x-ray system.
- (3) The evaluation of a CT x-ray system shall be performed after initial installation and before use on human patients; and ~~annually, or at intervals not to exceed 142 months from the date of the prior measurement. In addition, the QMP [QE] shall complete an evaluation of the CT system within 30 days or after any change or replacement of components which, in the opinion of the QMP [QE], could cause a change in the radiation output or image quality.~~ annually, or at intervals not to exceed 12 months from the date of the prior measurement.
- (4) The evaluation shall include but not be limited to:
 - (a) Geometric factors and alignment including:
 - (i) Alignment light accuracy;
 - (ii) Table increment accuracy.
 - (b) Image localization from scanned projection radiograph (localization image);
 - (c) Radiation beam width;
 - (d) Image quality including:
 - (i) High-contrast (spatial) resolution;
 - (ii) Low-contrast resolution;
 - (iii) Image uniformity;
 - (iv) Noise;

- (v) Artifact evaluation.
- (e) CT number accuracy;
- (f) Image quality for acquisition workstation display devices;
- (g) A review of the results of the routine QC required under F.11a.iii.;
- (h) A safety evaluation of audible and visual signals, posting requirements;
- (i) Dosimetry.

(5) The QMP [QE] shall complete an evaluation of the CT system within 30 days after any change or replacement of any component that, in the opinion of the QMP [QE], could cause a change in the radiation output or image quality. This evaluation may be limited to the relevant performance aspects of the CT system, as determined by the QMP [QE].

(65) The measurement of the radiation output of a CT x-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding 24 months-years.

iii. Routine Quality Control. A routine QC program on the CT system shall:

- (1) Be developed by a QMP [QE] and include acceptable tolerances for points evaluated;
- (2) Incorporate the use of a water equivalent phantom. At a minimum, noise, CT number, and artifacts shall be evaluated.
- (3) Be completed at time intervals and under system conditions specified by the QMP [QE]. The interval shall not to exceed 1 week.
- (4) Be documented and maintained for inspection by the Agency.

iv. Operating Procedures.

- (1) The operator of the CT x-ray system shall meet the minimum operator requirements of these regulations and be specifically trained on the operational features of the unit by a manufacturer's applications specialist, QMP [QE], or someone deemed qualified by the Agency.
- (2) The following information shall be readily available to the CT operator:

- (a) Instructions on performing routine QC, including the use of the CT phantom(s), a schedule of routine QC appropriate for the system, allowable variations set by the QMP [QE] for the indicated parameters, and the results of at least the most recent routine QC completed on the system; and
 - (b) Scanning protocols established by the RPC, including instructions on reporting deviations .
 - (3) If the QMP [QE] evaluation or routine QC of the CT x-ray system identifies that a system operating parameter has exceeded a tolerance established by the QMP [QE], use of the CT x-ray system on patients shall be limited to those uses permitted by established written instructions of the QMP [QE].
- d. CT Radiation Protocol Committee (RPC). The registrant [licensee] shall develop and maintain an RPC in accordance with the following:
- i. Members of the RPC.
 - (1) Members of the RPC shall include but not be limited to the:
 - (a) Lead CT radiologist;
 - (b) Lead CT technologist;
 - (c) QMP [QE]; and
 - (d) Other individuals as deemed necessary by the registrant [licensee] (e.g., Radiation Safety Officer, Chief Medical or Administrative Officer, Radiology Department Administrator/Manager).
 - (2) If the registrant [licensee] has more than one site with CT, they may establish a system-wide RPC.
 - (3) Two or more registrants [licensees] may form a cooperative RPC as long as each facility has a representative on the committee.
 - (4) If the registrant [licensee] has already established a radiation safety committee, the requirements of this subsection may be delegated to that committee if the members meet the requirements of F.11d.i.
 - ii. Responsibilities of the RPC. The RPC shall:
 - (1) Review existing CT protocols along with the evaluation and implementation of new and innovative technologies that can improve image quality and/or lower patient dose in comparison with the older protocol.
 - (2) Review the capabilities of the individual CT scanner to ensure maximum performance is achieved.

- (3) Determine and review the protocols used frequently or could result in significant doses. This review shall include acquisition and reconstruction parameters, image quality, and radiation dose. At a minimum, the facility shall review the following clinical protocols, if performed, at intervals not to exceed 12 months:
 - (a) Pediatric Head;
 - (b) Pediatric Abdomen;
 - (c) Adult Head;
 - (d) Adult Abdomen;
 - (e) Adult Chest;
 - (f) Brain Perfusion.
- (4) Establish and implement written protocols, or protocols documented in an electronic reporting system, that include but are not limited to the following:
 - (a) A method to be used to monitor the CT radiation output.
 - (b) A standardized protocol naming policy.
 - (c) A DRL, notification value, and alert value for CT procedures reviewed in F.11d.ii.3. Notification and alert values may be applied by using trigger values in conformance with NEMA XR-29 or facility-established values and procedures as defined by the QMP [QE].
 - (d) Actions to be taken for cases when the dose alert value was exceeded which may include patient follow-up.
 - (e) A process determining who has access and authority to make changes to the protocol management systems, including a method to prevent inadvertent or unauthorized modifications to a CT protocol.
- (5) If CT fluoroscopy is performed, the RPC shall establish and implement operating procedures and training designed to minimize patient and occupational radiation exposure.
- (6) Provide an annual report to the radiation safety committee or radiation safety officer, in the absence of a radiation safety committee,

- (7) At a minimum the RPC members in F.11d.i.(1)(a) through (c) shall meet as often as necessary to conduct business but at intervals not to exceed 12 months.
- iii. Records.
- (1) A record of each RPC meeting shall be maintained. The record shall include the date, names of individuals in attendance, minutes of the meeting, and any action taken.
 - (2) The registrant [licensee] shall maintain a record of RPC policies and procedures.
 - (3) The registrant [licensee] shall maintain a record of radiation output information so the radiation dose may be estimated in accordance with established protocols (e.g., SSDE). The record shall include:
 - (a) Patient identification;
 - (b) Type and date of examination;
 - (c) Identification of the CT system used; and
 - (d) The dose values the CT system provides (e.g., CTDIvol, DLP, SSDE).
- e. CT systems used in treatment planning. CT systems solely used for treatment planning in radiation oncology shall meet the requirements in Part X-~~10~~ of these regulations.
- f. PET CT and SPECT CT Systems. CT systems solely used to calculate attenuation coefficients in nuclear medicine studies shall meet the requirements in Sections F.11.a. through F.11d. unless otherwise exempted below:
- i. F.11a.i. (Accreditation)
 - ii. In lieu of F.11c.ii., a QMP [QE] shall complete a performance evaluation on the CT system following nationally recognized guidelines or those approved by the Agency at intervals not to exceed 12 months.
 - iii. In lieu of F.11c.iii., routine QC checks shall be completed at intervals not to exceed 1 week. These checks shall be established and documented by a QMP [QE] following nationally recognized guidelines or those approved by the Agency.
 - iv. F.11c.iv.(2)(b) (RPC)
- g. Veterinary CT Systems. CT systems, including CBCT systems, solely used in non-human imaging shall meet the requirements of F.11c.i. (~~radiation protection surveys~~) and are ~~otherwise exempt~~ exempt from the standards of Section F.11-a.i, F.11b.i, and F.11d.
- h. Cone Beam Computed Tomography Systems.

- i. CBCT facilities shall meet F.4., F.6i. and k., and F.11a.ii through F.11a.vii., as applicable.
- ii. Beam alignment. The x-ray field in the plane of the image receptor shall not exceed beyond the edge of the image receptor by more than 2 percent of the SID, when the axis of the x-ray beam is perpendicular to the plane of the image receptor. In addition, the center of the x-ray field shall be aligned with the center of the image receptor to within 2 percent of the SID.
- iii. A performance evaluation shall be performed by, or under the direct supervision of, a QMP [QE]. The evaluation shall follow nationally recognized standards and tolerances or those recognized by the Agency. The evaluation shall be performed within 30 days of initial installation, at intervals not to exceed 12 months, and within 30 days after any change or replacement of components which, in the opinion of the QMP [QE], could cause a change in the radiation output or image quality. The facility shall maintain documentation of the established standards and tolerances and testing results.
- iv. The registrant [licensee] shall follow the QC recommendations provided by the CBCT manufacturer. In the absence of manufacturer provided QC recommendations, the registrant [licensee] shall implement and document QC guidelines established by a QMP [QE] in accordance to nationally recognized guidelines or those recognized by the Agency.
- v. The registrant [licensee] or RPC, if established, shall implement and document a policy addressing deviations from established protocols.
- vi. The CBCT x-ray system shall only be operated by an individual who has been specifically trained in its operation.
- vii. The following information shall be readily available to the CBCT operator:
 - (1) Instructions on performing routine QC, including the use of the CBCT phantom(s), a schedule of routine QC appropriate for the system, allowable variations set by the QMP [QE], if required, for the indicated parameters, and the results of at least the most recent routine QC completed on the system.
- viii. Exemption. A QMP [QE] performance evaluation on CBCT systems capable of operating at no greater than 100 kV or 20 mA shall be performed at intervals not to exceed 24 months, or an interval approved by the Agency.
- ix. Exemption. The registrant [licensee] using fluoroscopy systems capable of CBCT shall meet F.11h., except F.11a.ii. through F.11a.vii in F.11h.i.

Sec. F.15 - Dual-Energy X-ray Absorptiometry (DXA) (Bone Densitometry).

- a. DXA systems shall be:
 - i. 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.;
 - ii. Registered [licensed] in accordance with Part B of these regulations; and
 - iii. At a minimum, maintained and operated in accordance with the manufacturer’s specifications.
- b. Operator Requirements. In addition to the minimum qualifications outlined in Part Z of these regulations, operators shall complete training specific to patient positioning and the operation of the DXA system.
- c. During the operation of any DXA system:
 - i. In the absence of a survey performed by or under the supervision of a QMP [QE] determining the minimum distance the operator may be from the patient and radiation source, the operator, ancillary personnel, and members of the general public shall be positioned at least two meters from the patient and DXA system during the examination.
- d. Reserved.
- e. Quality Assurance. In addition to the applicable requirements in Part F.3b.i., a facility performing DXA shall:
 - i. Conform to the DXA system manufacturer recommendations and recommendations of recognized professional societies such as the International Society for Clinical Densitometry or the American College of Radiology;
- f. Records. The registrant [licensee] shall keep the following records for a minimum of 3 years:
 - i. The maintenance and QC tests as prescribed by F.15a.iii. and F.15e.

PART F

APPENDIX A

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

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

- a. Name and address of the applicant and, where applicable, the names and addresses of agents within this State;
- b. Diseases or conditions for which the x-ray examinations are to be used in diagnoses;
- c. A description of the x-ray examinations proposed in the screening program i.e., type and number of views;
- d. Description of the population to be examined in the screening program, i.e., age range, sex, physical condition, and other appropriate information;
- e. 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 instead of the x-ray examinations;
- f. An evaluation by a QMP [QE] of the x-ray system(s) to be used in the screening program. The evaluation shall include the following:
 1. Documentation that such system(s) satisfy all applicable requirements of these regulations;
 2. Measurement of appropriate patient exposures from the x-ray examinations to be performed;
- g. A description of the x-ray quality control program;
- h. A copy of the protocol **informaiton** for the x-ray examination procedures to be used;
- i. The qualifications of each individual who will be operating the x-ray system(s);
- j. The qualifications of the individual 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;
- k. The name and address of the practitioner licensed in the state who will interpret the radiograph(s);

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- l. Procedures to be used in advising the individuals screened and their practitioner of the healing arts or health care provider of the results of the screening procedure and any further medical needs indicated;
- m. Procedures for the retention or disposition of the radiographs and other records pertaining to the x-ray examinations;
- n. Frequency of screening of individuals; and
- o. The duration of the screening program.

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