DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Hazardous Materials and Waste Management Division

State Board of Health

RADIATION CONTROL - X-RAY IMAGING IN THE HEALING ARTS

6 CCR 1007-1 Part 06

[Editor's Notes follow the text of the rules at the end of this CCR Document.]

Adopted by the Board of Health August 19, 2020, effective date October 15, 2020.

PART 6: X-RAY IMAGING IN THE HEALING ARTS

6.1 Purpose and Scope.

6.1.1 Authority.

6.1.1.1 Rules and regulations set forth herein are adopted pursuant to the provisions of sections 25-1-108, 25-1.5-101(1)(l), and 25-11-104, CRS.

6.1.2 Basis and Purpose.

6.1.2.1 A statement of basis and purpose accompanies this part and changes to this part. A copy may be obtained from the Department.

6.1.3 Scope.

6.1.3.1 Part 6 establishes requirements, for which a registrant is responsible, for use of diagnostic and interventional x-ray equipment and imaging systems in the healing arts.

6.1.4 Applicability

6.1.4.1 The provisions of this part are in addition to, and not in substitution for, other applicable provisions in Part 1, 2, 4, 7, 10, 24 and other parts of these regulations.

6.1.4.2 Part 24 also applies to certain healing arts x-ray imaging registrants.

6.1.4.3 The requirements and provisions of this part apply to each registrant or applicant for registration subject to this part unless specifically exempted.

6.1.5 Published Material Incorporated by Reference.

6.1.5.1 Throughout this Part 6, federal regulations, state regulations, and standards or guidelines of outside organizations have been adopted and incorporated by reference. Unless a prior version of the incorporated material is otherwise specifically indicated, the materials incorporated by reference cited herein include only those versions that were in effect as of the most recent effective date of this Part 6 (October, 2020), and not later amendments or editions of the incorporated material.

6.1.5.2 Materials incorporated by reference are available for public inspection, and copies (including certified copies) can be obtained at reasonable cost, during normal business hours from the Colorado Department of Public Health and Environment, Hazardous Materials and Waste Management Division, 4300 Cherry Creek Drive South, Denver, Colorado 80246. Additionally, https://www.colorado.gov/cdphe/radregs identifies where the incorporated federal and state regulations are available to the public on the internet at no cost. A copy of the materials incorporated in this Part is available for public inspection at the state publications depository and distribution center.

6.1.5.3 Availability from Source Agencies or Organizations.

(1) All federal agency regulations incorporated by reference herein are available at no cost in the online edition of the Code of Federal Regulations (CFR) hosted by the U.S. Government Printing Office, online at www.govinfo.gov.

(2) All state regulations incorporated by reference herein are available at no cost in the online edition of the Code of Colorado Regulations (CCR) hosted by the Colorado Secretary of State's Office, online at https://www.sos.state.co.us/CCR/RegisterHome.do.

(3) Copies of the standards or guidelines of outside organizations are available either at no cost or for purchase from the source organizations listed below.

a. American Association of Physicists in Medicine (AAPM)
1631 Prince Street
Alexandria, VA 22314
Phone 571-298-1300
aapm.org

b. National Council on Radiation Protection and Measurements (NCRP)
7910 Woodmont Avenue, Suite 400
Bethesda, MD 20814-3095
Phone: 301-657-2652
ncrponline.org

6.2 Definitions.

As used in Part 6, these terms have the definitions set forth as follows:

"AAPM Online Report 03" means "Assessment of Display Performance for Medical Imaging Systems", AAPM Online Report No. 03 by Task Group 18 of the American Association of Physicists in Medicine (April 2005).

"AAPM Report 96" means "The Measurement, Reporting, and Management of Radiation Dose in CT", AAPM Report No. 96 by Task Group 23 (CT Dosimetry) of the Radiography and Fluoroscopy Subcommittee of the Diagnostic Imaging Council CT Committee of the American Association of Physicists in Medicine (January 2008).

"Alert value" means a dose index that is set by the registrant to trigger an alert to the CT operator prior to scanning within an ongoing examination. The alert value represents a universal dose index value well above the registrant's established range for the examination that warrants more stringent review and consideration before proceeding.

“Aluminum equivalent” means the thickness of aluminum (type 1100 alloy with a nominal chemical composition of aluminum 99.00 percent minimum and copper 0.12 percent maximum) affording the same attenuation, under specified conditions, as the material in question.

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

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

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

“Automatic exposure rate control” (AERC) means a device that automatically controls one or more technique factors in order to obtain at the pre-selected location(s) a required quantity of radiation per unit time.

“Automatic film processor” means a device that produces an image from a film-screen system in mechanical steps with limited human intervention.

“Barrier”. See “protective barrier”.

“Beam axis” means, for purposes of Part 6, a line from the source through the center of the x-ray field.

“Beam-limiting device” means a device that 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. A bone densitometer is synonymous with dual-energy x-ray absorptiometry (DXA) systems.

“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.

“Cephalometric” means imaging equipment or methods that are used for the radiographic visualization and measurement of the dimensions of the human head.

“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:

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

21 cfr

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

“Computed radiography” (CR). See “photostimulable storage phosphor system.”

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

"Cone Beam Computed Tomography (CBCT)" means a volumetric imaging modality that uses a two-dimensional digital flat-panel detector to yield a three dimensional volumetric image in one rotation. Reconstruction algorithms can be used to generate images of any desired plane.

“Control panel” means that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons, keypads, touchscreens, and other hardware or software necessary for the operator to manually select exposure settings.

"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, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in 6.2.

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

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

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

where:

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

μ_x = Linear attenuation coefficient of the material of interest;

μ_w = Linear attenuation coefficient of water.

“Dead-man switch” means a switch so constructed that a circuit-closing contact can be maintained only by continuous pressure on the switch by the operator.

“Detector” (See “Radiation detector”)

“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 is used to capture an x-ray image.

"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-cm^2, so it does not change with distance from the x-ray tube.

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

“Equipment”. See “x-ray equipment”.

“Examination” means performing a procedure, including selection of exposure settings, positioning the x-ray system and the patient, and initiating and terminating the exposure.

“Facility”, for mammography (to supplement the Part 1 meaning of “facility”), means a hospital, outpatient Department, clinic, radiology practice, mobile unit, office of a physician, or other facility that conducts mammography activities, including the following: operation of equipment to produce a mammogram, initial interpretation of the mammogram, and maintaining viewing conditions for that interpretation.

“Field emission equipment” means equipment that 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.

“Floor plan” means, for purposes of Part 6, a plan view of the overall layout to scale of a room or group of rooms, including the location and configuration of any radiation producing machines in each room.

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

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

"Fluoroscopically-Guided Interventional (FGI) Procedures" means an interventional diagnostic or therapeutic procedure performed via percutaneous or other access routes, usually with local anesthesia or intravenous sedation, which uses external ionizing radiation in the form of fluoroscopy to localize or characterize a lesion, diagnostic site, or treatment site, to monitor the procedure, and to control and document therapy.

“FGI Procedures Committee” means the representative group of individuals in a FGI facility responsible for the ongoing review and management of FGI procedures 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.

“Fluoroscopy” means a technique for generating x-ray images and presenting them simultaneously and continuously as visible images.

“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.

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

“Hand-held x-ray equipment” means a type of portable x-ray equipment that is designed to be held in the operators hand during operation. See “x-ray equipment”.

“Healing arts screening” means, for purposes of these regulations, the testing or evaluation resulting in the exposure of any human being to an x-ray machine for the detection or evaluation of health indications when such a test is not specifically and individually ordered by a licensed physician, chiropractor, dentist, podiatrist or other person legally authorized to prescribe such a test 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 (kVp - mA - second).

“HVL”. See “half-value layer”.

“Image intensifier” means a device, installed in its housing, that instantaneously converts an x-ray pattern into a corresponding visible light image and electronically amplifies the brightness of that visible image.

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

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

“Kerma-area product (KAP)”. See “Dose area product”

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

“kV” means kilovolt.

“kVp”. See “Peak tube potential”.

“kWs” means kilowatt-second.

"Last image hold radiograph" (LIH) means an image obtained either by retaining one or more fluoroscopic images, which may be temporarily integrated, at the end of a fluoroscopic exposure.

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

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

(1) The useful beam; and

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

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

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

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

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

“Light field” means that area of the intersection of the light beam from the beam-limiting device, and one of the set of planes parallel to, and including, the plane of the image receptor, whose perimeter is the locus of points, at which the illumination is one-fourth of the maximum in the intersection.

“Mammogram” means a radiographic image produced through mammography.

"Mammography" means radiography of the breast, but for purposes of this part, does not include:

(1) Radiography of the breast performed during invasive interventions for localization or biopsy procedures; or

(2) Radiography of the breast performed with an investigational mammography device as a scientific study conducted in accordance with FDA regulations.

"Mammography phantom" means a test object used to simulate radiographic characteristics of compressed breast tissue and containing components that radiographically model aspects of breast disease and cancer.

"Manual film developing" means a way to produce an image that requires human intervention to move the film from developer to fixer to wash.

"mAs" means milliampere-seconds (mAs), a measure of electrical current produced over a set amount of time via an x-ray tube.

"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.

(1) The set of distinct technique factors and control settings for the mode may be selected by the operation of a single control.

(2) Examples of distinct modes of operation include normal fluoroscopy (analog or digital), high-level control fluoroscopy, cineradiography (analog or digital), digital subtraction angiography, electronic radiography using the fluoroscopic image receptor, and photospot recording.

(3) In a specific mode of operation, certain system variables affecting air kerma, AKR, or image quality, such as image magnification, x-ray field size, pulse rate, pulse duration, number of pulses, source-image receptor distance (SID), or optical aperture, may be adjustable or may vary; their variation per se does not comprise a mode of operation different from the one that has been selected.

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

"NCRP Report 147" means National Council on Radiation Protection and Measurements Report No. 147, "Structural Shielding Design For Medical Imaging Facilities" (November 2004).

"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:

$\overline{CS}$ = Contrast scale (the change in linear attenuation coefficient per CT number relative to water).

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.

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

"Notification value" means a protocol-specific dose index that is set by the registrant to trigger a notification to the CT operator prior to scanning when the dose index exceeds the established range for the examination.

“Optical Density” (OD) equals log (1/transmittance), where the transmittance of the film is the fraction of incident light transmitted by the film.

“Patient” means a human being or an animal to whom machine-produced radiation is delivered for healing arts examination, screening, diagnosis, or treatment.

“PBL”. See “positive beam limitation”.

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

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

“Picture element” (pixel) means an elemental area of a digitally acquired image.

“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, without regard to whether the device incorporates or serves as a beam-limiting device.

“Positive beam limitation” (PBL) 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 to attenuate the useful beam for radiation protection purposes.

“Protective apparel” means a garment made of radiation-absorbing materials used to reduce radiation exposure to the wearer.

“Protective barrier” means a barrier of radiation absorbing material(s) used to reduce radiation exposure.

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

"Pulsed mode" means operation of a fluoroscopic 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 inspector (QI)” is as defined in Section 2.2 of Part 2 of these regulations.

“Qualified trainer” is as defined in Section 2.2 of Part 2 of these regulations.

“Quality assurance (QA)” means a written monitoring and verification program which uses testing, auditing and inspection to ensure that deficiencies, deviations, defective equipment, or unsafe practices, or a combination thereof, relating to the use, disposal, management, or manufacture of radiation devices are identified, promptly corrected, and reported to the department where required.

“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 individuals in a CT facility responsible for the ongoing review and management of CT 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 or a computed tomography system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

“Radiograph” means an image created directly or indirectly by x-rays resulting in a permanent visible image on film or digital record.

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

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

“Registered medical physicist (RMP)” is as defined in Section 2.2 of Part 2 of these regulations.

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

"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 of x-ray transmission data for a single scan.

“Scatter radiation” means ionizing radiation that, during passage through matter, has been deviated in direction.

"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.

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

“SID”. See “source-image receptor distance”.

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

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

“Source” means the focal spot of the x-ray tube.

“Source-image receptor distance” (SID) means the distance from the source to the center of the input surface of the image receptor.

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

“Spot image” means a radiograph that is made during a fluoroscopic examination to permanently record conditions that exist during that fluoroscopic procedure.

“Spot-image 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. A spot-film device is an older type of spot-image device.

“SSD”. See “source-skin distance”.

“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 reference 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. There is no implication that radiation levels above an SRDL will always cause an injury or that radiation levels below an SRDL will never cause an injury.

“Technique factor” means an exposure control setting that specifies the peak tube potential in kV and

(1) For capacitor energy storage equipment, quantity of charge in mAs; or

(2) For field emission equipment rated for pulsed operation, number of x-ray pulses; or

(3) For CT systems designed for pulsed operation, scan time in seconds and either:

(a) Tube current in mA, x-ray pulse width in seconds and the number of x-ray pulses per scan; or

(b) The product of tube current, x-ray pulse width, and the number of x-ray pulses in mAs;

(4) For CT systems not designed for pulsed operation, either:

(a) Tube current in mA and scan time in seconds; or

(b) 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, either:

(a) Tube current in mA and exposure time in seconds; or

(b) The product of tube current and exposure time in mAs.

“The Report of AAPM Task Group 270” means the report on Display Quality Assurance issued by the American Association of Physicists in Medicine (AAPM), January 2019.

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

“Tomographic plane” means that geometric plane that is identified as corresponding to the output tomogram.

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

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

“Tube housing assembly” means the tube housing with tube installed, including high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.

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

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

“Volumetric dental imaging system” means an x-ray machine that produces, for oral and maxillofacial structures, a three-dimensional tomographic data set or a time sequence of three-dimensional tomographic data sets. A dental x-ray machine only capable of producing a two-dimensional image is not considered to be a volumetric dental imaging system.

"X-ray control" means a device which controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices, which control the technique factors of an x-ray exposure.

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

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

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

(2) “Portable x-ray equipment” means x-ray equipment designed to be hand-carried;

(3) “Stationary x-ray equipment” means x-ray equipment that is installed in a fixed location.

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

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

"X-ray high-voltage generator" means a device that transforms electrical energy from the potential supplied by the x-ray exposure 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 elements.

"X-ray imaging system" or "x-ray system" means an assemblage of components for the controlled production of x-rays.

(1) At a minimum, an x-ray imaging system includes an x-ray high-voltage generator, an x-ray exposure control, a tube housing assembly, a beam-limiting device, and necessary supporting structures.

(2) Additional components such as the image receptor(s) that function with the system are considered integral parts of the system.

"X-ray table" means a patient support device with its patient support structure (tabletop) interposed between the patient and the image receptor or x-ray tube 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-image device beneath the tabletop.

"X-ray tube" means any electron tube that is designed to be used primarily for the production of x-rays.

"X-ray system". See "x-ray imaging system".

GENERAL REGULATORY PROVISIONS

6.3 General and administrative requirements.

6.3.1 Administrative Controls.

6.3.1.1 Each radiation machine used in the healing arts in the State of Colorado shall be registered with the Department as required by Part 2, Section 2.4 and inspected as prescribed in Part 2, Section 2.5.

6.3.1.2 Each radiation machine used on humans shall meet the Federal Performance Standards, Subchapter J - Radiological Health, 21 CFR 1020.30 through 1020.33.

(1) Diagnostic X-ray systems and their associated components used on humans and certified pursuant to the Federal X-Ray Equipment Performance Standard (21 CFR 1020.30 through 1020.33) shall be maintained in compliance with applicable requirements of that standard.

(2) 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 requirement of 21 CFR Part 1020 or Part 6.

(3) The owner of a diagnostic x-ray system who uses the system in a professional or commercial capacity may have the system modified provided the modification does not result in the failure of the system or component to comply with the applicable requirements of Part 6 and any modification is completed by a registered service company in accordance with 6.3.3.1(5).

(a) The owner who causes such modification need not submit the reports required by Part 6, provided the owner records the date and the details of the modification in the system and maintains this information, and provided the modification of the x-ray system does not result in a failure to comply with Part 6.

(b) Registered service companies shall submit to the Department, records of modifications of the x-ray system, as required by these regulations.

(4) Limited exemption from this requirement may be granted by the Department for a radiation machine manufactured prior to August 4, 1974, provided the registrant demonstrates that such exemption will not result in undue risk.

6.3.1.3 The registrant or the registrant's agent shall use approved providers of services, consistent with Part 2, Section 2.6., including but not limited to operation of equipment, inspection of radiation machines and facilities, and assembly, installation, service and/or calibration of radiation machines.

6.3.1.4 An x-ray imaging system that is found to be non-compliant with the requirements of these regulations 30 days beyond initial discovery, may continue to be used for up to 90 days provided:

(1) The system has not been determined to be unsafe for routine use in accordance with Appendix 6D;

(2) Continued use poses no significant radiation risk to patients, members of the public or employees;

(3) Does not significantly result in degraded image quality; and

(4) The registrant obtains in writing, an authorization for continued use from the Department.

6.3.1.5 An x-ray imaging system that is determined as provided in Appendix 6D to be unsafe for human, animal, or other use shall not be operated for diagnostic or therapeutic purposes.

6.3.1.6 A radiation machine in the healing arts shall be operated:

(1) By a physician, chiropractor, dentist, podiatrist or veterinarian who has a current active State of Colorado license to practice the healing arts and has met the applicable requirements of Part 2 of the regulations; or

(2) By an individual authorized by and licensed in accordance with State of Colorado statutes to engage in the healing arts and has met the applicable requirements of Part 2 of the regulations; and

(a) Whose license, licensing body, or licensing regulations and requirements authorize such operation; and

(b) Such operation is within the standard and acceptable scope of practice for the licensed individual; or

(3) By an individual who is under the general supervision of a licensed individual authorized in 6.3.1.6(1) or 6.3.1.6(2), where:

(a) The individual operator being supervised has met the applicable training requirements of Part 2; and

(b) Such supervision by a licensed individual is consistent with the individual's license, licensing body, regulations, and the standard and acceptable scope of practice for the supervising individual.

6.3.1.7 Exposure under Part 6 of any human being to the useful beam of an x-ray system shall be solely for healing arts purposes and only after such exposure has been authorized by:

(1) A physician, chiropractor, dentist, or podiatrist who has a current active State of Colorado license to practice in the healing arts; or

(2) An individual authorized by and licensed in accordance with State of Colorado statutes to engage in the healing arts, and:

(a) Whose license, licensing body, or licensing regulations and requirements permit authorizing such exposure; and

(b) Such exposure is within the standard and acceptable scope of practice for the licensed individual.

6.3.1.8 The requirements of 6.3.1.7 specifically prohibits deliberate exposure for the following purposes:

(1) Exposure of an individual for training, demonstration or other non-healing-arts purposes; and

(2) Exposure of an individual for the purpose of healing arts screening except as authorized by the Department in accordance with Section 6.3.3.4

6.3.1.9 Adequate Radiation Safety Training and Experience for a Radiation Machine Operator.

(1) Each individual who will be operating an x-ray imaging system shall:

(a) Be adequately instructed in the safe operating procedures;

(b) Be competent in the safe use of the equipment; and

(c) Meet each applicable requirement of Part 2, Section 2.6.1.

6.3.1.10 If radioactive materials are also present at the facility, the facility registrant shall coordinate, as appropriate, requirements under Part 6 with any related requirement of the radioactive materials license.

6.3.1.11 The registrant shall maintain for inspection, for each x-ray imaging system, the model and serial number of each tube housing assembly and control panel:

(1) One unique identification number that designates the entire radiation machine shall be permanently assigned by the facility registrant to each radiation machine and provided in all correspondence with the Department.

(a) If feasible, the identification number shall be the “control serial number” in Item 4 on U.S. Food and Drug Administration (FDA) Form 2579, or equivalent.

(2) If available, the serial number(s) from the manufacturer shall be clearly visible as a label or stencil on the control panel and on the tube housing assembly.

(a) Each serial number shall be the same as the corresponding number found on FDA Form 2579, unless prior written approval is obtained from the Department.

(3) If either the control panel or the tube housing assembly serial number from the manufacturer is used as the one unique identification number that designates the entire radiation machine, and then subsequently the designated control panel or the tube housing assembly is replaced, the registrant shall assign a new unique identification number for the entire radiation machine and immediately provide that new number to the Department.

6.3.2 General Specifications for Facility and Equipment Design, Configuration and Preparation.

6.3.2.1 Evaluation of Shielding Design Prior to Commencement of Operation.

(1) The floor plan and equipment configuration of a radiation machine facility shall be designed to meet all applicable requirements of these regulations and in particular to preclude an individual from receiving a dose in excess of the limits in Part 4, Sections 4.6, 4.12, 4.13, 4.14 and 4.15.

(2) The floor plan and equipment configuration of each radiation machine facility shall be submitted to a qualified expert for determination of shielding requirements in accordance with Appendices 6A, 6B and 6C.

(3) The qualified expert shielding design required by 6.3.2.1 shall be completed prior to:

(a) Construction of a new facility;

(b) Any renovation or modification of an existing facility that has a potential to reduce the effectiveness of existing shielding from x-ray radiation; or

(c) Installation of a new radiation machine in an existing facility.

(4) A qualified expert who completes the shielding design required by 6.3.2.1(2) shall provide the shielding design to the facility registrant, including the annotated dimensional drawing specified by 6.3.2.3.

(a) The shielding design shall meet the requirements of Appendix 6C.

(5) The facility registrant shall construct the shielding and configure the equipment in accordance with the recommendation(s) provided by the qualified expert pursuant to 6.3.2.1(4).

6.3.2.2 Evaluation of Shielding Design After Commencement of Operations.

(1) A qualified expert shall review and modify a shielding design, consistent with 6.3.2.1 and Appendices 6A, 6B and 6C, whenever:

(a) A certification evaluation or a survey during operation shows that a dose in excess of a limit in Part 4 is possible;

(b) An existing facility is to be modified such that the existing shielding might be inadequate;

(c) The primary beam orientation is changed;

(d) The primary shielding is altered due to the modification or renovation of a facility;

(e) Mobile or non-hand-held portable x-ray equipment is used frequently and regularly in the same area or room.

(f) Radiation machine workload (for example, mA-minute-per-week workload) has increased or is projected to increase above that which was the basis for the original shielding design; or

(g) The registrant is unable to produce for inspection a written shielding design completed in accordance with 6.3.2.1 and/or 6.3.2.2.

(2) If qualified expert analysis of operating conditions required by 6.3.2.2(1) indicates that an individual might receive a dose in excess of the limits in Part 4, Sections 4.6, 4.12, 4.13, 4.14 or 4.15, then the facility registrant shall modify the shielding and/or equipment configuration in accordance with the recommendation(s) of the qualified expert.

6.3.2.3 Except for facilities exempted in 6.3.2.4, the registrant shall retain a copy of a current dimensional drawing for each room in which a stationary x-ray imaging system is located. The dimensional drawing shall include the following information:

(1) Identification and use of each area adjacent to the x-ray room and an estimation of the extent of occupancy in each such area; and

(2) Results of calculations (as provided by a qualified expert) indicating the type and thickness of material(s) in each protective barrier (for example, lead equivalency):

(a) After installation and, if possible, prior to commencement of operation, consistent with 6.3.2.1; and

(b) Whenever shielding is modified, consistent with 6.3.2.2.

(c) Calculations should be performed prior to construction. When pre-construction calculations are not available, other methods must be used to verify the presence of any necessary shielding.

(3) If the registrant is unable to produce for inspection the calculation(s) required by 6.3.2.3(2), survey(s) shall be conducted by a qualified expert to determine radiation levels present under specified test conditions at the operator's position and at clearly identifiable points outside the room.

(4) The registrant shall maintain for inspection, for each x-ray imaging system for which a shielding design is required:

(a) The installation as-built drawing(s); and

(b) The signed statement required by Part 2, Section 2.7.1.1 and retained in accord with Part 2, Section 2.4.1.1, that all floor plan and equipment configuration specifications in any applicable written shielding designs required by 6.3.2 were explicitly followed.

6.3.2.4 A facility, or room within a facility, where x-ray imaging is conducted, is exempt from the requirements of 6.3.2.1, 6.3.2.2, and 6.3.2.3 under the following conditions:

(1) Only dental intraoral, hand-held intraoral, dental panoramic, mini-c-arm or bone densitometry x-ray equipment is used in the area or room; or

(2) Mobile or portable x-ray equipment is used infrequently in the same area or room and the facility has established a written procedure or policy prescribing any limitations necessary to demonstrate that such use will preclude any individual from receiving a dose in excess of the public or occupational dose limits in Part 4 and that such use is consistent with the As Low As Reasonably Achievable (ALARA) concept of Part 4, Section 4.5.2; or

(3) Exemption for a particular area or room has been applied for in writing and granted by the Department.

6.3.3 General Radiation Safety and Control of Radiation Exposure.

The registrant shall be responsible for directing the operation of the x-ray system(s) under their administrative control and shall assure that the requirements of Parts 1, 2, 4, 6 and 10 are met in the operation of the x-ray system(s).

6.3.3.1 Consistent with Part 4, Section 4.5.1 of the regulations, each facility registrant shall have a radiation protection program. In addition to the provisions necessary for compliance with Part 4, the radiation protection program shall include requirements that:

(1) The use of ionizing radiation be within the registrant's scope of practice for healing arts purposes and shall be performed in accordance with existing laws and regulations;

(2) Portable and mobile x-ray equipment requirements.

(a) Except for dental and veterinary use, portable or mobile x-ray equipment be used only:

(i) For examinations where it is impractical to transfer the patient to a stationary x-ray installation; or

(ii) When the medical status of the patient prohibits transfer of the patient to a stationary x-ray installation.

(b) Each facility develop a written procedure specific to the use of portable and mobile x-ray systems that prescribes the requirements necessary to limit an individual from receiving a dose in excess of the applicable public or occupational dose limits in Part 4 and that such use is consistent with the As Low As Reasonably Achievable (ALARA) concept in Part 4, Section 4.5.2.

(c) The Radiation Safety Officer shall review the implementation of procedures for portable or mobile x-ray equipment use annually.

(3) Except for veterinary use, neither the x-ray tube housing nor the collimating device be held during an exposure with the exception of Department approved devices specifically designed to be hand-held during operation and in accordance with Appendix 6E.

(4) The useful x-ray beam be limited to the area of clinical interest.

(5) All x-ray equipment be installed by a registered service company except those systems that do not require a physical installation to become operational.

(a) For those x-ray systems that do not require a physical installation to initially operate the machine, the facility registrant be responsible for submitting the information required by Part 2, Section 2.7.2.1 through 2.7.2.4 to the department. Such systems may include hand-held x-ray units and certain mobile or portable systems.

(6) All x-ray equipment be used in accordance with the equipment manufacturer's specifications, unless otherwise directed by the licensed practitioner authorized in 6.3.1.6(1) or (2).

(7) The registrant use auxiliary equipment designed to minimize human patient and personnel exposure commensurate with the needed diagnostic information.

The requirements of 6.3.3.1(8) and 6.3.3.1(9) are not applicable to veterinary facilities.

(8) Consideration be given to selecting the appropriate technique and employing available dose reduction methods and technologies across all patient sizes and clinical indications.

(9) A documented procedure be in place for verification of patient identity and exam to be performed, including identification of the appropriate body part.

6.3.3.2 Written safety procedures shall be developed and provided for safe operation of each x-ray imaging system.

(1) The written safety procedures shall be readily available to each individual radiation machine operator prior to operating x-ray imaging equipment.

(2) The operator shall be able to demonstrate familiarity with the procedures applicable to safe use of the system being operated.

(3) The procedures shall include:

(a) Any restriction on the operating technique particular to the system, consistent with 6.3.3.3;

(b) Limitation on beam size, to the smallest area that is clinically necessary, including appropriate collimation:

(i) For each tube with variable collimation, the collimation procedure shall specify whether positive beam limitation (PBL) or manual collimation shall be used; and

(ii) For tubes collimated manually, all images shall provide a positive indication of collimation, except when diagnosis might be compromised;

(c) Patient holding instructions consistent with 6.3.3.8.

(d) Requirements and limitations on the use of portable or mobile x-ray systems consistent with 6.3.3.1(2).

6.3.3.3 To reduce radiation exposure to the minimum that is necessary for general radiographic systems not equipped or not used with an anatomic programming option, protocols shall be documented and readily available to the operator.

(1) Written exam protocol(s) shall be located near each system's control panel or available to the operator in digital form.

(a) The exam protocols shall state the exposure settings to be used corresponding to the patient's (adult and pediatric, if appropriate) body part and anatomical size, or body part thickness, or age (for pediatrics), including but not limited to:

(i) Technique factors (kVp, mAs if manual mode is used);

(ii) Type of image receptor to be used;

(iii) Type of grid, if any;

(iv) Source to image receptor distance to be used, except for intraoral radiography in accordance with 6.7.2.3;

(v) Mode of operation; and

(vi) Type and location of placement of patient shielding if used.

(2) For computed and digital radiography, the exam protocols required by 6.3.3.3(1) shall:

(a) Portray how to determine applicable exposure settings in accord with documented protocol;

(b) Specify a control range for the exposure indicator in accordance with the manufacturer's or RMP recommendation; and

(c) Specify pediatric protocol for each unit that images pediatric patients.

(3) The settings to be used during an exposure shall be indicated before the exposure begins.

(a) If automatic exposure controls are used, the exposure settings that are set prior to the exposure shall be indicated.

(b) The requirement of 6.3.3.3(3) may be met by permanent markings on equipment having fixed exposure settings.

(4) The exam protocol shall be revised as necessary whenever a component is replaced or added.

6.3.3.4 Healing Arts Screening.

(1) Any person proposing to conduct a healing arts screening program on living humans shall not initiate such a program without prior approval of the Department. Authorization for healing arts screening may be granted by the Department provided the registrant demonstrates that such healing arts screening will not result in undue risk.

(a) Each healing arts screening program shall obtain prior written approval by the Department.

(b) Each applicant for Department approval of a healing arts screening program shall submit to the Department a completed Form R-300, "Application for Registration – Healing Arts Screening," including as provided in Part 2, Section 2.4.1.2 all of the information required by Appendix 6F and/or by Form R-300 and any accompanying instructions, together with the required fee(s).

(c) The registrant shall immediately notify the Department if any information related to the healing arts screening program previously submitted to the Department becomes invalid or outdated.

(2) FDA/MQSA-certified facilities that are registered with the department for the use of dedicated mammographic equipment for mammography screening are approved for mammography screening only and are considered to have met the healing arts screening requirements of 6.3.3.4(1).

6.3.3.5 When imaging human patients, the registrant 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 a 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 at least 0.5 millimeter lead equivalent material except where the radiation safety officer has determined that use of protective equipment is not in the best interest of radiation safety for the patient or individuals in the immediate area.

(2) All persons shall be protected from scatter radiation by protective garments, safety equipment or whole body protective barriers of at least 0.25 millimeter lead equivalent material except where the radiation safety officer has determined that use of protective equipment is not in the best interest of radiation safety for the patient or individuals in the immediate area.

(3) Instances may warrant having human patients other than the one being examined in the room during the exam.

(a) If the procedure results in scatter radiation in excess of 0.02 mSv (2 mR) in any one hour at the position of these non-imaged patients, they shall be protected from the scatter radiation by whole body protective barriers or apparel of at least 0.25 millimeter lead equivalent material or shall be positioned so that the 0.02 mSv (2 mR) in any one hour limit is met.

6.3.3.6 Each facility shall have a sufficient number of lead equivalent protective apparel, equipment and shields available to provide the necessary radiation protection to all individuals who are involved with x-ray operations and who are otherwise not shielded.

(1) All protective apparel and auxiliary shields shall be evaluated annually for integrity.

Registrants shall establish a written procedure and criteria for the integrity evaluation and shall:

(a) Visually inspect the protective apparel and shields for breaks, tears or holes that would significantly compromise the protective capability of the equipment;

(b) Perform a tactile test by placing the protective apparel on a smooth surface and feeling for broken or missing shield material.

(2) Protective garments and shields shall be:

(a) Clearly labeled with their lead equivalence;

(b) Hung and not folded to prevent damage, as applicable.

(3) If results of the integrity test indicate breaks, tears, holes, missing material or gaps in that would significantly compromise the protective capability of the material, the protective apparel shall be:

(a) Removed from service and marked as such; or

(b) Repaired or replaced as required.

(4) Records of the integrity check required by 6.3.3.6 shall be maintained by the registrant for 3 years after the integrity checks are completed.

6.3.3.7 Beam collimation, positioning, and shielding of radiosensitive organs from the useful beam that will not interfere with the imaging or medical procedure, or is contraindicated for radiation safety reasons, shall be used to reduce radiation exposure to the patient whenever possible.

6.3.3.8 In cases where a patient or image receptor requires additional support, mechanical support devices shall be used whenever possible. If a patient or image receptor must be provided with additional support during a radiation exposure:

(1) Written safety procedures, as required by 6.3.3.2, shall indicate the requirements for selecting a human holder and the procedure the human holder shall follow.

(2) The human holder shall be instructed in personal radiation safety and protected as required by 6.3.3.2;

(3) No individual shall be used routinely to hold the image receptor or patients 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 at least 0.5 millimeter lead equivalent material except where use of protective equipment would interfere with the examination or is contraindicated for radiation safety reasons.

6.3.3.9 The speed of film, or film-screen combination, imaging plate or receptor and image processing, shall be the fastest speed or speed equivalent consistent with the diagnostic objective of the examinations.

6.3.3.10 If anti-scatter grids are used between the patient and the image receptor to decrease scattered radiation to the image receptor and improve contrast, the grid shall be:

(1) Positioned properly, with the tube side facing the correct direction, and centered to the central ray; and

(2) Of the proper focal distance for the SID being used.

6.3.3.11 When individual exposure monitoring is required by Part 4, Section 4.18, each occupationally exposed individual who is associated with the operation of an x-ray imaging system shall meet the requirements of Part 4, Sections 4.6, 4.10, 4.12, 4.13, 4.14, and 4.18.

(1) When personnel dosimetric monitoring devices are required, they shall be worn in accordance with Part 4, Section 4.6.3.

(2) Each operator of hand-held x-ray equipment shall follow the requirements of Appendix 6E regarding personnel monitoring devices

(3) Deliberate exposure of a personnel dosimetric monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

6.3.4 Maintenance of Records.

6.3.4.1 The registrant shall maintain the following information on each x-ray system for inspection by the Department as specified below:

(1) The records in (a) through (d) are required to be retained for 3 years:

(a) Records of surveys, calibrations, maintenance, and modifications (e.g., major software and hardware upgrades) performed on the x-ray system(s);

(b) Records of certification evaluations pursuant to 2.5, Department Forms 59-1 and 59-2, and corrective actions for each x-ray imaging system with the names of persons who performed such services;

(c) A copy of all correspondence with the Department regarding the x-ray system.

(d) Each facility shall maintain a printed or electronic record containing each patient's identifier, the type of examination(s), machine operator identifier, and the date(s) the examination(s) were performed.

The records in (2) are required to be retained for the life of the system:

(2) Model and serial numbers of all major components, and user's manuals for those components, including software.

The records in (3) and (4) are required to be retained for the life of the facility:

(3) The most recent dimensional drawing and accompanying calculation(s) and/or survey(s) as provided in 6.3.2.3 for each room in which a stationary x-ray system is located, except as exempted under 6.3.2.4.

(4) Consistent with Part 2, Section 2.4.1, and 6.3.2, the registrant shall retain on file at the facility the most recent shielding design along with installer as-built drawings.

6.3.5 Quality Assurance (QA) Program.

6.3.5.1 The registrant shall establish and maintain a quality assurance (QA) program. In addition to the standards in the modality specific sections of Part 6, the registrant shall:

(1) Maintain documentation of credentials for practitioners, radiation safety officers, and x-ray operators, as required by Part 2 of the regulations.

(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 or use standards of an appropriate nationally recognized organization, for example, the American College of Radiology or American Association of Physicists in Medicine.

(4) Evaluate image quality by checking each imaging study for artifacts. If an artifact impacting image interpretation or indicating an imaging system problem is present, the source shall be identified and appropriate action taken.

(5) With the exception of Dental facilities performing only intra-oral, panoramic, cephalometric or volumetric dental imaging, Podiatry facilities, and Veterinary facilities, perform repeat / reject analysis of radiographic images at least quarterly following specifications of a nationally recognized organization.

(6) Perform periodic preventative maintenance on the x-ray systems in accordance with manufacturer requirements or those of nationally accepted standards.

(7) Maintain documentation showing the calibration date and serial number for testing instruments used in determining compliance with the provisions of section 6.3.5. Test instrument calibration frequency shall be consistent with the regulations or nationally accepted standards.

(8) Complete and document an annual review of the QA program.

(9) Retain QA/QC records of evaluations and reviews for no less than three years.

(10) Follow manufacturer's recommendations for image processing systems, except where otherwise specified in the regulations or where it is inconsistent with nationally accepted standards.

6.3.5.2 Each registrant that uses analog image receptors (e.g., radiographic film) shall have available suitable equipment for handling and processing radiographic film in accordance with the following provisions:

Manually developed film:

(1) Processing tanks shall be constructed of mechanically rigid, corrosion resistant material; and

(2) Developing solutions shall be prepared, replenished, and replaced following manufacturer recommendations.

(3) 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, use the time-temperature chart found in Appendix 6H;

(4) Devices shall be utilized which will indicate the actual temperature of the developer solution and signal the passage of a preset time.

(5) Measure and log developer temperature each day of use;

(6) Document in a written log the change of developer chemicals at least every month.

Automatic processors and other closed processing systems:

(7) Shall be operated and maintained following manufacturer specifications.

(8) 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 chart in Appendix 6G.

6.3.5.3 Deviations from the processing requirements of 6.3.5.2 shall be documented by the registrant in such manner that the requirements are shown to be met or exceeded (e.g., extended processing, and special rapid chemistry).

6.3.5.4 Additional requirements for facilities using x-ray film

(1) All film storage and 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.

(6) The film and intensifying screen shall be spectrally compatible.

(7) Facilities shall maintain a light-tight darkroom or closed processing system, 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 or an event that may impact the integrity of the closed processing system.

(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, an RMP, or a nationally recognized organization.

(b) Maintain a light-tight darkroom or processing system 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.

6.3.5.5 Facilities Using Computed Radiography (CR), Digital Radiography (DR), or Direct Digital Radiography (DDR).

(1) Facilities shall establish and follow an image quality control program in accord with the recommendations of an RMP, the system manufacturer, or a nationally recognized organization.

(2) In addition to 6.3.5.5(1), CR facilities shall perform erasure of all CR cassettes, at least on a weekly basis.

6.3.5.6 The registrant shall ensure that each monitor under the control of the registered facility used for primary image interpretation is evaluated according to specifications of the manufacturer and/or a registered medical physicist and/or a nationally recognized organization, for example, in The Report of AAPM Task Group 270 (January 2019), or AAPM Online Report OR-03 (April 2005), including but not limited to:

(1) Frequent careful cleaning of each primary image interpretation workstation and data acquisition workstation monitor;

(2) Periodic visual assessment using nationally accepted test patterns appropriate for the evaluation;

(3) Verification that monitor calibration conforms with the DICOM Part 14 Grayscale Standard Display Function, or equivalent:

(a) Visualization of low contrast patches;

(b) Visualization of spatial resolution targets;

(c) Evaluation of ambient light levels;

(d) Measurement of the luminance from a sufficient number of driving levels;

(e) Measurements to assure that the luminance for multiple monitors are within 10% of each other when more than one monitor is being utilized at a primary image interpretation workstation.

(4) The requirements of 6.3.5.6(1) through (3) must be completed initially, annually, and when a monitor is replaced or undergoes a significant repair.

(5) For monitors used in mammography image interpretation, the applicable monitor QA requirements of MQSA shall be followed.

6.4 Requirements for use of all diagnostic and interventional x-ray imaging systems.

6.4.1 Administrative Controls.

6.4.1.1 In addition to the general requirements of 6.3, the requirements of 6.4 apply to all diagnostic and interventional x-ray imaging systems and associated facilities, except as provided by 6.7.5.1 for dental uses and 6.8.5.1 for veterinary uses.

Additional requirements specific to dental intra-oral, panoramic, cephalometric, and volumetric dental imaging equipment are included in Section 6.7.

6.4.1.2 Each individual who operates an x-ray imaging system used on living humans shall meet the applicable radiation safety training and experience requirements of Part 2, Section 2.6.1.

6.4.2 Each diagnostic x-ray imaging system shall meet the following equipment design and configuration requirements.

6.4.2.1 Warning Label.

(1) On systems manufactured on or before June 10, 2006, the control panel containing the main power switch shall bear this or an equivalent warning statement, or the warning statement in 6.4.2.1(2), legible and accessible to view:

"WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

(2) 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."

6.4.2.2 Battery Charge Indicator.

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

6.4.2.3 Leakage Radiation from the Diagnostic Source Assembly.

(1) 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 (100 milliroentgen (mR) exposure) in any 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.

(2) Compliance shall be determined by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm.

6.4.2.4 Radiation from Components Other Than the Diagnostic Source Assembly.

(1) The radiation emitted by a component other than the diagnostic source assembly shall not exceed an air kerma of 18 microgray (μGy) (2 milliroentgens (mR) exposure) in any one hour at 5 cm 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.

(2) Compliance shall be determined by measurements averaged over an area of 100 square centimeters (cm) with no linear dimension greater than 20 cm.

6.4.2.5 Beam Quality: Half-value Layer

(1) The half-value layer of the useful beam for a given x-ray tube potential shall not be less than the values shown in Appendix 6I.

(2) If it is necessary to determine such half-value layer at an x-ray tube potential that is not listed in Appendix 6I, linear interpolation or extrapolation is acceptable. 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.

(3) Optional filtration on fluoroscopic systems. Fluoroscopic systems manufactured on or after June 10, 2006, incorporating an x-ray tube(s) with 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 6.4.2.5. 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.

(4) For capacitor energy storage x-ray equipment still in use, compliance with the applicable requirements of 6.4.2.5 shall be determined with the system fully charged and for the highest clinically used mAs.

(a) Due to reduced image quality and potential for higher patient exposures, capacitor energy storage x-ray equipment shall no longer be used for human patient imaging beyond January 1, 2022.

6.4.2.6 Tube Heads.

(1) 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.

(2) Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes that have been selected shall be clearly indicated prior to initiation of the exposure. Only the selected tube(s) can be energized.

(a) This indication shall be both on the x-ray control panel and at or near the tube housing assembly that has been selected.

(3) Information displayed at the tube housing assembly meet manufacturer's specifications.

6.4.2.7 Locks.

(1) All position locking, holding, and centering devices on the x-ray system and/or components shall function as intended.

6.4.2.8 The x-ray control shall provide:

(1) Visual indication observable at or from the operator's protected position whenever x-rays are produced; and

(2) A signal audible to the operator to indicate that the exposure has terminated.

6.5 Requirements for use of a fluoroscopy system.

6.5.1 In addition to the provisions of 6.3 and 6.4, the requirements of 6.5 apply to all fluoroscopic facilities and equipment used for fluoroscopic imaging or for recording images from the fluoroscopic image receptor.

6.5.1.1 Only image-intensified or direct-digital receptor fluoroscopic equipment shall be used for fluoroscopy.

6.5.2 Primary Protective Barrier.

6.5.2.1 Limitation of useful beam.

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

(2) The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam.

(3) 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.

(4) Radiation therapy simulation systems shall be exempt from 6.5.2.1 provided the systems are intended only for remote control operation.

6.5.2.2 Measuring compliance.

(1) The AKR shall be measured in accordance with 6.5.5.

(2) 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.

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

(4) If the source is above the tabletop and the SID is variable, the AKR 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.

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

(6) For all AKR 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.

6.5.3 Field Limitation.

6.5.3.1 Angulation.

(1) 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.

(2) Compliance with 6.5.3.5 and 6.5.3.6 shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

6.5.3.2 Further means of limitation.

(1) Means shall be provided to permit further limitation of the x-ray field to sizes smaller than the limits of 6.5.3.5 and 6.5.3.6.

(2) 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 cm^2, shall be provided with means for stepless adjustment of the x-ray field.

(3) Equipment with a fixed SID and the capability of a visible area of no greater than 300 cm^2 shall be provided with either:

(a) Stepless adjustment of the x-ray field; or

(b) A means to further limit the x-ray field size at the plane of the image receptor to 125 cm^2 or less.

(4) 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.

(5) Compliance with 6.5.3.2 shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(a) Measurement shall be made in perpendicular directions corresponding to the vertical and horizontal directions on the video monitor image.

(b) For collimating systems that are not circular, measurement shall be made along the directions closest to the vertical and horizontal direction on the video monitor image yielding the smallest dimension in each direction.

6.5.3.3 Spot-image devices.

The following requirements shall apply to spot-image devices, except when the spot-image device is provided for use with a radiation therapy simulation system:

(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-image selector.

(a) 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.

(b) 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.

(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.

(a) The sum, without regard to sign, of the length and width differences shall not exceed 4 percent of the SID.

(b) On spot-image 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.

(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.

(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:

(a) For spot-image 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

(b) For spot-image 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.

6.5.3.4 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"

6.5.3.5 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:

(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.

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

(2) For fluoroscopic equipment manufactured on or after 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:

(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

(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.

6.5.3.6 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:

(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.

(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.

6.5.3.7 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

6.5.4 Activation of Tube.

6.5.4.1 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.

6.5.4.2 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.

6.5.5 Air Kerma Rates.

6.5.5.1 Except for fluoroscopic equipment used for radiation therapy simulation purposes, the following requirements apply to 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 (10 R/min exposure rate) at the measurement point specified in 6.5.5.4, except as specified in 6.5.5.1(5).

(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 (5 R/min exposure rate) at the measurement point specified in 6.5.5.4, except as specified in 6.5.5.1(5).

(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 (10 R/min exposure rate) in either mode at the measurement point specified in 6.5.5.4, except as specified in 6.5.5.1(5).

(4) Equipment may be modified in accordance with this Part to comply with 6.5.5.2. When the equipment is modified, it shall bear a label indicating the date of the modification and the statement:

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

(5) The AKR requirements of 6.5.5.1(1) through (3) are not applicable during:

(a) Recording of (spot) fluoroscopic images; or

(b) Operation in high-level control mode(s) as equipped.

6.5.5.2 Except for fluoroscopic equipment used for radiation therapy simulation purposes, the following requirements apply to 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 (5 R/min exposure rate) at the measurement point specified in 6.5.5.4. Provision for manual selection of technique factors may be provided.

(2) Shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (10 R/min exposure rate) at the measurement point specified in 6.5.5.4, except as specified in 6.5.5.2.(3).

(3) The AKR limits of 6.5.5.2(1) and (2) are not applicable to 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.

(4) The AKR limits of 6.5.5.2(1) and (2) are not applicable to: equipment manufactured on or after June 10, 2006:

(a) During recording of spot images from the fluoroscopic image receptor;

(b) To images resulting from a last-image-hold feature that are not recorded;

(c) During operation in high-level control mode(s) as equipped.

6.5.5.3 Except for fluoroscopic equipment used for radiation therapy simulation purposes, the following requirements apply to 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 (20 R/min exposure rate) at the measurement point specified in 6.5.5.4.

(2) Special means of activation of high-level controls shall be required.

(a) The high-level control shall be operable only when continuous manual activation is provided by the operator.

(b) A continuous signal audible to the fluoroscopist shall indicate that the high-level control is employed.

6.5.5.4 Measuring compliance.

Except for fluoroscopic equipment used for radiation therapy simulation purposes, the following requirements apply to compliance with 6.5.5.1 through 6.5.5.3 and 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.

(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.

(3) For 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.

(4) For a C-arm type of fluoroscope having an SID less than 45 cm, the AKR shall be measured at the minimum SSD.

(5) For a fixed 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.

(a) 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.

(6) For fluoroscopic systems not specifically addressed in 6.5.5.4(1) through (5) above, the RMP shall determine the measurement point(s) representing the highest expected dose rate and which is based on nationally accepted standards and practices.

6.5.6 Indication of potential and current.

6.5.6.1 During fluoroscopy and cinefluorography, x-ray tube potential and current shall be continuously indicated.

6.5.6.2 Deviation of x-ray tube potential and current from the indicated value shall not exceed the maximum deviation as stated by the manufacturer.

6.5.7 Source-skin distance.

6.5.7.1 Means shall be provided:

(1) 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.

(2) In addition, for fluoroscopes intended for specific surgical or interventional applications that would be prohibited at the source-skin distances specified in 6.5.7.1(1), provisions may be made for operating at shorter source-skin distances but in no case less than 20 cm, provided a process for such use is justified and documented in the facility procedures and is periodically reviewed by the FGI procedures committee or RMP.

6.5.7.2. 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.

(1) Such systems shall be labeled for extremity use only; and

(2) For those systems intended for specific surgical or interventional applications that would be prohibited at the source-skin distance specified in 6.5.7.2, provisions may be made for operation at shorter source-skin distances but in no case less than 10 cm, provided a process for such use is justified and documented in the facility procedures and is periodically reviewed by the FGI procedures committee or RMP.

6.5.8 Fluoroscopic irradiation time, display, and signal.

6.5.8.1 Fluoroscopic equipment manufactured before June 10, 2006:

(1) Shall be provided with means to preset the cumulative irradiation time of the fluoroscopic tube.

(a) The maximum cumulative time of the timing device shall not exceed 5 minutes without resetting.

(b) A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative irradiation time.

(c) Such signal shall continue to sound while x-rays are produced until the timing device is reset.

(d) Fluoroscopic equipment may be modified in accordance with 21 CFR 1020.30(q) to comply with the requirements of 6.5.8.1.

(e) When the equipment is modified, it shall bear a label indicating the statement:

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

(2) As an alternative to the requirements of 6.5.8.1, 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.

6.5.8.2. 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 6.5.8.2(2). The following requirements apply:

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

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

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

(2) A signal audible to the fluoroscopist shall sound for each passage of 5 minutes of fluoroscopic irradiation time during an examination or procedure.

(a) The signal shall sound until manually reset or, if automatically reset, for at least 2 seconds.

6.5.9 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.

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

6.5.9.2 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.

6.5.9.3 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.

6.5.10 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:

6.5.10.1 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.

6.5.10.2 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.

6.5.10.3 The display of the AKR shall be clearly distinguishable from the display of the cumulative air kerma.

6.5.10.4 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.

(1) For fluoroscopes with x-ray source below the x-ray table, x-ray source above the table, or of fixed lateral type, the reference location shall be the respective locations specified in 6.5.5.4(1). 6.5.5.4(2), or 6.5.5.4(5).

(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.

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

6.5.10.6 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.

(1) Compliance shall be determined with an irradiation time greater than 3 seconds.

6.5.11 Protection from scatter radiation.

6.5.11.1 For stationary fluoroscopic systems, ancillary shielding, such as drapes, self-supporting curtains, or viewing shields, shall be available and used as supplemental protection for all individuals other than the patient in the room during a fluoroscopy procedure.

6.5.11.2 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 6.5.11.1 shall be maintained to the degree possible under clinical conditions;

(2) All persons, except the patient, in the room where fluoroscopy is performed shall wear protective apparel (aprons) or shall be positioned behind a stationary or portable shield that provides a lead equivalent shielding of at least 0.25mm;

(3) The fluoroscopic field size shall be reduced to the minimum required for the procedure being performed (area of clinical interest); and

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

6.5.12 Fluoroscopy specific operator qualifications

6.5.12.1 Operation of a fluoroscopic x-ray system shall be performed under direct supervision.

6.5.12.2 In addition to the applicable sections of these regulations, all persons operating or supervising the operation of a fluoroscopic x-ray system (including for FGI procedures) for clinical purposes on living humans shall be limited to persons meeting the applicable requirements of 6.3.1.6, 6.3.1.9, and Part 2, Section 2.4.5.5, and 2.6.1.5.

6.5.13 Equipment operation

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

6.5.13.2 Operators shall be instructed in accordance with Part 2 requirements.

6.5.13.3 Procedure planning for fluoroscopic procedures on pregnant patients shall include feasible modifications to minimize the dose to the conceptus.

6.5.13.4 Procedure planning for fluoroscopic procedures on pediatric patients shall include feasible modifications to minimize dose.

6.5.13.5 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.

(1) Consistent with facility policy and procedures, the operator shall use methods available on the fluoroscopy system to monitor dose during a fluoroscopic procedure.

(2) The written policy shall include a requirement to designate a person in the room to notify the operator that a SRDL or other dose metric value specified in the facility policy is approaching or has been exceeded.

6.5.14 Registered Medical Physicist evaluations of fluoroscopic equipment.

6.5.14.1 Fluoroscopic equipment shall be evaluated by a RMP within 90 days of installation and following maintenance of the system that may affect the exposure rate. Thereafter, the measurements shall be made as specified in Part 2, Section 2.5.

At a minimum these evaluations shall include:

(1) A measurement of entrance exposure rates that covers a representative sample 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, and acquisition, 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 Section 6.5.5.4.

(3) An evaluation of image quality in the modes necessary to achieve the clinical imaging task(s).

(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 mode. Additional evaluation may be needed where magnification impacts collimation.

(6) An evaluation of the availability and accuracy of technique indicators and integrated radiation dose displays.

(7) An evaluation of changes to the fluoroscopy system impacting radiation safety.

(8) When operating in the spot image mode, an evaluation of the coefficient of variation of air kerma for both manual and automatic exposure control systems to ensure the value does not exceed 0.05.

6.5.14.2 Measurements required in 6.5.14.1 shall be:

(1) Performed in accordance with manufacturer recommendations or nationally accepted standards using a calibrated dosimetry system;

(2) Dosimetry systems used for measurements shall be calibrated in accordance with manufacturer recommendations or nationally accepted standards not to exceed 2 years.

(3) Records indicating the model, serial number and calibration date of equipment used for dosimetry calibrations on FGI systems shall be maintained for 3 years for inspection by the Department.

6.5.15 Additional requirements for facilities performing fluoroscopically-guided interventional (FGI) procedures.

The requirements of 6.5.15 and other requirements associated with an FGI Procedure Committee in 6.5.15 shall become effective on or after January 1, 2022.

6.5.15.1 A registrant performing FGI procedures shall establish a FGI Procedure Committee in accordance with the following:

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

(2) Two or more registrants may form a cooperative FGI Procedure Committee as long as each facility has a representative on the committee; and

(3) If the registrant has already established a radiation safety committee, the requirements of 6.5.15 may be delegated to that committee if the members meet the requirements of 6.5.15.5.

6.5.15.2 At a minimum the FGI Procedure Committee members in 6.5.15.5(1) through (3) shall meet as often as necessary to conduct business, but at intervals not to exceed 12 months.

6.5.15.3 A record of each FGI Procedure Committee meeting shall include the date, names of individuals in attendance, minutes of the meeting, and any actions taken. The registrant shall maintain the record for 3 years for inspection by the Department.

6.5.15.4 Provide an annual report summarizing the details and activities of the FGI Procedure Committee to the radiation safety committee or radiation safety officer, in the absence of a radiation safety committee.

6.5.15.5 FGI Procedure Committee members shall include but not be limited to the following individuals involved in FGI procedures:

(1) A supervising physician of the healing arts who meet the requirements in 6.3.1.6(1);

(2) A Registered Medical Physicist;

(3) A technologist, where applicable

(4) A licensed individual who meets the requirements of 6.3.1.6(2), where applicable; and

(5) Other individuals as deemed necessary by the registrant.

6.5.15.6 Establish and implement FGI procedures

(1) The registrant shall establish and implement written procedures, or procedures documented in an electronic recordkeeping 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) Methods for patient radiation dose management during FGI procedures.

(c) Establishing dose metric notification levels for fluoroscopy procedures at which point the physician, or other authorized operator is notified.

(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 processes and procedures at an interval not to exceed 12 months.

(2) A record of each procedure developed by the registrant shall be maintained for inspection by the Department. If the registrant revises a procedure, documentation shall be maintained that includes the justification for the revision and the previous procedure for inspection by the Department.

(3) The FGI Procedure Committee shall review and approve the procedures developed or modified under 6.5.15.6.

6.5.16 Procedures for maintaining records for fluoroscopic systems

6.5.16.1 A record of radiation output information shall be maintained in the event a dose reconstruction calculation or estimate is necessary in accordance with established procedures. The record shall include the following:

(1) Operator identification;

(2) Patient identification;

(3) Type and date of examination;

(4) Identification of the fluoroscopic system used; and

(5) Peak skin dose, cumulative air kerma or dose area product used, beam entry angle(s), and patient position if the information is available on the fluoroscopic system.

(6) If the peak skin dose, cumulative air kerma or dose area product are not displayed on the fluoroscopic system, records shall include other available information in the event a dose reconstruction calculation or estimate is necessary in accordance with established procedure or the following as necessary:

(a) Fluoroscopic mode, such as, high-level or pulsed mode of operation;

(b) Cumulative fluoroscopic exposure time; and

(c) Number of films or recorded exposures.

(7) The registrant shall maintain records required by 6.5.16.1 for inspection by the Department for 3 years.

6.6 Requirements for use of general purpose x-ray imaging systems

6.6.1 Administrative controls.

6.6.1.1 The requirements of Section 6.6 apply to all registrants using general diagnostic imaging systems, excluding the following:

(1) Fluoroscopy use which is described in 6.5;

(2) Dental use which is described in 6.7;

(3) Veterinary use which is described in 6.8;

(4) Computed tomography use which is described in 6.9;

(5) Mammography use which is described in 6.10.

6.6.1.2 Certification evaluation (testing) requirements.

(1) Within 90 days of use:

(a) Digital radiographic systems shall have an initial certification evaluation performed by a RMP;

(b) Non-digital radiographic systems shall have an initial certification evaluation performed by a Qualified Inspector authorized for the specific machine type.

(2) Periodic certification evaluations shall be performed at the frequency specified in Part 2, Section 2.5 by Qualified Inspectors authorized for the specific machine type.

(3) Testing of display monitors which are under the control of the registrant shall be performed by or under the supervision of an RMP in accordance with 6.3.5.6.

(4) Certification evaluations and testing shall follow nationally accepted standards or those recognized by the Department.

6.6.2 Field limitation and alignment for mobile, portable, and stationary general purpose x-ray systems. Mobile, portable, and stationary general purpose radiographic x-ray systems shall meet the following requirements:

6.6.2.1 Variable x-ray field limitation. A means for stepless adjustment of the size of the x-ray field shall be provided.

(1) Each dimension of the minimum field size at an SID of 100 cm shall be equal to or less than 5 cm.

6.6.2.2 Visual definition. Means for visually defining the perimeter of the x-ray field shall be provided.

(1) The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed two (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.

(2) A light localizer used to define the x-ray field of a certified system shall provide illumination sufficient to permit visual determination of the x-ray field under ambient light conditions of up to 500 lux (46 foot candles).

6.6.2.3 Field indication and alignment on stationary general purpose x-ray equipment. Except when spot-image devices are in use, stationary general purpose x-ray systems shall meet the following requirements in addition to those prescribed in 6.6.2.

(1) Means shall be provided to:

(a) Indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor;

(b) Align the center of the x-ray field with respect to the center of the image receptor to within two (2) percent of the SID; and

(c) Indicate the SID to within two (2) percent.

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

(3) Indication of field size dimensions and SID's shall be specified in inches and/or cm, and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor that correspond to those indicated by the beam-limiting device to within two (2) percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

(4) Compliance measurements will be made at discrete SIDs and image receptor dimensions in common clinical use or at any other specific dimensions at which the beam-limiting device or its associated diagnostic x-ray system is uniquely designed to operate.

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

(1) X-Ray Systems Designed for One Image Receptor Size.

(a) 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 the image receptor to within two (2) percent of the SID; or

(b) Radiographic equipment designed for only one image receptor size at a fixed SID 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 any edge of the image receptor.

6.6.2.5 Beam Limitation Requirements for Each X-Ray System Not Governed by 6.6.2.1 through 6.6.2.4:

(1) Which are also designed for use with extraoral image receptors and when used with an extraoral image receptor shall:

(a) Be provided with means to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than two (2) percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor; and

(b) Be provided with means to align the center of the x-ray field with the center of the image receptor to within two (2) percent of the SID, or means shall be provided 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 any edge of the image receptor.

(2) The requirements of 6.6.2.5(1) may be met with a system that meets the requirements for a general purpose x-ray system as specified in 6.6.2 and 6.6.2.3, or, when alignment means are also provided, may be met with either:

(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 with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

(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.

6.6.2.6 Positive Beam Limitation (PBL). The requirements of 6.6.2.6 shall apply to radiographic systems which contain PBL.

(1) Field size. When a PBL system is provided, it shall prevent x-ray production when:

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

(b) The sum of the length and width differences as stated in 6.6.2.6(1)(a) without regard to sign exceeds four (4) percent of the SID.

(c) The beam-limiting device is at a SID for which PBL is not designed for sizing.

(2) Conditions for PBL. When provided, the PBL system shall function as described in 6.6.2.6(1) whenever all the following conditions are met:

(a) The image receptor is inserted into a permanently mounted cassette holder;

(b) The image receptor length and width are less than 50 cm;

(c) The x-ray beam axis is within ± three (3) degrees of vertical and the SID is 90 cm to 130 cm inclusive; or the x-ray beam axis is within ± three (3) degrees of horizontal and the SID is 90 cm to 205 cm inclusive;

(d) The x-ray beam axis is perpendicular to the plane of the image receptor to within ± three (3) degrees;

(e) Neither tomographic nor stereoscopic radiography is being performed;

(3) Measuring compliance.

(a) Compliance with the requirements of 6.6.2.6(1) shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of 6.6.2.6(2) are met; and

(b) Compliance shall be determined no sooner than 5 seconds after insertion of the image receptor.

(4) Override of PBL.

(a) A capability may be provided for overriding PBL in case of system failure and for servicing the system.

(b) This override may be for all SIDs and image receptor sizes.

(c) A key shall be required for any override capability that is accessible to the operator.

(i) It shall not be possible to remove the key while PBL is overridden.

(ii) Each such key switch or key shall be clearly and durably labeled as follows:

"FOR X-RAY FIELD LIMITATION SYSTEM FAILURE"

(d) The override capability is considered accessible to the operator:

(i) If it is referenced in the operator's manual, or in other materials intended for the operator; or

(ii) If its location is such that the operator would consider it part of the operational controls.

(e) Not be used as a substitute for prompt repair.

(5) 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.

(a) Each dimension of the minimum field size at an SID of 100 cm shall be equal to or less than 5 cm.

(b) Return to PBL function as described in 6.6.2.6(1) shall occur automatically upon any change of image receptor size or SID.

(6) 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.

6.6.3 Radiation Exposure Control.

6.6.3.1 Exposure initiation

(1) Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action.

(2) 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.

6.6.3.2 Exposure Indication

(1) Means shall be provided for visual indication observable at or from the operator’s protected position whenever x-rays are produced.

(2) In addition, a signal audible to the operator shall indicate that the exposure has terminated.

6.6.3.3 Timers.

(1) Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.

(a) 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.

(b) Except during panoramic dental radiography, termination of exposure shall cause automatic resetting of the timer to its initial setting or to “zero”.

(c) 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.

6.6.3.4 X-ray Control.

(1) Except for only bone densitometry systems, hand-held intraoral systems, each x-ray control shall be located in such a way as to meet the following requirements:

(a) Stationary radiographic systems.

Stationary radiographic systems shall be required to have the x-ray control, including the exposure switch, permanently mounted in a protected (shielded) area so that the operator is required to remain in that protected area during the entire exposure. Design of the operator protected area shall be consistent with Appendix 6B.

(b) Mobile and portable systems.

When any one or combination of mobile or portable x-ray systems are:

(i) Used daily for seven (7) or more consecutive working days in the same location (a room or area), the system(s) shall meet the requirements of a stationary system in 6.6.3.4(1)(a), or the facility shall employ the use of at least one of the items in 6.6.3.4(b)(ii) and establish a written procedure or policy prescribing any limitations necessary to demonstrate that such use will preclude any individual from receiving a dose in excess of the public or occupational dose limits in Part 4 and that such use is consistent with the As Low As Reasonably Achievable (ALARA) concept of Part 4, Section 4.5.2;

(ii) Used daily for less than seven (7) consecutive working days in the same location (a room or area), shall be provided with at least one of the following:

1. A lead-equivalent protective barrier at least 2 meters (more than 6 feet) high for operator protection during exposures; or

2. Means to allow the operator to be at least 2 meters (more than 6 feet) from the patient, x-ray tube and the useful beam during the exposure; or

3. A lead-equivalent protective garment with thyroid shielding.

(c) Podiatry facilities shall meet the protection requirements in 6.6.3.4(1)(b)(ii).

(2) 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.

(a) When automatic exposure controls are used, the exposure settings that are set prior to the exposure shall be indicated.

(b) On equipment having fixed technique factors, the requirement of 6.6.3.4(2)(a) may be met by having permanent markings on the equipment. Technique factors shall be visible from the operator's position except when performing spot imaging during fluoroscopy.

(c) 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.

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

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

(2) When the x-ray tube potential is equal to or greater than 51 kilovolts peak (kVp), the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two (2) pulses;

(3) The minimum exposure time for all other equipment other than that specified in 6.6.3.5(2) shall be equal to or less than one-sixtieth (1/60) second or a time interval required to deliver 5 miliampere seconds (mAs), whichever is greater;

(4) 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 that, 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 2000 mAs per exposure; and

(5) A visible signal shall indicate when an exposure has been terminated at the limits required by 6.6.3.5(4), and manual resetting shall be required before further automatically timed exposures can be made.

6.6.3.6 Accuracy.

(1) Deviation of technique factors under Section 6.6.3.3 and 6.6.3.5 from indicated values shall not exceed the limits given by the manufacturer.

(2) If manufacturer specifications are not available, the following criteria shall be used:

(a) The kVp shall not deviate from indicated values by more than ten (10) percent.

(b) The timer accuracy shall not deviate from indicated values by more than:

(i) Ten (10) percent for an indicated time of greater than 20 ms; or

(ii) Fifty (50) percent for an indicated time of 20 ms or less, or 1 pulse, whichever is greater.

6.6.3.7 Reproducibility.

(1) Coefficient of variation. For any specific combination of selected technique factors, the estimated coefficient of variation of the air kerma shall be no greater than 0.05.

(2) Measuring compliance.

(a) Determination of compliance shall be based on 10 (or as otherwise specified in nationally accepted standards) consecutive measurements of air kerma taken within a time period of 1 hour.

(b) 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.

(c) 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 operations or no less than one-tenth second.

6.6.3.8 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 value:

(1) For equipment having independent selection of x-ray tube current (mA), the average ratios of air kerma to the indicated milliampere-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.

(2) 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 milliampere-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.

(3) Measuring compliance.

(a) Determination of compliance will be based on 10 exposures (or as specified in nationally accepted standards), made within 1 hour, at two or more settings over a range of clinically relevant mAs values.

(i) These 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.

(ii) For purposes of this requirement, focal spot size is the focal spot size specified by the x-ray tube manufacturer.

6.6.3.9 Source-Skin Distance.

(1) Each mobile, portable or hand-held radiographic x-ray imaging system shall be provided with means to limit the source-skin distance to equal to or greater than 30 cm.

(2) The minimum source-skin distance shall not be less than 30 cm, excluding dental systems addressed in 6.7, and veterinary systems addressed in 6.8.

6.6.3.10 Exposure Reproducibility.

(1) When all exposure settings are held constant, including control panel selections associated with automatic exposure control systems the coefficient of variation of air kerma for both manual and automatic exposure control systems shall not exceed 0.05.

6.6.3.11 Radiation from Capacitor Energy Storage Equipment.

Radiation emitted from the x-ray tube shall not exceed:

(1) An air kerma of 0.26 microGy (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.

(a) Compliance shall be determined by measurements averaged over an area of 100 cm, with no linear dimensions greater than 20 cm; and

(2) An air kerma of 0.88 milliGy (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.

(a) 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).

(b) The measurements shall be averaged over an area of 100 square cm with no linear dimension greater than 20 cm.

6.6.4 Tube stands for portable 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 that are not intended to be hand-held during operation.

6.7 Requirements for use of dental imaging systems.

6.7.1 Administrative Controls.

6.7.1.1 Intraoral dental x-ray machines shall not be operated at less than a measured 51 kVp, after January 1, 2022.

6.7.1.2 All dental facilities using any type of x-ray equipment for dental x-ray imaging, shall:

(1) Follow the applicable requirements of 6.3 and 6.4;

(2) Follow the applicable requirements of this Section 6.7

6.7.1.3 In addition to the requirements of 6.7.1.2, dental facilities using cone beam computed tomography (CBCT) x-ray equipment for dental x-ray imaging, shall also follow the requirements of Section 6.9 that are applicable to CBCT.

6.7.1.4 Quality assurance. In addition to the general quality assurance provisions in Section 6.3, the following requirements apply to a dental facility:

(1) If using a filmless system, maintain and operate PSP and DDR systems according to manufacturer specifications, or nationally accepted standards.

(2) If using film:

(a) Maintain a light tight darkroom or processor system;

(b) Use proper safelighting and safeguards; and

(c) Evaluate darkroom or processor system integrity and daylight loading systems for film fog every six months and after a change that may impact film fog.

6.7.1.5 Each individual who operates a dental x-ray imaging system shall meet the applicable adequate radiation safety training and experience requirements of 2.6.1, in particular 2.6.1.11.

(1) Records of training shall be maintained for inspection by the Department in accordance with Part 2, Section 2.6.6.4.

6.7.2 Each dental x-ray imaging system shall meet the following equipment design and configuration requirements.

6.7.2.1 Warning Label.

(1) Warning labels shall be maintained in accordance with 6.4.2.1.

6.7.2.2 Cephalometric and volumetric dental imaging systems shall meet the equipment design and configuration requirements of 6.3.2 and 6.6.2, except that:

(1) The shielding design described in 6.3.2 is required for the imaging room(s) of any facility having a cephalometric or volumetric dental imaging system, or a system that can be operated in a cephalometric mode regardless of the occupancy of adjoining rooms.

(2) A dental facility may apply to the Department in writing and may be granted an exemption from the requirements of 6.7.2.2 for a particular room and x-ray equipment configuration.

6.7.2.3 Intraoral and panoramic dental x-ray systems shall meet the following requirements:

(1) The useful x-ray beam shall be limited to the area of clinical interest.

(2) Source-Skin Distance (SSD) for Intraoral Dental X-ray Systems.

(a) X-ray imaging system designed for use with an intraoral image receptor shall be provided with means to limit the SSD, to not less than 18 cm if operable above 50 kVp.

(3) Field Limitation for Intraoral Dental X-ray Systems.

(a) Each x-ray imaging system designed for use with an intraoral image receptor shall be provided with means to limit the beam such that:

(i) If the minimum SSD is 18 cm or more, the x-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than 7 cm; and

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

(b) Excluding hand-held units, endodontic procedures, and those procedures which require a broader exposure field, after January 1, 2025, only rectangular collimators shall be used for routine intraoral dental imaging.

(4) As provided in 6.3.2.4, neither the shielding design described in 6.3.2 nor the dimensional drawing, calculation or survey described in 6.3.2.3 are required for intraoral or panoramic dental equipment.

6.7.2.4 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.

The requirements of 6.7.2.4(1) may be met with:

(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

(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.

6.7.2.5 Modification of diagnostic x-ray components and systems shall be done only in accordance with 6.3.1.2(3).

6.7.3 Each dental x-ray imaging system shall meet the following radiation exposure operational control requirements.

6.7.3.1 Cephalometric and volumetric beam dental x-ray systems shall meet the radiation exposure control requirements of 6.6.3:

6.7.3.2 Intraoral and panoramic dental x-ray systems shall meet the following radiation exposure control requirements:

(1) Timers.

(a) Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.

(b) 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.

(c) Termination of exposure shall cause automatic resetting of the timer to its initial setting or to "zero".

(d) Timer Reproducibility.

(i) With a timer setting of 0.5 seconds or less, the average exposure period (T_{avg}) shall be greater than or equal to five (5) times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when four (4) timer tests are performed: $T_{avg} \geq 5(T_{max} - T_{min})$.

(2) X-ray Control for Intraoral or Panoramic Dental X-ray Systems.

(a) Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action.

(b) A control shall be incorporated into each x-ray imaging system such that an exposure can be terminated by the operator at any time, except for exposures of one-half (0.5) second or less.

(c) Exposure control location and operator protection.

Except for units designed to be hand-held during operation, the exposure control shall allow the operator to be:

(i) Behind a protective barrier at least 2 meters (more than 6 feet) tall; or

(ii) At least 2 meters (more than 6 feet) from the patient, x-ray tube, and the useful beam, while making exposures.

The requirements of Appendix 6E shall be followed for x-ray equipment intended to be hand held during operation.

(3) Accuracy.

(a) Deviation of exposure settings from indicated values shall not exceed the limits specified for that system by its manufacturer.

(b) If manufacturer specifications are not available, accuracy of all exposure factors shall be within ten (10) percent of the selected factor(s).

(4) Beam Quality.

(a) All dental x-ray systems shall have a minimum half-value layer not less than 1.5 millimeters aluminum equivalent.

(b) Systems operating above 70 kVp are subject to the filtration requirements of 6.4.2.5(1).

(c) 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 Appendix 6I. If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in Appendix 6I, linear interpolation or extrapolation may be made.

(i) 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.

(ii) 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.

(5) Patient and image receptor holding devices shall be used when the techniques permit.

(6) Except for units designed to be hand held during operation, the tube housing and position indicating device (PID) shall not be hand-held during an exposure.

(7) The x-ray system shall be operated in such a manner that the area of the useful beam at the patient's skin is minimized while ensuring adequate coverage of relevant anatomy.

(8) Dental fluoroscopy without image intensification or direct digital receptors shall not be used.

6.7.3.3 The x-ray control shall provide:

(1) Visual indication observable at the operator's protected position whenever x-rays are produced; and

(2) A signal audible to the operator shall indicate that the exposure has terminated.

6.7.3.4 Excluding cases in which shielding would interfere with the diagnostic procedure, thyroid shielding shall be required for pediatric patients when performing intra-oral imaging.

6.7.3.5 Absent structural protection against scatter radiation, during radiation machine operation at least a 2-meter distance (more than 6 feet) shall be maintained from any bystander location and between patient operating chairs.

6.7.3.6 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.

(1) This indication shall be both on the x-ray control panel and at or near the tube housing assembly which has been selected.

6.7.3.7 Mechanical support of tube head. Excluding hand-held systems, 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.

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

6.7.3.9 All position locking, holding, and centering devices on the x-ray system and/or components shall function as intended.

6.7.3.10 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.

(1) If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated.

(2) The requirement of 6.7.3.10(1) may be met by permanent markings on equipment having fixed technique factors.

6.7.3.11 For any specific combination of selected technique factors, the coefficient of variation of the air kerma shall be no greater than 0.05.

6.7.3.12 Deviation of technique factors from indicated values shall not exceed the limits provided by the manufacturer.

(1) At a minimum, the kVp on variable kVp units shall be accurate to within 10 percent and within 20 percent on fixed kVp units.

6.7.4 For each dental x-ray imaging system, manufacturer maintenance specifications shall be followed.

6.7.5 For each dental x-ray imaging system, written quality control and quality assurance procedures shall include:

6.7.5.1 For manual processing of intraoral films, performance of the following:

(1) Follow applicable manufacturer's time and temperature specifications, which shall be available for review;

(2) Measure and log temperature each day of use; and

(3) Document in a written log the change of developer chemicals at least every month.

6.7.5.2 For volumetric dental imaging systems, conduct periodic calibrations and annual quality control tests according to the manufacturer's specifications, including any additional or more frequent testing necessary at the recommendation of the registered medical physicist or consistent with the standards of an appropriate nationally recognized organization, for example, the American Association of Physicists in Medicine.

6.7.5.3 Annual review of all quality control tests.

6.8 Requirements for use of a veterinary medicine imaging system.

6.8.1 Administrative Controls.

6.8.1.1 In addition to the provisions of 6.3 and 6.4, the requirements of this 6.8, and as appropriate also 6.5 and 6.9, apply to equipment and associated facilities used for veterinary x-ray imaging.

6.8.1.2 Each individual who operates a veterinary x-ray imaging system shall meet the applicable adequate radiation safety training and experience requirements of Part 2.6.1, in particular 2.6.1.12.

6.8.2 Each veterinary medicine installation shall meet the following equipment design and configuration requirements.

6.8.2.1 Equipment.

(1) The protective tube housing shall be equivalent to the requirements of 6.4.2.3.

(2) Diaphragms or cones shall be provided for collimating the useful beam to the area of clinical interest and shall provide the same degree of protection as is required of the housing.

(3) The total filtration permanently in the useful beam shall meet the requirement of 6.4.2.5(1).

(4) All stationary, mobile or portable x-ray systems shall be provided with either:

(a) A lead-equivalent protective garment with thyroid shielding and lead-equivalent eye protection.

(b) A 2 meter (more than 6 feet) high protective barrier for operator protection during exposures; or

(c) Shall be provided with means to allow the operator to be at least 2 meters (more than 6 feet) from the patient, x-ray tube, and the useful beam during exposures.

6.8.2.2 A method shall be provided for visually defining the perimeter of the x-ray field.

(1) 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 (two) 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.

6.8.2.3 Structural Shielding.

(1) All wall, ceiling, and floor areas shall be equivalent to or provided with applicable protective barriers to assure compliance with 4.6, 4.12, 4.13, and 4.14.

(2) A veterinary installation shall meet the requirements of 6.3.2 in order to minimize radiation exposure to personnel and individual members of the public.

(3) Veterinary facilities are exempt from the requirements of Appendix 6B so long as the requirements of 6.8.3 are met.

6.8.2.4 Linearity shall be in accord with 21 CFR 1020.31(c)(3).

6.8.2.5 Accuracy.

(1) Deviation of exposure settings from indicated values shall not exceed the limits specified for that system by its manufacturer.

(2) If manufacturer specifications are not available, the following criteria shall be used:

(a) The kVp shall not deviate from indicated values by more than ten (10) percent.

(b) The timer accuracy shall not deviate from indicated values by more than:

(i) Ten (10) percent for an indicated time of greater than 20 ms; or

(ii) Fifty (50) percent for an indicated time of 20 ms or less, or 1 pulse, whichever is greater.

6.8.2.6 Timers.

(1) Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.

(2) 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.

(3) Termination of exposure shall cause automatic resetting of the timer to its initial setting or to “zero”.

6.8.2.7 Exposure Reproducibility.

(1) The coefficient of variation of exposure shall not exceed 0.05 when all exposure settings are held constant.

6.8.2.8 A dead-man type of exposure switch or equivalent remote device shall enable the operator to stand out of the useful beam.

6.8.3 Each veterinary medicine installation shall have the following operating and radiation exposure control procedures.

6.8.3.1 Whenever possible, the operator shall be positioned during radiographic exposures so that the nearest portion of the body is at least 2 meters (more than 6 feet) from the patient, x-ray tube and the useful beam.

6.8.3.2 No individual, other than the operator, shall be in the x-ray room while exposures are being made, unless such individual's assistance is required and the person is adequately protected by shielding and/or distance.

(1) All other staff and ancillary personnel required for the procedure shall:

(a) Be protected from scatter radiation by protective apparel (aprons) or whole body protective barriers of not less than 0.25 millimeter lead equivalent; and

(b) Be protected from the useful beam by 0.5 millimeter lead equivalent.

6.8.3.3 When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used.

(1) Each individual other than the animal being examined shall be positioned such that no part of the body will be struck by the useful beam unless protected by a minimum of 0.5 millimeter lead equivalent protective apparel or shield.

(2) If the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, such as protective apparel (gloves and apron), and the individual shall be so positioned that no part of the individual’s body will be struck by the useful beam.

(3) The exposure of any individual used for this purpose shall be maintained below the limits specified in 4.6, 4.12, and 4.13.

6.8.3.4 No human shall hold the image receptor during radiography unless that individual is protected with appropriate shielding devices or protective apparel (gloves and apron), and that any part of his/her body struck by the useful beam shall be monitored.

(1) The exposure of any individual used for this purpose shall be maintained below the limits specified in 4.6, 4.12, and 4.13.

6.8.3.5 Use of hand-held x-ray equipment shall be consistent with Appendix 6E.

6.8.4 Each veterinary x-ray imaging system shall follow manufacturer maintenance specifications.

6.8.5 Each veterinary x-ray imaging system shall have written quality control and quality assurance procedures that include:

6.8.5.1 For processing of veterinary films, performance of the following:

(1) Follow applicable manufacturer’s time and temperature specifications, which shall be available for review;

(2) Measure and log temperature each day of use; and

(3) Document in a written log the change of developer chemicals at least every month.

6.8.5.2 Annual review of all quality control tests.

6.9 Requirements for use of computed tomography (CT) imaging systems.

6.9.1 Administrative Controls.

6.9.1.1 In addition to the provisions of 6.3 and 6.4, the requirements of 6.9 apply to equipment and associated facilities used for computed tomography.

6.9.1.2 Supervision and operation of a computed tomography system used on living humans shall be by an individual who has adequate radiation safety training and experience.

(1) Supervision shall be consistent with 6.3.1.6.

(2) Training and experience shall be as provided in 6.3.1.6.

6.9.1.3 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 for the life of the machine.

6.9.2 Each computed tomography facility shall meet the following equipment design and configuration requirements.

6.9.2.1 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.

(a) 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 that monitor equipment function.

(2) A visible signal shall indicate when the x-ray exposure has been terminated through the means required by 6.9.2.1(1).

(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.

6.9.2.2 Tomographic Plane Indication and Alignment.

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

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

(3) If a mechanism using a light source is used to satisfy 6.9.2.2(1) or 6.9.2.2(2), the light source shall allow visualizing the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux (46 foot candles).

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

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

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

6.9.2.4 Patient Communication.

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

(2) 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.

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

(4) Patient scanning shall be allowed only when a viewing system is available and in use.

6.9.3 Each computed tomography facility shall have the following operating procedures and radiation exposure controls.

6.9.3.1 Console Performance.

(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 application specialist, RMP, or someone deemed as a qualified trainer.

(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 RMP for the indicated parameters, and the results of at least the most recent routine QC completed on the system;

(b) Scanning protocols reviewed and approved by the RPC, including instructions on reporting deviations.

(3) If the RMP evaluation or routine QC of the CT x-ray system identifies that a system operating parameter has exceeded a tolerance established by the RMP, use of the CT x-ray system on patients shall be limited to those uses permitted by established written instructions of the RMP.

6.9.3.2 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.

(2) On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings.

(3) Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

6.9.3.3 CT Radiation Protocol Committee (RPC)

The requirements of 6.9.3.3 and other requirements associated with a Radiation Protocol Committee shall become effective on or after January 1, 2022.

The registrant shall develop and maintain an RPC in accordance with the following:

(1) Members of the RPC.

(a) Members of the RPC shall include but not be limited to the:

(i) Lead CT radiologist;

(ii) Lead CT technologist;

(iii) RMP; and

(iv) Other individuals as deemed necessary by the registrant (e.g., Radiation Safety Officer, Chief Medical or Administrative Officer, Radiology Department Administrator or Manager).

(b) If the registrant has more than one site with CT, they may establish a system-wide RPC.

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

(d) If the registrant has already established a radiation safety committee, the requirements of 6.9.3.3 may be delegated to that committee if the members meet the requirements of 6.9.3.3(1).

(2) Responsibilities.

(a) The registrant shall:

(i) Review existing CT protocols, taking into consideration the capabilities and diagnostic tasks of the system, 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.

(ii) Determine and review the protocols used frequently or that could result in significant doses. The 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:

(1) Pediatric Head;

(2) Pediatric Abdomen;

(3) Adult Head;

(4) Adult Abdomen;

(5) Adult Chest;

(6) Brain Perfusion.

(iii) Establish and implement written protocols, or protocols documented in an electronic recordkeeping system, that include but are not limited to the following:

(1) A method to be used to monitor the CT radiation output (dose indices).

(2) To the extent possible, a standardized protocol naming process.

(3) A notification value and alert value for CT protocols reviewed in 6.9.3.3(2)(a)(ii). Notification and alert values may be applied by using trigger values in conformance with nationally accepted standards or facility established values and procedures as defined by the RMP.

(4) Actions to be taken when the notification or alert value is exceeded.

(5) 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.

(iv) The RPC shall review and approve protocols developed or modified under 6.9.3.3(2)(a)(iii).

(v) If CT fluoroscopy is performed, the registrant shall establish and implement operating procedures and training designed to minimize patient and occupational radiation exposure.

(vi) Provide an annual report summarizing the details and activities of the RPC to the radiation safety committee or radiation safety officer, in the absence of a radiation safety committee.

(vii) At a minimum the RPC members in 6.9.3.3(1)(a)(i) through (iii) shall meet as often as necessary to conduct business but at intervals not to exceed 12 months.

(3) Records

(a) 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.

(b) The registrant shall maintain a record of RPC policies and procedures.

(c) The registrant shall maintain a record of radiation output (dose indices) information so the radiation dose may be estimated in accordance with established protocols (e.g., SSDE). The record shall include:

(i) Patient identification;

(ii) Type and date of examination;

(iii) Identification of the CT system used;

(iv) The dose values the CT system provides (e.g., Dose-Length Product, SSDE); and

(v) Any change to the established protocol for the specific patient.

(d) Records required by this section shall be retained for inspection by the department for a period of 3 years following the date of the record.

6.9.3.4 CT systems used in treatment planning.

CT systems solely used for treatment planning in radiation oncology shall meet the requirements in Part 24.9 of these regulations.

6.9.3.5 PET CT and SPECT CT Systems

CT systems solely used for localization and calculation of attenuation coefficients in nuclear medicine studies shall meet the requirements in Sections 6.9.1, 6.9.2.4, 6.9.3.1, 6.9.3.3, and 6.9.4.1 unless otherwise exempted below:

(1) In lieu of 6.9.4.2, a RMP shall complete a performance evaluation on the CT system following nationally recognized guidelines or those of the manufacturer at intervals not to exceed 12 months.

(2) In lieu of 6.9.4.3, routine QC checks shall be completed at intervals not to exceed 1 week. These checks shall be established and documented by a RMP following nationally recognized guidelines or those of the manufacturer.

(3) 6.9.3.1(2)(b) (RPC)

6.9.3.6 Veterinary CT Systems.

CT systems, including CBCT systems, solely used in non-human imaging shall meet the requirements of 6.9.4.1(1) (area radiation surveys) and are otherwise exempt from the standards of Section 6.9.

6.9.3.7 Cone Beam Computed Tomography Systems.

(1) CBCT facilities shall meet the following requirements, as applicable:

(a) Excluding veterinary imaging systems the minimum source-skin distance for CBCT imaging systems shall be consistent with the applicable requirements in 21 CFR subchapter J;

(b) 6.4;

(c) 6.6.3.1, 6.6.3.2, 6.6.3.4(1), and 6.8.2.1(4); and

(d) 6.9.1.3, 6.9.2.1, 6.9.2.3, 6.9.3.2, and 6.9.3.8 as applicable.

(2) Beam alignment.

(a) 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.

(b) 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.

(3) A performance evaluation shall be performed by, or under the direct supervision of a RMP.

(a) The evaluation shall follow nationally recognized standards and tolerances or those recognized by the Agency.

(b) The evaluation shall be performed in accordance with Part 2, Section 2.5.1.

(c) The facility shall maintain documentation of the established standards and tolerances and testing results.

(4) The registrant shall follow the QC recommendations provided by the CBCT manufacturer.

(a) In the absence of manufacturer provided QC recommendations, the registrant shall implement and document QC guidelines established by a RMP in accordance to nationally recognized guidelines or those recognized by the Agency.

(5) The registrant or RPC, if established, shall implement and document a policy addressing deviations from established protocols.

(6) The CBCT x-ray system shall only be operated by an individual who has been specifically trained in its operation.

(7) The following information shall be readily available to the CBCT operator:

(a) 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 RMP, if required, for the indicated parameters, and the results of at least the most recent routine QC completed on the system.

(8) Exemption.

(a) The registrant using fluoroscopy systems capable of CBCT shall meet the applicable requirements of 6.9.3.7 excluding 6.9.3.7(1)(d).

6.9.3.8 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.

(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.

(3) The deviation of indicated scan increment versus actual increment shall not exceed plus or minus 2 millimeter with any mass from 0 to 100 kg resting on the support device.

(a) The patient support device shall be incremented from a typical starting position to the maximum incremented distance, the manufacturer's specified distance, or 30 cm, whichever is less, and then returned to the starting position.

(b) Measurement of actual versus indicated scan increment may be taken anywhere along this travel.

(c) When table increment is not the primary means of slice position location, the registered medical physicist may provide for prior written Department review and approval alternative measurement procedures to determine the accuracy of slice position.

(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.

CT surveys, performance evaluations, routine QC, and operating procedures

6.9.4 Each computed tomography facility shall conduct required surveys, performance evaluations, and routine QC.

6.9.4.1 Radiation Protection Evaluations.

(1) An area radiation survey or measurement shall be made by, or under the direct supervision of, a registered medical physicist or QE, to verify and document compliance with Part 4, Section 4.14 and 4.15 under the following conditions:

(a) All CT x-ray systems installed shall have an area radiation survey or measurement completed by, or under the direct supervision of, the RMP or QE within 90 days of installation;

(b) Any change in the facility or equipment that might cause a significant increase in radiation hazard; or

(c) Upon first use of a portable or mobile CT imaging system, consistent with the applicable requirements of 6.3.2.4..

(d) The registrant shall obtain from the registered medical physicist, a written report of the measurements required by 6.9.4.1, and a copy of the report shall be made available to the Department upon request.

6.9.4.2 CT System performance evaluations.

(1) The testing of the CT x-ray system shall be performed by, or under the personal supervision of, a registered medical physicist who assumes responsibility and signs the final performance evaluation report.

(2) Evaluation standards and tolerances shall be established by the registered medical physicist and maintained by the facility. The standards and tolerances shall be:

(a) In accordance with protocols published by nationally recognized organizations (for example, AAPM Report 96), unless the registered medical physicist determines that a particular recommendation of such report is not warranted for the clinical tasks for which the equipment will be used;

(3) The evaluation of a CT x-ray system shall be performed by or under the personal supervision of an RMP in accordance with Part 2, Section 2.5.1 prior to use on human patients and within 90 calendar days of:

(a) Initial installation or acceptance testing; or

(b) Any change or service that could cause a change in the radiation output (dose indices) or image quality.

(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;

(h) A safety evaluation of audible and visual signals, and posting requirements;

(i) Dosimetry.

(5) The measurement of the radiation output (dose indices) of a CT x-ray system shall be performed with a calibrated dosimetry system. The calibration of such system hall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding 2 years.

6.9.4.3 Routine quality control.

A routine QC program on the CT system shall:

(1) Be developed by a registered medical physicist 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 a registered medical physicist. The interval shall not exceed 1 week.

(4) Be documented and maintained for inspection by the Department for a period of 3 years following the date of the record.

6.10 Requirements for use of mammography and other x-ray based breast imaging systems.

6.10.1 Administrative Controls.

6.10.1.1 The requirements of 6.3 and 6.4 apply to all mammography and x-ray based breast imaging equipment and associated facilities.

6.10.1.2 Each facility performing mammography (as defined in Section 6.2) shall:

(1) Use imaging systems that comply with the Mammography Quality Standards Act of 1988.

(2) Meet the requirements of Subpart B of 21 CFR 900;

(3) Ensure that 21 CFR 900 quality control and quality assurance standards for maintaining viewing conditions and interpretation of an image are met.

6.10.1.3 Each RMP who conducts a mammography facility and x-ray machine certification evaluation shall meet the requirements of Part 2, Appendix 2I.

6.10.1.4 Each Individual who performs a mammography examination shall meet the adequate radiation safety training and experience requirements of Part 2, Section 2.4.5.4, 2.6.1.5 and Appendix 2M.

6.11 Use of dual-energy x-ray absorptiometry (DXA) bone densitometry systems.

6.11.1 In addition to the provisions of 6.3 and 6.4, the requirements of 6.11 apply to all facilities using DXA machines.

6.11.2 DXA Systems shall be:

6.11.2.1 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;

6.11.2.2 Registered in accordance with Part 2 of these regulations; and

6.11.2.3 At a minimum, maintained and operated in accordance with the manufacturer's specifications

6.11.3 Operator requirements.

6.11.3.1 In addition to the minimum qualifications outlined in 6.3.1.6 of these regulations, operators shall complete training specific to patient positioning and the operation of the DXA system.

6.11.4 During operation of any DXA system:

6.11.4.1 In the absence of a radiation survey performed by or under the supervision of a RMP the operator, ancillary personnel, and members of the general public shall be positioned at least 2 meters (at least 6 feet) from the patient, x-ray tube, and useful beam during the examination.

6.11.5 Quality assurance.

6.11.5.1 In addition to the applicable requirements in 6.3.5.1, a facility performing DXA shall:

(1) Conform to the DXA system manufacturer recommendations and recommendations of recognized professional societies such as the International Society for Clinical Dosimetry or the American College of Radiology.

6.11.6 Records.

6.11.6.1 The registrant shall keep the following records for a minimum of 3 years:

(1) The maintenance and QC tests as prescribed by 6.11.2.3 and 6.11.5.1.

PART 6, APPENDIX 6A: INFORMATION REQUIRED FOR EVALUATION OF RADIATION SHIELDING

6A.1 In order to provide an evaluation and technical advice on shielding requirements for a radiation installation, the following information shall be submitted to the qualified expert or registered medical physicist.

6A.1.1 The submittals shall include a dimensional, scaled drawing of the facility which shows the following:

(1) The normal location of the x-ray imaging system's radiation port; the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; the location of the operator's booth; and the location of the x-ray control panel.

(2) The structural composition and thickness of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

(3) The dimensions of the room(s) concerned and inter-floor distances if space above or below is occupied.

(4) The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned.

(5) If there is an exterior wall, the distance to the closest area(s) where it is likely that individuals may be present.

(6) A description of the x-ray imaging system and components, including the make and model of the equipment.

(7) The type of examination(s) or treatment(s) that will be performed with the equipment.

6A.1.2 Information on the anticipated workload of the x-ray imaging system(s).

PART 6, APPENDIX 6B: DESIGN REQUIREMENTS FOR AN OPERATOR'S BOOTH

6B.1 Space Requirements:

6B.1.1 The operator shall be allotted not less than 0.7 m2 (8 ft2) of unobstructed floor space in the booth.

6B.1.2 The operator's booth may be of any geometric configuration with no dimension less than 0.6 m (2 ft).

6B.1.3 The space shall be allotted excluding any encumbrance by the x-ray control panel, such as overhang, cables, or other similar encroachments.

6B.1.4 The booth shall be located or constructed such that unattenuated scatter radiation originating on the examination table or at the wall cassette cannot reach the operator's location within the booth.

6B.2 Structural Requirements:

6B.2.1 The booth walls shall be permanently fixed barriers at least 2 m (6.5 ft) high.

6B.2.2 When a door or movable panel is used as an integral part of the booth structure, it must have an interlock that will prevent an exposure when the door or panel is not closed in its shielding position.

6B.2.3 Shielding shall be provided to meet the requirements of Part 4.

6B.3 Viewing System Requirements:

6B.3.1 Each booth shall have at least one viewing device that will:

(1) Be so placed that the operator can view the patient during any exposure, and

(2) The device shall be so placed that the operator can have full view of any occupant of the room and should be so placed that the operator can view any entry into the room. If any door that allows access to the room cannot be seen from the booth, then that door must have either an interlock controlling the exposure that will prevent the exposure if the door is not closed; or a warning light must be activated at the control panel when the door is opened.

6B.3.2 When the viewing system is a window, the following requirements also apply:

(1) The viewing area shall be at least 0.1 m2 (1 ft2).

(2) The design of the booth shall be such that the operator's expected position when viewing the patient and operating the x-ray system is at least 0.5 m (1.5 ft) from the edge of the booth.

(3) The material constituting the window shall have at least the same lead equivalence as that required in the booth's wall in which it is mounted.

6B.3.3 When the viewing system is by mirrors, the mirror(s) shall be so located as to accomplish the general requirements of 6B.3.1.

6B.3.4 When the viewing system is by electronic means:

(1) The camera shall be so located as to accomplish the general requirements of 6B.3.1.

(2) There shall be an alternate viewing system as a backup for the primary system, unless the x-ray room is not used in the case of viewing system failure.

PART 6, APPENDIX 6C: CONTENT OF A SHIELDING DESIGN

6C.1 Each written shielding design prepared by a qualified expert shall include identifying information, if available, such as the facility name, address, owner, contact telephone numbers and contact e-mail addresses.

6C.2 Each written shielding design prepared by a qualified expert shall include:

6C.1.2 Evaluation from a radiation protection point-of-view of the overall layout of the room(s) floor plan, including the location and configuration any radiation producing machines in each room, based on the information required in Appendix 6A and 6B.

6C.1.3 Evaluation of suitable workload, based on the volume of work and equipment usage anticipated in the information provided pursuant to 6A.1.2, in relation to the overall layout.

6C.1.4 Detailed consideration, using guidelines based on National Council on Radiation Protection and Measurements Report No. 147, “Structural Shielding Design for Medical Imaging Facilities”, or equivalent guidance, of:

(1) Location and types of permanent and temporary barriers and shielding;

(2) Location of controls and any control booth;

(3) Location of exposure switch; and

(4) Interior and exterior walls, doors and windows, and floors and ceilings.

6C.1.5 Calculations of potential exposures based on occupancy and workload distribution.

6C.1.6 For each room in which a stationary x-ray imaging system is located, a current dimensional drawing as required by 6.3.2.3 with accompanying specifications for construction and layout to meet all requirements of these regulations, in particular to preclude an individual from receiving a dose in excess of the limits in Part 4, Sections 4.6, 4.12, 4.13, 4.14 and 4.15.

6C.1.7 The signature of the qualified expert who prepared the shielding design and the date signed.

PART 6, APPENDIX 6D: CRITERIA FOR CLASSIFYING A RADIATION MACHINE UNSAFE FOR ROUTINE HUMAN, ANIMAL OR OTHER USE

6D.1 The operating condition of an radiation machine and related equipment shall not be such that the continued operation of that machine endangers the public health and safety.

6D.2 An radiation machine shall be considered unsafe for human, animal or other use if:

6D.2.1 The radiation machine system has a malfunctioning component or components that could result in an inadvertent exposure to members of the public, the operator, or the patient. Examples include but are not limited to: a timer that fails to terminate the exposure, an exposure switch when activated once produces multiple exposures, a system that produces x-rays without activation of the exposure switch.

6D.2.2 The radiation machine is not equipped with a means of determining when x-rays are in production.

6D.2.3 The radiation machine is equipped with variable exposure settings and the selectors and/or indicators of these exposure settings do not permit the operator to determine the factors in use or if the indicated versus the exposure settings are in error by fifty (50) percent or more, except for exposure times selected less than 50 millisecond.

6D.2.4 The collimation of the x-ray beam of a fluoroscopic/spot film system is such that either the length or width of the x-ray field in the plane of the image receptor differs (in excess) from the corresponding image receptor dimensions by more than 25 percent of the source to image distance (SID).

6D.2.5 The half-value layer of aluminum (or equivalent) filtration in the useful beam is more than fifty (50) percent below the values specified in 6.4.2.5.

6D.2.6 The quality of the imaging is significantly degraded such that significant additional exposures or imaging is needed to obtain an adequate image.

6D.2.7 In addition to the above items a fluoroscopic x-ray system will be considered unsafe if:

(1) In normal fluoroscopic mode:

(a) No operational image intensifier or direct digital image receptor is provided.

(b) Except for radiation oncology simulators, the primary protective barrier does not intercept 100 percent of the x-ray beam of a fluoroscopic x-ray system.

(c) Except for radiation oncology simulators, the fluoroscopic x-ray system is capable of producing x-rays when the primary protective barrier is not in position to intercept the beam.

(d) The fluoroscopic x-ray system has a tabletop AKR equal to or greater than 220 mGy per minute (25 R/min) at the point where the useful beam enters the patient, except:

(i) During the recording of fluoroscopic images, or

(ii) When an optional high-level control is activated.

(2) When using a high-level control, the equipment is operable at any combination of tube potential and current that will result in an AKR in excess of 176 mGy per minute (20 R/min), consistent with 21 CFR 1020.32(d)(2)(iii)(C).

6D.2.8 An electro-mechanical defect exists that endangers human life or safety when a radiograph is made or fluoroscopy is performed.

PART 6, APPENDIX 6E: USE OF HAND-HELD X-RAY EQUIPMENT

6E.1 The following requirements are applicable, as determined by the Department, to any x-ray radiographic device that is designed to be held in the hand during operation.

6E.1.1 Requirements for any location:

(1) The facility shall adopt and follow procedures provided by the manufacturer regarding the safe operation of the device.

(2) The facility shall maintain documentation that each operator has completed training as specified by the manufacturer.

(3) The operator shall ensure there are no bystanders within a radius of at least 2 meters (more than 6 feet) from the patient being examined with a hand-held radiographic unit.

(4) If a hand-held device was designed with an optional, removable scatter radiation block, it shall be installed and used during patient examination and shall:

(a) Provide not less than 0.25 mm lead equivalent;

(b) Be at least 15.2 cm (6 inches) in diameter;

(c) Be positioned as close as practicable to the distal end of the position indication device.

(5) When operating a hand-held x-ray system, operators shall:

(a) Wear whole body dosimetry in accordance with Part 4, Section 4.6.3; and

(b) Wear 0.25 mm lead-equivalent protective apparel, unless the device is used with a scatter shield meeting the requirements of 6E.1.1(4) or as otherwise exempted in writing by the Department.

(6) In order to prevent repeat imaging due to motion that reduces image quality, motion shall be minimized as much as possible when holding and operating the device. If the operator has difficulty in holding the device stationary, the operator shall use a stand or tripod to immobilize the device.

6E.1.2 Additional requirements for use of hand-held x-ray equipment in permanent facilities:

(1) A hand-held device shall not be used for patient examinations in hallways and waiting rooms.

6E.2 When not under the control of the operator, the registrant shall secure the hand-held device from unauthorized removal or use.

PART 6, APPENDIX 6F: INFORMATION TO BE SUBMITTED BY A PERSON PROPOSING TO CONDUCT HEALING ARTS SCREENING

6F.1 A person requesting that the Department approve a healing arts screening program shall submit the following information and evaluation when completing Department Form R-300:

6F.1.1 Name and address of the applicant and, when applicable, the names and addresses of all locations within this State, where the service will be provided.

6F.1.2 Diseases or conditions for which the x-ray examinations are to be used in diagnoses.

6F.1.3 A detailed description of the x-ray examinations proposed in the screening program.

6F.1.4 Description of the population to be examined in the screening program, i.e., age, sex, physical condition, and other appropriate information.

6F.1.5 An evaluation of any known alternate methods not involving ionizing radiation that could achieve the goals of the screening program and why these methods are not used instead of the x-ray examinations.

6F.1.6 An evaluation by a qualified expert of the x-ray system(s) to be used in the screening program prior to being placed into operation. The evaluation by the qualified expert shall show that such system(s) do satisfy all requirements of these regulations.

6F.1.7 A description of the image processing quality control program, if applicable.

6F.1.8 A copy of the technique protocols for the x-ray examination procedures to be used as required under 6.3.3.3.

6F.1.9 Documentation that each individual who will be operating the x-ray system(s) fulfills Department requirements for adequate radiation safety training and experience.

6F.1.10 Documentation that each individual who will be supervising the operators of the x-ray system(s) fulfills Department requirements for adequate radiation safety training and experience. The extent of supervision and the method of work performance evaluation shall be specified.

6F.1.11 The name and address of the individual who will interpret the radiograph(s) or other results from the x-ray examinations.

6F.1.12 Name of an individual who meets the requirements of 6.3.1.6(1) or 6.3.1.6(2) who will oversee the program. Such oversight by a licensed individual shall be consistent with the individual's license, licensing body, regulations, and the standard and acceptable scope of practice for the individual providing that oversight.

6F.1.13 A copy of the imaging order(s) applicable to the screening program to be conducted, prescribed by an individual who meets the requirements of 6.3.1.6(1) or 6.3.1.6(2). The order by the licensed individual shall be consistent with the individual's license, licensing body, regulations, and the standard and acceptable scope of practice for the individual providing that oversight.

6F.1.14 A description of the procedures to be used by an individual who meets the requirements of 6.3.1.6(1) or 6.3.1.6(2) to advise the individuals screened about the results of the screening procedure and any further medical needs indicated. Such advice by a licensed individual shall be consistent with the individual's license, licensing body, regulations, and the standard and acceptable scope of practice for the individual providing that advice.

6F.1.15 A description of the procedures for the retention or disposition of the radiographs, if applicable, and other records pertaining to the x-ray examinations.

6F.1.16 A shielding analysis, if applicable.

6F.1.17 A copy of the policy and procedures to ensure that all applicable dose limitation requirements of Part 4, "Standards for Protection Against Radiation", are met.

6F.1.18 A copy of the ALARA policy and procedures.

6F.1.19 Copies of personnel monitoring reports for any employee involved in screening.

6F.1.20 Any additional information that has been requested by the Department.

PART 6, APPENDIX 6G: AUTOMATIC FILM PROCESSOR TECHNIQUE 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.*

PART 6, APPENDIX 6H: MANUAL FILM DEVELOPING TECHNIQUE CHART

Manual Film Developing Technique Chart				
Developer Temperature °C / °F	Developing Time (Minutes)		Developer Temperature °C / °F	Developing 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			

PART 6, APPENDIX 6I: TABLE OF HALF VALUE LAYERS FOR A SPECIFIED kVp AND SYSTEM.

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

Editor's Notes

6 CCR 1007-1 has been divided into separate parts for ease of use. Versions prior to 04/01/2007 are located in the first section, 6 CCR 1007-1. Prior versions can be accessed from the All Versions list on the rule's current version page. To view versions effective on or after 04/01/2007, select the desired part of the rule, for example 6 CCR 1007-1 Part 01 or 6 CCR 1007-1 Part 10.

History

Part 06 entire rule eff. 07/01/2010.

Part 06 rules 6.3.3.7, 6.3.5.8, 6.5.5, 6.7.1.2, 6.8.1.2, 6.9.1.2, 6F.1.20 eff. 07/30/2010.

Part 06 entire rule eff. 01/14/2020.

Part 06 rules 6.1.5, 6.2, 6.3.1.2, 6.3.1.2(1), 6.3.2.1(3), 6.4.2.5(2), 6.6.2.5(2), 6.6.3.9(2), 6.7.1.5, 6.7.3.2(2)(c), 6D.2.7(2) eff. 10/15/2020.