

**DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT**

**Hazardous Materials and Waste Management Division**

**STATE BOARD OF HEALTH**

**RULES AND REGULATIONS PERTAINING TO RADIATION CONTROL**

**6 CCR 1007-1 Part 06**

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

**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)(I), 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 x-ray imaging systems by or under the supervision of an individual authorized by and licensed in accordance with State of Colorado statutes to engage 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 and other parts of these regulations.

6.1.4.2 Part 9 and Part 24 specifically apply to some particular 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 Published material incorporated in Part 6 by reference is available in accord with 1.4.

**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 2003).

“AAPM Report 4” means “Basic Quality Control In Diagnostic Radiology” , AAPM Report No. 4 by the Diagnostic Radiology Committee, Task Force on Quality Assurance Protocol of the American Association of Physicists in Medicine (November 1977).

“AAPM Report 74” means “Quality Control in Diagnostic Radiology” , AAPM Report No. 74 by Task Group 12 of the Diagnostic X-ray Imaging Committee of the American Association of Physicists in Medicine (July 2002).

“AAPM Report 93” means “Acceptance Testing and Quality Control of Photostimulable Storage Phosphor Imaging Systems” , AAPM Report No. 93 by Task Group 10 of the Radiography and Fluoroscopy Subcommittee of the Diagnostic Imaging Council CT Committee of the American Association of Physicists in Medicine (October 2006).

“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).

“Added filtration” means addition of a filter to the inherent filtration.

“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.

“Attenuation block” means a block or stack that has a thickness of 3.8 cm, is made of aluminum (type 1100 aluminum alloy with a nominal chemical composition of aluminum 99.00 percent minimum and copper 0.12 percent maximum) or other material(s) having equivalent attenuation, and is large enough to intercept the entire x-ray beam.

“Automatic exposure control” (AEC) means a device that automatically controls settings in order to obtain at the pre-selected location a required quantity of radiation. See also “phototimer” .

“Automatic exposure rate control” (AERC) means a device that automatically controls one or more exposure settings 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 system” means a device that uses electronically-produced ionizing radiation for the sole or primary purpose of determining the density of bone structures in human patients.

“C-arm x-ray system” means an x-ray system in which the image receptor and x-ray tube housing assembly are connected by a common mechanical support system or coordinated in order to maintain a desired spatial relationship. This system is designed to allow a change in the projection of the beam through the patient without a change in the position of the patient.

“Cephalometric device” means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

“Certified component” means an x-ray imaging system component that is subject to regulations promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968.

“Certified system” means any x-ray system that has any certified component.

“Changeable filters” means any filter, exclusive of inherent filtration, that can be removed from the useful beam through any electronic, mechanical, or physical process under operator control.

“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:

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

where

s = Estimated standard deviation of the population

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

$x_i$  = i<sup>th</sup> 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.

“Contrast-to-noise ratio” (CNR) relates the contrast of an object in an acquired image to the inherent noise in the image.

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

“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 exposure settings.

“CT gantry” means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames that hold these components.

“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.

“Diagnostic imaging system” (also “diagnostic x-ray imaging system” or “diagnostic x-ray system”) means an assemblage of components for the generation, emission, and reception of x-rays and the

transformation, storage and visual display of the resultant x-ray image, with the assembled system designed and used for irradiation of any part of the human or animal body for the purpose of diagnosis or visualization.

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

“Digital radiography” means use of an x-ray imaging processing system to produce a radiographic image displayed on a video monitor after mathematical transformation.

“Direct scattered radiation” means that scattered radiation that has been deviated in direction only by materials irradiated by the useful beam. See “scattered radiation” .

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

“Elemental area” means the smallest area within a digitally acquired image for which the x-ray attenuation properties of a body are depicted. See also “picture element” .

“Equipment” . See “x-ray equipment” .

“Established operating level” means the value of a particular quality assurance parameter that has been established as an acceptable normal level by the facility's quality assurance program.

“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 air kerma display device” means a device, subsystem, or component that provides the display of air kerma rate and cumulative air kerma. It includes radiation detectors (if any), electronic and computer components, associated software, and data displays.

“Fluoroscopic imaging assembly” means a subsystem in which x-ray photons produce a set of visible images. 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-enabled x-ray tube activation in any fluoroscopic mode of operation.

“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 that, by design, is not limited to radiographic examination of specific anatomical regions.

“Gonad shield” means a protective barrier for the testes or ovaries.

“Half-value layer” (HVL) means the thickness of specified material needed to reduce a radiation beam to one-half of its original intensity. This definition excludes all scattered radiation other than any present initially in the beam.

“Hand-held x-ray equipment” . See “x-ray equipment” , under “portable x-ray equipment” .

“Hard copy processor” means a device that produces a printed image from digital image data.

“Healing arts screening” means, for purposes of these regulations, the exposure of any human being using an x-ray imaging 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 or podiatrist 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 or 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.

“Image receptor support device” means, for mammographic systems, that part of the system designed to support the image receptor perpendicular to the beam axis during a mammographic examination and also designed to provide a primary protective barrier.

“Inherent filtration” means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

“Irradiation” means the exposure of matter to ionizing radiation.

“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 or by initiating a separate and distinct radiographic exposure automatically and immediately in conjunction with termination of the fluoroscopic exposure.

“Laterality” , in mammography, means the designation of either the left or right breast.

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

“Leakage control settings” means the exposure settings associated with the diagnostic source assembly that are used in measuring leakage radiation, 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 millicoulomb, that is, 10 mAs, or the minimum obtainable from the unit, whichever is larger;
- (2) For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential.
- (3) For all other diagnostic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for that maximum-rated peak tube potential.

“Leakage radiation” means the portion of ionizing radiation originating from the x-ray imaging system that is not part of the useful beam. See “useful beam” .

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

“Line-voltage regulation” means the difference between the no-load and the load line potentials expressed as a percent of the load line potential. Percent line-voltage regulation =  $100 (V_n - V_l) / V_l$  , where  $V_n$  = no-load line potential and  $V_l$  = load line potential.

“Luminance” means the amount of light that passes through or is emitted from a particular area and falls within a given solid angle.

“Mammogram” means a radiographic image produced through mammography.

“Mammography” means radiography of the breast. See also 6.10.1.1.

“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.

“Mammography medical outcomes audit” means a systematic comparison of positive mammogram assessment data to corresponding pathology results.

“Mammography modality” means a technology for radiography of the breast.

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

“Maximum line current” means the root-mean-square current in the supply line of an x-ray machine operating at its maximum rating.

“Mini-c-arm x-ray system” means a system that meets the following criteria:

- (1) Source-image receptor distance less than or equal to 45 cm (18 inches);
- (2) Field of view less than or equal to 15 cm (6 inches);

(3) Maximum kVp less than or equal to 80 kVp; and

(4) Maximum mA less than or equal to 0.25 mA.

“Mobile x-ray equipment” . See “x-ray equipment” .

“Mode of operation” means a distinct method of fluoroscopy, mammography, or radiography provided by the manufacturer and selected with a set of several exposure control settings uniquely associated with the mode.

(1) The set of distinct 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, mammography 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.

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

“Noise” means the fluctuation of a signal within a measured region of interest, for example, as a result of statistical fluctuation of the signal and electronic noise in the detector.

“Optical Density” (OD) equals  $\log(1/\text{transmittance})$ , 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 radioactive materials or machine-produced radiation is delivered for healing arts examination, diagnosis, or treatment. In addition, for mammography, patient means any individual who undergoes a mammography evaluation in a facility, regardless of whether the person is referred by a physician or is self-referred.

“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 imaging” (PSP) means an x-ray image processing system that employs reusable imaging plates and associated hardware and software to acquire and display digital projection radiographs.

“Phototimer” means a method for controlling radiation exposure to image receptors by the amount of radiation that reaches radiation monitoring device(s) as part of an electronic circuit that controls the duration of time the tube is activated. See “automatic exposure control” .

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

“PID” . See “position indicating device” .

“Pixel” . See “picture element” .

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

“Protective barrier” means a barrier of radiation absorbing material(s) used to reduce radiation exposure. See “primary protective barrier” and “secondary protective barrier” .

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

"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.

“Radiation therapy simulation system” means a radiographic/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 receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record.

“Radiographic imaging system” means any system whereby a permanent or semipermanent image is recorded on an image receptor by the action of ionizing radiation.

“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.

“Rating” means the operating limits specified by the manufacturer.

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

“Reference plane” means a plane that is displaced from and parallel to the tomographic plane.

“Response time” means the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state midscale reading.

“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.

“Scattered radiation” means ionizing radiation emitted by interaction of ionizing radiation with matter, the interaction being accompanied by a change in direction of the radiation. See “direct scattered radiation” .

“Secondary protective barrier” means a barrier sufficient to attenuate scattered and leakage radiation for

radiation protection purposes.

“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” .

“Signal-to-noise ratio” (SNR) means the magnitude of the signal of interest compared to the magnitude of the noise of the background of that signal.

“Solid state x-ray imaging device” means an assembly that intercepts x-ray photons and converts the photon energy into a modulated electronic signal representative of the x-ray intensity over the area of the imaging device.

“Source” , for an x-ray machine, 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 between the source and the skin of the patient.

“Spot check” means a procedure that is performed to assure that a previous calibration continues to be valid.

“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 (for example, a film-screen cassette or a CR cassette) 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.

“SSD” . See “source-skin distance” .

“Standard breast” means a 4.2-cm-thick compressed breast consisting of fifty (50) percent glandular and fifty (50) percent adipose tissue.

“Stationary x-ray equipment” . See “x-ray equipment” .

“Stray radiation” means the sum of leakage and scattered radiation.

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

- (1) Either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs; or
- (2) For capacitor energy storage equipment, quantity of charge in mAs; or
- (3) For field emission equipment rated for pulsed operation, number of x-ray pulses; or
- (4) For CT systems, either:
  - (a) Tube current in mA and scan time in seconds; or

- (b) The product of tube current and rotation time in mAs, as modified to account for helical pitch.

“Termination of irradiation” means the stopping of irradiation in a fashion that will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

“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.

“Tomosynthesis” means to mathematically reconstruct a planar image using views acquired from multiple x-ray beam projection angles.

“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.

“Tube rating chart” means the set of curves that specify the rated limits of operation of the tube in terms of the exposure settings. These curves are typically displayed on a graph.

“Useful beam” means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam limiting device when the exposure controls are in a mode to cause the system to produce radiation.

“Variable-aperture beam-limiting device” means a beam-limiting device that has capacity for stepless adjustment of the x-ray field size at a given SID.

“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.

“Wedge filter” means a filter that effects continuous change in transmission over all or a part of the useful beam.

“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.

- (1) “Mobile or portable x-ray equipment” means x-ray equipment that is designed to be transported from place to place.

- (a) Mobile x-ray equipment is often mounted in a vehicle or on a permanent base with wheels and/or casters for moving while completely assembled.

(b) Portable x-ray equipment includes x-ray equipment that is designed to be hand-carried and hand-held during use.

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

"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 image processing system" means an assemblage of components for creating a visible or viewable image.

"X-ray imaging subsystem" means any combination of two or more components of an x-ray imaging system.

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

"X-ray tube" means any electron tube that 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 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 2.4 and inspected as prescribed in 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 (July 1, 2009).

(1) X-ray imaging systems and their associated components certified pursuant to 21 CFR 1020.30 through 1020.33 (July 1, 2009) shall be maintained in compliance with applicable requirements of 21 CFR 1020.30 through 1020.33 (July 1, 2009).

- (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 shall keep a record of the date, service provider and details of each component or system modification.
- (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 shall direct operation of the x-ray imaging system(s) under the registrant's administrative control.

6.3.1.4 The registrant or the registrant's agent shall assure that all applicable requirements of Parts 1, 2, 4, 6 and 10 are met in the operation of the x-ray imaging system(s).

6.3.1.5 The registrant or the registrant's agent shall use approved providers of services, consistent with 2.6.1, including but not limited to operation of equipment, inspection of radiation machines and facilities, and assembly, installation, service and/or calibration of radiation machines.

6.3.1.6 An x-ray imaging system that continues to be in noncompliance with a requirement of these regulations shall not be used for any purpose unless such use or operation is explicitly authorized by the Department, for example, by correction in accordance with 2.6.3 and/or Form 59-1.

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

6.3.1.8 Use of a radiation machine in the healing arts shall be by or under the general supervision of a physician, chiropractor, dentist, podiatrist or veterinarian who has a current active State of Colorado license to practice the healing arts.

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 registration requirement of 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 license.

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

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(2) 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.
- (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 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-handheld portable x-ray equipment is used regularly in the same location;
  - (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 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 The registrant shall retain, for each room in which a stationary x-ray imaging system is located, a current dimensional drawing that includes indication of the:

- (1) Use of each area adjacent to the room and an estimation of the extent of occupancy in each such area; and
- (2) Results by a qualified expert from calculation(s) for 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; and/or
- (3) If the registrant is unable to produce for inspection the calculation(s) required by 6.3.2.3(2), results from survey(s) conducted by a qualified expert to determine radiation levels present under specified test conditions at the operator's position and at cognizable points outside the room.

6.3.2.4 A facility area is exempt from the requirements of 6.3.2.1 (and consequently exempt from 6.3.2.2 and 6.3.2.3) if:

- (1) Only dental intraoral, dental panoramic, mini-c-arm or bone densitometry equipment is used in the area;
- (2) Mobile or portable x-ray equipment is used infrequently not routinely in the same location; or
- (3) Exemption for a particular area or location has been applied for in writing and granted by the Department.

6.3.2.5 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 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.

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

- (1) The installation as-built drawing(s); and
- (2) The signed statement required by 2.7.1.1 (without exception after June 30, 2010) and retained in accord with 2.4.1.1(4), that all floor plan and equipment configuration specifications in any applicable written shielding designs required by 6.3.2 were explicitly followed.

### 6.3.3 General Radiation Safety and Control of Radiation Exposure.

6.3.3.1 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 technique particular to the system, consistent with 6.3.3.2;
  - (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 as provided by 6.10.2.3 or when diagnosis might be compromised;
  - (c) Patient holding instructions consistent with 6.3.3.8.

6.3.3.2 To reduce radiation exposure to the minimum that is necessary, the registrant shall maintain a documented protocol for technique selection for each type of examination performed by each x-ray imaging system.

- (1) A chart based on the protocol(s) shall be located near each system's control panel.
  - (a) The chart shall state the exposure settings to be used corresponding to the patient's body part and anatomical size, or body part thickness, or age (for pediatrics), including but not limited to:
    - (i) Type of image receptor to be used;
    - (ii) Type and focal distance of the grid to be used, if any and if variable;
    - (iii) Source to image receptor distance to be used, except for intraoral radiography in accordance with 6.7.2.2(1);

- (iv) kVp;
  - (v) Mode of operation; and
  - (vi) mAs, if manual mode is used; and
- (b) Type and location of placement of patient shielding (for example, gonad or thyroid shielding) to be used.
- (2) The requirement of 6.3.3.2(1)(a) is considered met if anatomically programmable controls are used.
- (3) For computed and digital radiography, the chart required by 6.3.3.2(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 recommendation; and
  - (c) Specify pediatric protocol for each unit that images pediatric patients.
- (4) 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 6.3.3.2(4) may be met by permanent markings on equipment having fixed exposure settings.
- (5) The chart shall be revised as necessary whenever a certified component is replaced or added.

6.3.3.3 Exposure under Part 6 of any human being to the useful beam shall be solely for healing arts purposes and only after such exposure has been authorized by a physician, chiropractor, dentist, or podiatrist who has a current active State of Colorado license and has met all applicable requirements of Part 2.

- (1) Deliberate exposure of an human being for training, demonstration or other non-healing-arts purposes is strictly prohibited; and
- (2) 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 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 Department shall be notified immediately if any information submitted to the Department becomes invalid or outdated.

(3) 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 6.3.3.3(2).

6.3.3.4 Except for patients who cannot be moved out of the room, only the staff and ancillary personnel required for the medical procedure or training shall be in the room during the radiographic or fluoroscopic exposure.

6.3.3.5 Each facility shall have protective aprons and gloves available in sufficient numbers to provide protection to all individuals who are involved with x-ray operations and who are otherwise not shielded.

6.3.3.6 To reduce direct radiation exposure, individual shielding shall be provided for all modalities (except for a case in which shielding would interfere with the gonad, thyroid, dental or other diagnostic procedure).

(1) For a human patient who has not passed beyond the reproductive age, during radiographic procedures in which the gonads are in the useful beam, gonad shielding of not less than 0.5 millimeter lead equivalent shall be used.

(2) For a human patient during all radiographic procedures in which the thyroid is in the useful beam, thyroid shielding of not less than 0.25 millimeter lead equivalent shall be used.

(3) In a case where the patient must hold the image receptor (except during an intraoral dental examination), any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material.

(4) Each individual other than the patient 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.

6.3.3.7 To reduce scatter radiation exposure, individual shielding shall be provided as follows:

(1) The operator, other staff and ancillary personnel, and each other individual required for the medical procedure or who cannot be removed from the room, shall be protected from direct scatter radiation:

(a) By a protective apron or whole body protective barrier of not less than 0.25 millimeter lead equivalent, and/or:

(b) Shall be so positioned that the nearest portion of the body is at least a distance of 2 meters (more than 6 feet) from the:

(i) Tube head; and

(ii) Nearest edge of the image receptor; and

(iii) Patient;

(c) Except that protective positioning shall be as determined by the operator of a

mini-c-arm x-ray system or a portable hand-held x-ray device (as provided in Appendix 6E).

6.3.3.8 When a patient or image receptor must be provided with auxiliary support during a radiation exposure:

- (1) Mechanical holding devices shall be used when the technique permits; and
- (2) The written safety procedures required by 6.3.3.1 shall:
  - (a) Indicate the requirements for selecting a holder and the procedure the holder shall follow; and
  - (b) Expressly limit routine use of personnel who are subject to the occupational dose limits in 4.6 for holding a patient solely to immobilize the patient during radiographic examinations; and
- (3) The human holder shall be instructed in personal radiation safety and protected as required by 6.3.3;
- (4) No individual shall be used routinely to hold image receptors or patients.

6.3.3.9 Image processing procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.

- (1) 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.
- (2) X-ray systems subject to 6.6 shall not be utilized in procedures where the source to patient distance is less than 30 cm, except for veterinary systems.
- (3) If anti-scatter grids are used between the patient and the image receptor to decrease scattered radiation to the film and improve contrast, the grid shall be:
  - (a) Positioned properly, with the tube side facing the correct direction, and centered to the central ray; and
  - (b) Of the proper focal distance for the SID being used.

6.3.3.10 Each individual who is associated with the operation of an x-ray imaging system shall meet the requirements of 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 4.6.3.
- (2) Each operator of portable hand-held x-ray equipment shall wear whole body and extremity personnel dosimetric monitoring devices.
- (3) Deliberate exposure of a personnel dosimetric monitoring device to deceptively indicate a dose delivered to an individual is strictly prohibited.

6.3.4 Measurements, Maintenance, and Records.

- 6.3.4.1 The registrant shall maintain for inspection by the Department records for the previous three (3) years of survey measurements, calibrations, maintenance, modifications, 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.
- 6.3.4.2 The registrant shall retain a 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.
- 6.3.4.3 Consistent with 2.4.1 and 6.3.2, the registrant shall retain on file at the facility for the life of the facility each shielding design along with installer as-built drawings.
- 6.3.4.4 Each facility shall have available a printed or electronic record containing each patient's name, the type of examination(s), and the date(s) the examination(s) were performed.

#### 6.3.5 Quality Assurance (QA) Program.

- 6.3.5.1 To avoid unnecessary or duplicative radiation exposures, each human use facility shall have an active image processing quality control and quality assurance (QA) program that follows manufacturers' specifications and/or the standards of an appropriate nationally recognized organization, for example, the American College of Radiology or American Association of Physicists in Medicine.
- 6.3.5.2 Each registrant that uses a hard copy imaging system with transmission viewing, whether with or without liquid chemistry, shall document that quality control and quality assurance have been performed according to specifications of the manufacturer or a registered medical physicist and/or a nationally recognized organization, including:
  - (1) Periodic printing of a sensitometric strip or pattern;
  - (2) Documentation of low, medium and high density calibration and that any calibration which failed to meet a manufacturer's specification was corrected before the image printer was used to print another image; and
  - (3) Annual review of all quality control tests.
- 6.3.5.3 Each registrant that uses an automatic film processor shall adopt an acceptable sensitometric quality control program.
  - (1) Film processors used to develop radiographs shall be adjusted and maintained to meet the technical development specifications for the radiography film in use.
  - (2) For all x-ray imaging systems, a continuous and documented sensitometric quality control program, including quality control tests for speed, contrast and fog, shall be performed according to specifications of the manufacturer and/or a registered medical physicist and/or a nationally recognized organization.
- 6.3.5.4 Each registrant that uses a manual film process shall:
  - (1) Follow applicable manufacturer's development time and temperature specifications, which shall be available for review;
  - (2) Measure and log development temperature each day of use; and

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

6.3.5.5 The registrant shall control darkroom lighting such that:

- (1) Exposure of a film to the darkroom safelight for one minute does not increase the optical density of that film by more than 0.1 optical density units when the test film has a latent image sufficient to produce a density between 1.0 and 2.0 optical density units prior to safe light exposure.
- (2) If used, daylight film handling boxes preclude fogging of the film.
- (3) The base plus fog of an unexposed film does not exceed 0.25 optical density units when developed by the routine procedure used by the facility.

6.3.5.6 All film storage, including 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.

6.3.5.7 The registrant shall ensure that each monitor 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 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 of Society of Motion Picture and Television Engineers (SMPTE) Pattern or equivalent test pattern;
- (3) Initial and annual verification that monitor calibration conforms with the DICOM Part 14 Grayscale Standard Display Function (see AAPM Online Report OR-03), or equivalent:
  - (a) Visualization of low contrast patches;
  - (b) Visualization of spatial resolution targets;
  - (c) Measurement 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 5% of each other when more than one monitor is being utilized at a primary image interpretation workstation.

6.3.5.8 The registrant shall ensure that computed radiography cassettes and cassette readers used for primary image interpretation are evaluated periodically according to specifications of the manufacturer and/or a registered medical physicist and/or a nationally recognized organization, for example, in AAPM Report 93, in a program reviewed annually by a registered medical physicist.

6.3.5.9 Special requirement for viewboxes and lighting in mammography.

- (1) A viewbox used for clinical quality review and interpreting mammograms shall be

capable of producing a luminance of at least 3,000 candela per square meter ( $\text{cd-m}^{-2}$ ).

- (2) The registrant shall make special lights for film illumination (that is, hot lights), capable of producing light levels greater than that provided by the view box, available to the interpreting physician.

#### **6.4 Requirements for Safe Use of a Diagnostic X-ray Imaging System of Any Kind.**

##### **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 x-ray imaging equipment and associated facilities, except as provided by 6.7.5.1 for dental uses and 6.8.5.1 for veterinary uses.

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 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) The control panel containing the main power switch shall bear this or an equivalent warning statement, legible and accessible to view:

“WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions 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 mGy (100 mR) in any 1 hour when the x-ray tube is operated at its leakage exposure settings.
- (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  $18 \mu\text{Gy}$  (2 mR) in any one hour at 5 cm from any accessible surface (that can be easily or accidentally touched by an individual without the use of a tool) 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 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 Table 6-1.

Table 6-1					
X-Ray Tube Voltage (kilovolt peak)		Minimum HVL (mm of aluminum)			
Designed Operating Range	Measured Operating Potential	Dental X-ray Systems With Intraoral Image Receptors		All X-ray Systems Other Than Dental X-ray Systems	
		Made On, Before, or After December 1, 1980		Made Before June 10, 2006	Made On or After June 10, 2006
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	1.5	1.8
Above 70	71	2.1	2.1	2.1	2.5
	80	2.3	2.3	2.3	2.9
	90	2.5	2.5	2.5	3.2
	100	2.7	2.7	2.7	3.6
	110	3.0	3.0	3.0	3.9
	120	3.2	3.2	3.2	4.3
	130	3.5	3.5	3.5	4.7
	140	3.8	3.8	3.8	5.0
	150	4.1	4.1	4.1	5.4

- (2) If it is necessary to determine such half-value layer at an x-ray tube potential that is not listed in Table 6-1, linear interpolation or extrapolation is acceptable.

#### 6.4.2.6 Beam Quality: Additional Special Requirements.

- (1) Beryllium window tubes, except those used for mammography, shall have a minimum of 0.5 mm aluminum equivalent filtration permanently installed in the useful

beam.

- (2) For capacitor energy storage equipment, compliance with the requirements of 6.4.2.5 shall be determined with the system fully charged and for the highest clinically used mAs.
- (3) The required minimal aluminum equivalent filtration shall include the filtration contributed by all materials that are always present between the source and the patient.
- (4) For x-ray systems that have variable kVp and variable filtration for the useful beam, a filtration control device shall:
  - (a) Link the kVp selector with the filter(s); and
  - (b) Prevent an exposure unless the minimum amount of filtration required by 6.4.2.5 is in the useful beam for the given kVp that has been selected.

#### 6.4.2.7 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.
  - (a) This indication shall be both on the x-ray control and at or near the tube housing assembly that has been selected.
- (3) Any information displayed at the tube head shall meet manufacturer's specifications.

#### 6.4.2.8 Locks.

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

#### 6.4.2.9 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 Special Requirements for Safe Use of Fluoroscopy Systems.**

#### 6.5.1 Administrative Controls.

- 6.5.1.1 In addition to the provisions of 6.3 and 6.4, the requirements of 6.5 apply to all fluoroscopic x-ray imaging equipment and facilities.
- 6.5.1.2 Supervision and use of a fluoroscopic x-ray system for the purpose of localization to obtain images for diagnostic purposes shall be by an individual who has adequate radiation safety training and experience.

- (1) A physician, chiropractor, podiatrist or veterinarian who has a current active State of Colorado license to practice the healing arts shall directly supervise use of a fluoroscopic x-ray system.
- (2) Training and experience shall be as provided in 2.6.1, in particular 2.6.1.5 and any applicable appendix to Part 2, and 6.3.1.9.
- (3) Interpretation of both real-time and stored fluoroscopic images shall be by a physician, chiropractor, podiatrist or veterinarian who has a current active State of Colorado license to practice the healing arts.

6.5.2 Each fluoroscopic x-ray system shall meet the following equipment design and configuration requirements.

6.5.2.1 Only image-intensified or direct-digital-receptor fluoroscopic equipment shall be used.

6.5.2.2 Limitation of the Useful Beam.

(1) Primary Protective Barrier to Limit the Useful Beam.

- (a) The fluoroscopic imaging assembly shall be provided with a primary protective barrier that intercepts the entire cross section of the useful beam at any SID.
- (b) The x-ray tube used for fluoroscopy shall not produce x-rays unless the primary protective barrier is in position to intercept the entire useful beam.

(2) Limitation of the X-ray Field.

- (a) For fluoroscopic equipment manufactured before June 10, 2006, other than radiation therapy simulation systems, the following apply:
  - (i) Neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID.
  - (ii) The sum of the excess length and the excess width shall be no greater than 4 percent of the SID.
  - (iii) The error in alignment shall be determined along the length and width dimensions of the x-ray field that pass through the center of the visible area of the image receptor.

(3) To permit further limitation of the x-ray field, the following specifications shall also be met.

- (a) Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID and/or a visible area of greater than 300 square cm shall be provided with means for stepless adjustment of the x-ray field.
- (b) All equipment with a fixed SID and a visible area of 300 square cm or less shall be provided with either stepless adjustment of the x-ray field or with means to further limit the x-ray field size at the plane of the image

receptor to 125 square cm or less.

- (c) If provided, stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size of 5cm by 5cm or less.
- (d) For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable:
  - (i) Means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor; and
  - (ii) The entire cross section of the useful beam shall be intercepted by the primary protective barrier at any SID.
- (e) Compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.
  - (i) Measurement shall be made in perpendicular directions corresponding to the vertical and horizontal directions on the video monitor image.
  - (ii) 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.

(4) Additional X-ray Field Specifications for Spot-film Devices:

- (a) Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the image receptor to the size of that portion of the image receptor that has been selected on the spot film selector.
  - (i) Such adjustment shall be automatically accomplished except when the x ray field size in the plane of the image receptor is smaller than that of the selected portion of the image receptor.
  - (ii) If the x-ray field size is less than the size of the selected portion of the image receptor, the field size shall not open automatically to the size of the selected portion of the image receptor unless the operator has selected that mode of operation.
- (b) Neither the length nor the width of the x-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than three (3) percent of the SID when adjusted for full coverage of the selected portion of the image receptor.
  - (i) The sum, without regard to sign, of the length and width differences shall not exceed four (4) percent of the SID.
- (c) It shall be possible to adjust the x-ray field size in the plane of the image receptor to a size smaller than the selected portion of the image receptor.

- (i) The minimum field size at the greatest SID shall be equal to, or less than, 5cm by 5cm, or 125cm<sup>2</sup> for a fixed SID.
  - (d) The center of the x-ray field in the plane of the image receptor shall be aligned with the center of the selected portion of the image receptor to within two (2) percent of the SID.
  - (e) On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.
- (5) Override.
  - (a) If a means exists to override any of the automatic x-ray field size adjustments required in 6.5.2.2, that means shall:
    - (i) Be designed for use only in the event of system failure and not as a substitute for prompt repair;
    - (ii) Incorporate a signal visible at the operator's position that will indicate whenever the automatic field size adjustment is overridden; and
    - (iii) Be clearly and durably labeled as follows:

“FOR X-RAY FIELD LIMITATION SYSTEM FAILURE”

#### 6.5.2.3 Activation of the Fluoroscopic Tube.

- (1) X-ray production in the fluoroscopic mode shall be controlled by a device that requires continuous pressure by the operator for the entire time of any exposure.
- (2) When recording serial fluoroscopic images, 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.

#### 6.5.2.4 Fluoroscopic Timer for Units Made Before June 10, 2006.

- (1) Means shall be provided to preset the cumulative irradiation time of the fluoroscopic x ray tube.
- (2) The maximum cumulative time of the timing device shall not exceed five (5) minutes without resetting.
- (3) A signal audible to the operator shall indicate the completion of any preset cumulative irradiation time and shall continue to sound while x-rays are produced until the timing device is reset.
- (4) Fluoroscopic equipment may be modified in accordance with 1020.30(q) to comply with the requirements of 1020.32(h)(2), and, if modified, shall bear a label indicating the statement: “Modified to comply with 21 CFR 1020.32(h)(2).”

#### 6.5.2.5 For x-ray controls manufactured on or after June 10, 2006, each fluoroscopic tube shall

be provided with both a display and audible signal.

- (1) The display, which shall show the fluoroscopic irradiation time in minutes and tenths of minutes at the fluoroscopist's working position independently of the audible signal required by 6.5.2.5(2), shall:
  - (a) Display continuously when the x-ray tube is activated and be updated at least once every 6 seconds (0.1 minute);
  - (b) Display within 6 seconds (0.1 minute) of termination of an exposure and remain displayed until reset; and
  - (c) Be provided with means 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:
  - (a) For each passage of 5 minutes of fluoroscopic irradiation time during an examination or procedure; and
  - (b) Until manually reset or, if automatically reset, for at least 2 seconds.

#### 6.5.2.6 Indication of potential and current is required.

- (1) During fluoroscopy and cinefluorography the kV and the mA shall be continuously indicated.

#### 6.5.2.7 Last-Image-Hold (LIH) display.

- (1) For an LIH image obtained by retaining pre-termination fluoroscopic images, if the number of images and method of combining images are selectable by the user, the selection shall be indicated prior to initiation of the fluoroscopic exposure.
- (2) For an LIH image obtained by initiating a separate radiographic-like exposure at the termination of fluoroscopic imaging, the exposure settings 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.
- (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.
- (4) The predetermined or selectable options for producing the LIH radiograph shall include a description of any exposure settings applicable for the selected option and the impact of the selectable options on image characteristics and the magnitude of radiation emissions.

#### 6.5.2.8 The following requirements apply to displays of the values of AKR and cumulative air kerma for each x-ray tube used during an examination or procedure:

- (1) Fluoroscopic equipment manufactured on or after June 10, 2006, shall display at the fluoroscopist's working position the AKR and cumulative air kerma.

- (2) 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.
- (3) 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.
- (4) The display of the AKR shall be clearly distinguishable from the display of the cumulative air kerma.
- (5) 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. The reference location shall be identified and described specifically in the information provided to users as required by 2.7.1.3.
  - (a) For fluoroscopes with x-ray source below the x-ray table, x-ray source above the table, or of lateral type, the reference locations shall be the respective locations specified in 6.5.4.1 (1), 6.5.4.1 (2), or 6.5.4.1 (4) for measuring compliance with air-kerma rate limits.
  - (b) 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) Consistent with 6.5.2.8(1), a method shall be provided to reset to zero the display of cumulative air kerma prior to the commencement of a new examination or procedure.
- (7) The displayed AKR and cumulative air kerma shall not deviate from the actual values by more than +/-35 percent over the range of 6 mGy/min and 100 mGy to the maximum indication of AKR and cumulative air kerma, respectively. Compliance shall be determined with an irradiation time greater than 3 seconds.
- (8) AKR and air kerma display calibration shall be verified annually by a registered medical physicist.

#### 6.5.2.9 Spot Imager Exposure Reproducibility.

- (1) Fluoroscopic systems equipped with spot image mode shall meet the following exposure reproducibility requirements when operating in the spot image mode:
  - (a) When all exposure settings are held constant, including control panel selections associated with an automatic exposure control system, the coefficient of variation of air kerma for both manual and automatic exposure control systems shall not exceed 0.05.

#### 6.5.2.10 Barrier Transmitted Radiation Rate Limits.

- (1) The AKR due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed  $0.334 \times 10^{-6}$  of the entrance AKR (one-third of one millionth of the entrance AKR) at 10cm from any accessible surface

(that can be easily or accidentally touched by an individual without the use of a tool) of the fluoroscopic imaging assembly beyond the plane of the image.

### 6.5.3 Radiation Exposure Control Devices And Operation.

#### 6.5.3.1 Air Kerma Rate (AKR) Limits for Fluoroscopic Equipment Manufactured Before May 19, 1995.

- (1) Equipment without AERC is not permitted.
- (2) Fluoroscopic equipment that is provided with 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) measured per 6.5.4:
  - (a) Except during recording of fluoroscopic images when the recorded images are intended for subsequent interpretation by a physician, chiropractor, podiatrist or veterinarian who has a current active State of Colorado license to practice the healing arts; or
  - (b) Except when an optional high-level control is provided.
    - (i) Unless the high-level control is activated, the equipment shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 44 mGy per minute (5 R/min) at the point where the center of the useful beam enters the patient.
    - (ii) Special means of activation of high-level controls shall be operable only when continuous manual activation is provided by the operator.
    - (iii) A continuous signal audible to the operator shall indicate that the high-level control is being employed.
- (3) Fluoroscopic equipment that is 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) measured per 6.5.4:
  - (a) Except during recording of fluoroscopic images when the recorded images are intended for subsequent interpretation by a physician, chiropractor, podiatrist or veterinarian who has a current active State of Colorado license to practice the healing arts; or
  - (b) Except when the mode or modes have an optional high-level control.
    - (i) Unless the high-level control is activated, that mode or modes shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 6.5.3.1(1)(a), 6.5.3.1(2)(a), or 6.5.3.1(3)(a) as measured per 6.5.4.
    - (ii) Special means of activation of high-level controls shall be required.
    - (iii) The high-level control shall be operable only when continuous manual activation is provided by the operator.

(iv) A continuous signal audible to the operator shall indicate that the high-level is being employed.

(4) Fluoroscopic units that have the high-level control activated and an entrance AKR exceeding 0.1 Gy per minute (11 R/min) shall be posted with the measured maximum AKR, on a sign that:

(a) Is visible at the operator's position;

(b) States that "The system may exceed an entrance AKR exceeding 0.1 Gy per minute (more than 10 R/min)" .

#### 6.5.3.2 Entrance AKR Limits For Fluoroscopic Equipment Manufactured on and after May 19, 1995.

(1) Fluoroscopic equipment operable at any combination of tube potential and current that results in an AKR greater than 44 mGy per minute (5 R/min) at the point where the center of the useful beam enters the patient shall be equipped with AERC.

(a) Manual selection of exposure settings may also be provided.

(2) Fluoroscopic equipment 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) measured per 6.5.4.

(3) For equipment manufactured prior to June 10, 2006, exception to 6.5.3.2(2) is allowed during the recording of images from an x-ray image-intensifier tube using photographic film or a video camera when the x-ray source is operated in a pulsed mode when the recorded images are intended for subsequent interpretation by a physician, chiropractor, podiatrist or veterinarian who has a current active State of Colorado license to practice the healing arts.

(4) For equipment manufactured on or after June 10, 2006, exception to 6.5.3.2(2) is allowed during the recording of images from the fluoroscopic image receptor for the purpose of providing the user with a recorded image(s) after termination of the exposure.

(a) Such recording does not include images resulting from a last-image-hold feature that are not recorded.

(5) Exception to 6.5.3.2(2) is allowed when the high-level control is activated.

(a) The equipment shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 176 mGy per minute (20 R/min) at the point where the center of the useful beam enters the patient.

(b) Special means of activation of high-level controls shall be required. The high-level control shall only be operable when continuous manual activation is provided by the operator.

(c) A continuous signal audible to the operator shall indicate that the high-level control is being employed.

6.5.3.3 A mini-c-arm x-ray system shall have an exposure rate less than or equal to 88 mGy (10 R) per minute at the exit port.

6.5.3.4 Control of Scattered Radiation.

(1) Conventional fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation that originates from under the table.

(a) The attenuation required shall be not less than 0.25 millimeter lead equivalent.

(2) Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities or head, shall be exposed to unattenuated scattered radiation unless that individual:

(a) Is at least 2m (more than 6 feet) from the center of the useful beam, or

(b) The radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, drapes, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in 6.3.3.5.

(3) Exception to 6.5.3.4(2) is allowed if the facility has a written policy that applies to when the use of drapes or self-supporting curtains is contra-indicated and the diagnosis might be compromised, such as where a sterile field will not permit the use of the normal protective barriers.

(a) If the use of pre-fitted sterilized covers for the barriers is practical, exemption is not appropriate.

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

6.5.4 Each fluoroscopic x-ray system shall fulfill the following measurement and maintenance requirements.

6.5.4.1 Compliance with the requirements of 6.5.3 shall be determined as follows:

(1) If the source is below the table, AKR shall be measured one centimeter above the tabletop or cradle.

(2) If the source is above the table, the AKR shall be measured at 30cm 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 30cm from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the spacer assembly or beam-limiting device is not closer than 30cm from the input surface of the fluoroscopic imaging assembly.

(a) For a c-arm type of fluoroscope having an SID less than 45cm, the AKR shall be measured at the minimum SSD, or corrected to the minimum SSD

using the inverse square law.

- (4) Each lateral-type fluoroscope, either stationary or mobile, AKR shall be measured at a point 15cm from the centerline of the table (isocenter) 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 15cm to the centerline of the table.

- (5) Periodic measurement of AKR shall be performed as follows:

- (a) Such measurements shall be made annually or after any maintenance of the system that might affect the exposure rate.

- (b) Conditions of periodic measurement of AKR are as follows:

- (i) The measurement shall be made under the conditions that satisfy the requirements of 6.5.4.1;

- (ii) The kVp shall be the maximum kVp that can be produced by the x-ray system;

- (iii) The x-ray system(s) that incorporates automatic exposure rate control shall have the beam collimated to the size of the detector and have sufficient material placed in the useful beam to intercept the entire beam so that output of the machine is a maximum for the x-ray system; and

- (iv) X-ray system(s) that do not incorporate an automatic exposure rate control shall utilize the maximum milliamperage typical of the clinical use of the x-ray system.

- (6) For other fluoroscopic systems not described above, the AKR shall be measured at the point specified by the manufacturer for maximum dose rate measurements.

#### 6.5.4.2 Source-skin distance (SSD) shall not be less than:

- (1) 38 cm on stationary fluoroscopes;

- (2) 30 cm on all mobile and portable fluoroscopes, including c-arm fluoroscopes having a maximum source image receptor distance greater than or equal to 45 cm and o-arm fluoroscopes;

- (3) 20 cm for mobile fluoroscopes used for specific surgical application;

- (a) The written safety procedures must provide precautionary measures to be adhered to during the use of these systems;

- (4) 19 cm for stationary, mobile, or portable mini-c-arm fluoroscopic systems having a maximum source image receptor distance less than 45 cm manufactured on or after June 10, 2006;

- (a) Such systems shall be labeled for extremity use only;

(b) In addition, for those systems intended for specific surgical application that would be prohibited at the source-skin distances specified in this paragraph, provisions may be made for operation at shorter source-skin distances but in no case less than 10 cm;

(c) The written safety procedures must provide precautionary measures to be adhered to during the use of these systems; and

(5) The distance in cm recommended by the manufacturer for equipment not specified in 6.5.4.2(1) through 6.5.4.2(4).

#### 6.5.4.3 Measuring Barrier Transmission.

(1) The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm.

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

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

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

(5) The attenuation block shall be positioned in the useful beam 10 cm from the point of measurement of AKR and between this point and the input surface of the fluoroscopic imaging assembly.

#### 6.5.4.4 Each registered facility shall maintain records of:

(1) Cumulative fluoroscopic exposure time and/or other patient dose estimation data (for example, kerma-area-product); and

(2) The type and date of each examination, patient identification, system used, and operator's name.

#### 6.5.5 Each fluoroscopic x-ray system shall have written quality control and quality assurance procedures.

##### 6.5.5.1 The quality control and quality assurance procedures shall be consistent with 6.3.5 and shall follow:

(1) Specifications of the manufacturer; and

(2) Specifications of a registered medical physicist; and/or

(3) Standards of an appropriate nationally recognized organization.

##### 6.5.5.2 Systems shall be evaluated periodically by a registered medical physicist in accordance with standards and protocols published by nationally recognized organizations (for example, AAPM Report 4 and AAPM Report 74), 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.

#### 6.5.6 Radiation Therapy Simulation Systems.

6.5.6.1 Radiation therapy simulation systems shall be exempt from all the requirements of 6.5.2.2, 6.5.2.4, 6.5.2.5, 6.5.2.10, 6.5.3.1 and 6.5.3.2, provided that:

- (1) Each system is designed and used in such a manner that no individual other than the patient, required staff and ancillary personnel is in the x-ray room during any period of time when the system is producing x-rays; and
- (2) Each system that does not meet the requirements of 6.5.2.4 and 6.5.2.5 is provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. Procedures shall require in such cases that the timer be reset between examinations.
- (3) Staff and ancillary personnel shall be protected in accordance with 6.3.3.5, 6.3.3.6, 6.3.3.7 and 6.3.3.8.

### **SPECIAL REQUIREMENTS FOR GENERAL PURPOSE DIAGNOSTIC X-RAY IMAGING SYSTEMS**

#### **6.6 Design and Configuration for Safe Use of a General Purpose X-ray Imaging System (Other Than Dental, Fluoroscopic, Veterinary, Computed Tomography, or Mammography).**

##### 6.6.1 Administrative Controls.

6.6.1.1 In addition to the provisions of 6.3 and 6.4, the special requirements of 6.6 apply to all x-ray imaging equipment and associated facilities other than:

- (1) Fluoroscopy (in 6.5);
- (2) Dental (in 6.7, with cross-reference in 6.7.2.1 to 6.6.2 and in 6.7.3.1 to 6.6.3);
- (3) Veterinary (in 6.8);
- (4) Computed tomography (in 6.9);
- (5) Mammography (in 6.10).

6.6.1.2 Each individual who operates an x-ray imaging system subject to 6.6 shall meet the applicable adequate radiation safety training and experience requirements of 2.6.1.

6.6.2 For each general purpose stationary, mobile and/or portable x-ray imaging system subject to 6.6, the useful beam shall be limited to the area of clinical interest.

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

- (1) For certified systems, stepless adjustment of the size of the x-ray field shall be provided such that the minimum field size at an SID of 100 cm shall be equal to or less than 5 cm by 5 cm.

6.6.2.2 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 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 The Department may grant an exemption on non-certified x-ray systems to 6.6.2.1 and 6.6.2.2 provided the registrant makes a written application for such exemption and in that application demonstrates that:

- (1) It is impractical to comply with 6.6.2.1 and 6.6.2.2; and
- (2) The purpose of 6.6.2.1 and 6.6.2.2 will be met by other methods.

6.6.2.4 Additional Beam Limitation Requirements for Each Stationary General Purpose X-Ray System.

- (1) A method 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.

6.6.2.5 Beam Limitation Requirements for Each X-Ray System Designed for One Image Receptor Size.

- (1) 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
- (2) 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.

6.6.2.6 Beam Limitation Requirements for Each X-Ray System Other Than Governed by 6.6.2.1 through 6.6.2.5.

- (1) Means shall be provided 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.
- (2) Means shall be provided 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.
- (3) 6.6.2.6(1) and 6.6.2.6(2) may be met with a system that meets the requirements for a general purpose x-ray system as specified in 6.6.2.1 and 6.6.2.2, 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.

6.6.2.7 Positive Beam Limitation (PBL) for a diagnostic x-ray system with any certified component.

- (1) 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 6.6.2.7(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) When provided, the PBL system shall function as described in 6.6.2.7(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  $\pm$  three (3) degrees of vertical and the SID is 90 cm to 130 cm inclusive; or the x-ray beam axis is within  $\pm$  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  $\pm$  three (3) degrees;
  - (e) Neither tomographic nor stereoscopic radiography is being performed;

- (f) Manual collimation is not used;
- (g) The machine is used for procedures other than therapy simulation; and
- (h) The PBL system has not been intentionally overridden.

(a) Be designed for use only in the event of PBL system failure, or if the system is being serviced; and

(i) A key be utilized to defeat the PBL;

(iii) The key or key switch be clearly and durably labeled as follows:

“FOR X-RAY FIELD LIMITATION SYSTEM FAILURE” ; and

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

(4) Compliance with 6.6.2.7 shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of 6.6.2.7(2) are met.

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

(6) The PBL system shall be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size.

(7) The minimum field size at an SID of 100 cm shall be equal to or less than 5 cm by 5 cm.

(8) The PBL system shall be designed such that if a change in image receptor does not cause an automatic return to PBL function as described in 6.6.2.7, then any change of image receptor size or SID must cause the automatic return.

#### 6.6.3.1 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".

#### 6.6.3.2 X-ray Control.

- (1) An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time except for:
  - (a) Exposure of one-half (0.5) second or less, or
  - (b) During serial radiography when a means shall be provided to permit completion of any single exposure of the series in process.
- (2) Except for a bone densitometry system, each x-ray control shall be located in such a way as to meet the following requirements:
  - (a) For stationary x-ray systems, and mobile or portable systems used routinely in one location, the x-ray control permanently mounted in a separated area behind a whole body protective barrier (of not less than 0.25 millimeter lead equivalent) where the operator is required to remain during the entire exposure.
  - (b) Mobile and portable x-ray systems not routinely used in one location shall be required to have an exposure switch so arranged that the operator can stand at least 2 meters (more than 6 feet) from the patient, the x-ray tube and the useful beam.
    - (i) Mobile and portable x-ray systems used in surgery are considered to be not routinely used in one location.
    - (ii) A separate exposure switch is not required for portable hand-held x-ray equipment that has the control on the device.
- (3) The settings 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 exposure settings, permanent markings visible from the operator's position are acceptable.

#### 6.6.3.3 Automatic Exposure Controls.

- (1) When an automatic exposure control is provided, indication shall be made on the control panel when this mode of operation is selected;
- (2) If the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two (2) pulses;
- (3) The minimum exposure time for all equipment other than that specified in 6.6.3.3(2) shall be equal to or less than one-sixtieth (1/60) second or a time interval required to deliver 5 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 kW 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 50 kVp, 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 6.6.3.3(4), and manual resetting shall be required before further automatically timed exposures can be made.

#### 6.6.3.4 Timer Reproducibility.

- (1) 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 for linearity shall be in accord with 21 CFR 1020.31.

#### 6.6.3.5 Source-Skin Distance.

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

#### 6.6.3.6 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.
- (2) The facility registrant may request an exemption for any machines manufactured prior to 1974 that cannot meet this requirement. The exemption request must verify that this exposure reproducibility variation will not result in unnecessary patient radiation exposure due to the need for repeat examinations.

#### 6.6.3.7 Radiation from Capacitor Energy Storage Equipment in Standby Status.

- (1) Radiation emitted from the x-ray tube when the exposure switch or timer is not activated shall not exceed a rate of 0.5  $\mu\text{C/kg}$  (2 mR) per hour at 5 cm from any accessible surface (that can be easily or accidentally touched by an individual without the use of a tool) of the diagnostic source assembly, with the beam-limiting device fully open.

#### 6.6.3.8 Linearity for a diagnostic x-ray system with any certified component shall be in accord with 21 CFR 1020.31(c)(3).

#### 6.6.3.9 Accuracy for a diagnostic x-ray system with any certified component.

- (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.

6.6.4 For each general purpose x-ray imaging system, the registrant shall ensure that manufacturer maintenance specifications are followed.

6.6.5 For each general-use diagnostic radiographic x-ray system, the registrant shall ensure that written quality control and quality assurance procedures are available and in use, including for facility operations and emergencies.

6.6.5.1 The quality control and quality assurance procedures shall be consistent with 6.3.5 and shall follow:

- (1) Specifications of the manufacturer; and
- (2) Specifications of a registered medical physicist; and/or
- (3) Standards of an appropriate nationally recognized organization.

6.6.5.2 Routine periodic quality control shall be comparable to the following:

- (1) Cassette maintenance (for example, erasure and/or screen cleaning);
- (2) Images inspected for evidence of clinically relevant artifacts (for example, dust and non-uniformities) with appropriate corrective action (for example, cleaning of screens) taken as needed and documented;
- (3) Analysis of repeated and/or rejected images;
- (4) Investigation of errors outside a control range;
- (5) Measurements using phantoms, if required (for example, in bone densitometry); and
- (6) Measurements of scattered radiation at the operator's position, if required (for example, in bone densitometry).

6.6.5.3 Annual quality assurance shall be comparable to the following:

- (1) All quality control tests shall be reviewed annually;
- (2) Imaging systems shall be tested in accordance with standards and protocols published by a nationally recognized organization; and
- (3) The frequency of quality control testing and corrective actions taken as a result are followed and documented.

## **6.7 Safe Use of a Dental X-Ray imaging System.**

6.7.1 Administrative Controls.

6.7.1.1 In addition to the provisions of 6.3 and 6.4, the requirements of 6.7 apply to equipment

and associated facilities used for dental x-ray imaging.

6.7.1.2 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 2.6.1.10.

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

6.7.2.1 Cephalometric and volumetric dental x-ray 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 room(s) of any facility having a cephalometric and/or volumetric dental x-ray system regardless of occupancy.
- (2) A dental facility may apply in writing and be granted exemption by the Department for a particular room and x-ray equipment configuration.

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

(1) Source-Skin Distance (SSD) 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 SSD, to not less than 18 cm if operable above 50 kVp.

(2) 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.

(3) 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.

6.7.3 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 instead of the requirements in 6.6.3:

(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) 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.
- (b) Each control shall be located as follows:
  - (i) For stationary x-ray systems, and mobile or non-handheld portable systems used routinely in one location, the x-ray control permanently mounted in a separated area behind a whole body protective barrier (of not less than 0.25 millimeter lead equivalent) where the operator is required to remain during the entire exposure, or the exposure control shall be such that the operator can stand at least 2 meters (more than 6 feet) from the patient, the x-ray tube and the useful beam;
  - (ii) Mobile and non-hand-held portable x-ray systems not routinely used in one location shall be required to have an exposure switch so arranged that the operator can stand at least 2 meters (more than 6 feet) from the patient, the x-ray tube and the useful beam;  
or
  - (iii) Portable hand-held x-ray equipment shall meet Appendix 6E.

(3) Exposure Reproducibility.

- (a) The estimated coefficient of variation of radiation exposure shall be no greater than 0.05, for any specific combination of selected exposure settings.

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

(5) 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).

(6) 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).

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

(8) The tube housing and the PID shall not be hand-held during an exposure, except as provided in Appendix 6E for portable hand-held x-ray equipment.

(9) 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.

(10) 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 A thyroid shield shall be used to reduce patient exposure to scattered radiation (except for a case in which shielding would interfere with the diagnostic procedure).

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.

6.7.4 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 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 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.

6.7.5.3 Annual review of all quality control tests.

## **6.8 Safe 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).

#### **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 both the tube head and the nearest edge of the image receptor.

#### 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 be protected from direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 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.
- (2) If the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, such as protective gloves and apron, and 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, such as protective 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 portable 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.

## **SPECIAL REQUIREMENTS FOR COMPUTED TOMOGRAPHY**

### **6.9 Safe Use of a Computed Tomography System.**

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 6.3.1.8.
- (2) Training and experience shall be as provided in 2.6.1, in particular 2.6.1.9 and Appendix 2E, and 6.3.1.9.

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) Means shall be provided to permit visual determination of the location of a reference tomographic plane.
- (2) If a device using a light source is used to satisfy 6.9.2.2(1), the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux (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) 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 CT x-ray system shall not be operated except by an individual who has been specifically trained in its operation.
- (2) Information shall be readily available regarding the operation of the system.
- (3) Information regarding calibration of the system shall be readily available, including:
  - (a) Dates of the latest calibration and spot checks and the location within the facility where the results of those tests may be obtained;

- (b) Instructions on the use of the CT performance phantom(s) including a schedule of spot checks appropriate for the system, allowable variations for the indicated parameters, and the results of at least the most recent spot checks conducted on the system;
- (c) When operators must select exposure settings, a current protocol shall be available at the control panel that specifies for each routine examination the CT conditions of operation and the typical number of scans per examination, including guidance for age-appropriate scanning.

#### 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 Extraneous Radiation.

- (1) When data are not being collected for image production, the radiation adjacent to the tube port shall not exceed that permitted by 6.4.2.3.

#### 6.9.3.4 Additional Requirements Applicable to CT X-Ray Systems Containing a Gantry Manufactured After September 2, 1992.

- (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 1 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.

6.9.4 Each computed tomography facility shall conduct required surveys, evaluations, calibrations, and spot checks.

6.9.4.1 Surveys and Evaluations.

- (1) A radiation survey shall be made by, or under the direct supervision of, a registered medical physicist, to verify and document compliance with 4.14 and 4.15 for:
  - (a) Any change in the facility or equipment that might cause a significant increase in radiation hazard; or
  - (b) Any initial or new location for a CT imaging system that is designed to be transported from place to place.
- (2) Notwithstanding the provisions of 2.5.1.2, CT x-ray systems that have undergone an x-ray tube change within 12 months of the last annual evaluation do not require a complete calibration at the time of the x-ray tube change, provided that:
  - (a) The CT x-ray system operation after the tube change meets the criteria established by the registered medical physicist.
  - (b) Each CT system shall receive a certification evaluation (CE) at least within one year of the previous CE.

6.9.4.2 Radiation Dosimetry.

- (1) The radiation output of the CT x-ray system shall be measured by, or under the personal supervision of, a registered medical physicist:
  - (a) At intervals (not exceeding one year) specified by a registered medical physicist;
  - (b) 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;
  - (c) With a calibrated dosimetry system:
    - (i) Traceable to a national standard; and
    - (ii) Calibrated within the preceding two (2) years.
- (2) CT dosimetry shall be evaluated by a registered medical physicist in accordance with protocols published by a nationally recognized organization.
- (3) Records of measurements performed shall be maintained for a period of three (3) years for inspection by the Department.

6.9.4.3 Spot Checks.

- (1) The spot-check procedures shall be in writing and shall have been developed by a registered medical physicist.
- (2) The spot-check procedures shall incorporate the use of a commensurate CT performance phantom.
- (3) All spot checks shall be performed at time intervals and under system conditions specified by a registered medical physicist.
- (4) Images shall be retained, at least until a new calibration is performed, as follows:
  - (a) Photographic copies of the images obtained from the image recording device; or
  - (b) Images stored in digital form on a storage medium compatible with the CT x-ray system.
- (5) Written or electronic records of the spot checks performed shall be maintained for inspection by the Department.

6.9.5 Each computed tomography system shall have written quality control and quality assurance procedures, including:

6.9.5.1 If a calibration required by 6.9.4.2 or a spot check required by 6.9.4.3 identifies that a system operating parameter is outside a specified or recommended tolerance or range:

- (1) The CT x-ray system shall not be used on a patient except as permitted by documented instructions of the registered medical physicist; and
- (2) Correction or modification shall be made within 30 days of the date of the test identifying the problem.

6.9.5.2 The computed tomography system shall meet the specifications of the manufacturer or registered medical physicist and/or appropriate nationally recognized organization, or equivalent approved by the Department, for:

- (1) Alignment light accuracy;
- (2) Slice thickness;
- (3) Image quality; and
- (4) CT number accuracy.

6.9.5.3 All quality control tests shall be reviewed by a registered medical physicist at least annually.

## **SPECIAL REQUIREMENTS FOR MAMMOGRAPHY**

### **6.10 Safe Use at a Mammography Facility.**

#### **6.10.1 Administrative Controls.**

6.10.1.1 In addition to the provisions of 6.3 and 6.4, the requirements of 6.10 apply to equipment and associated facilities used for mammography.

6.10.1.2 Each facility performing mammography shall:

- (1) Meet the requirements of 21 CFR 900;
- (2) Have a valid certificate issued by the U.S. Department of Health and Human Services pursuant to the Mammography Quality Standards Reauthorization Act of 1998, Public Law 105-248, and 21 CFR 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 qualified inspector who conducts a mammography facility and x-ray machine certification evaluation shall meet the requirements of Appendix 2I.

6.10.1.4 Each Individual who performs a mammography examination shall meet the adequate radiation safety training and experience requirements of 2.4.5.4, 2.6.1.8 and Appendix 2M.

6.10.1.5 In the State of Colorado, the regulatory requirements of Part 6 shall also apply as appropriate to radiography of the breast performed:

- (1) During invasive interventions for localization or biopsy (for example, stereotactic biopsy procedures); or
- (2) With an investigational device as part of a scientific study conducted in accordance with FDA investigational device exemption regulations; or
- (3) During any other procedure for radiography of the breast that the Department determines and designates.

6.10.1.6 The registrant shall establish and maintain a quality assurance program to ensure the safety, reliability, clarity, and accuracy of mammography services performed at the facility, which program shall:

- (1) Follow manufacturers' specifications and/or the standards of an appropriate nationally recognized organization, for example, the American College of Radiology or American Association of Physicists in Medicine; and
- (2) Apply to and be adhered to for each procedure subject to 6.10.1.

## **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 show at least 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  $0.7 \text{ m}^2$  ( $8 \text{ ft}^2$ ) 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 direct 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 (7 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  $0.1 \text{ m}^2$  ( $1 \text{ ft}^2$ ).
- (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 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:

6C.1.4.1 Location and types of permanent and temporary barriers and shielding;

6C.1.4.2 Location of controls and any control booth;

6C.1.4.3 Location of exposure switch; and

6C.1.4.4 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 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 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) Note that this is normal fluoroscopic mode, and the FDA's regulations (21 CFR 1020.32(e)(2)(II), April 1, 2004) allow up to 176 mGy per minute (20 R/min) when recording or using high-level control.

6D.2.7 An electro-mechanical defect exists that endangers human life or safety when a radiograph is made or fluoroscopy is performed.

## **PART 6, APPENDIX 6E: HUMAN USE OF PORTABLE HAND-HELD X-RAY EQUIPMENT**

6E.1 The following requirements are applicable, as determined by the Department, to any human use x-ray radiographic device, in particular for dental intraoral use, that is designed to be operated as a hand-held unit.

6E.1.1 Requirements for any location:

6E.1.1.1 Each operator of a hand-held device shall be specifically trained to operate such equipment.

6E.1.1.2 The operator shall ensure there are no bystanders within a radius of at least 2 meters (six feet) from the patient being examined with a hand-held intraoral radiographic unit.

6E.1.1.3 If a hand-held device was designed with an optional, removable secondary radiation block, it shall be installed and used during patient examination.

6E.1.1.4 The device shall be held without any motion, in order to prevent repeat imaging due to motion that reduces image quality. If the operator has difficulty in holding the device stationary, the operator shall use a stand or tripod to immobilize the device.

6E.1.1.5 The operator shall be protected from direct scatter radiation by protective material of not less than 0.25 millimeter lead equivalent and a thyroid collar unless the radiation safety officer and Department determine that no added protection is needed for the device model and/or use.

6E.1.1.6 Personnel monitoring shall be at least as required by 6.3.3.10.

6E.1.2 Additional requirements for operations in permanent facilities:

6E.1.2.1 As provided in 6.3.2.4, a hand-held device is exempt from 6.3.2.1 and consequently is exempt from 6.3.2.2 and 6.3.2.3.

6E.1.2.2 A hand-held device shall not be used for patient examinations in hallways and waiting rooms.

6E.2 Portable hand-held x-ray equipment shall be kept in a secured location when not in 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 6.3.3.2.
- 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 who will oversee the program with a current license from Board of Medical Examiners of Physician(s) of a physician, chiropractor, dentist or podiatrist who has a current active State of Colorado license to practice the healing arts.
- 6F.1.13 A copy of the order for the screening program to be conducted, prescribed by a physician, chiropractor, dentist or podiatrist who has a current active State of Colorado license to practice the healing arts.
- 6F.1.14 A description of the procedures to be used by a physician, chiropractor, dentist or podiatrist who has a current active State of Colorado license to practice the healing arts to advise the individuals screened about the results of the screening procedure and any further medical needs indicated.
- 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.

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## **EDITOR'S NOTES**

6 CCR 1007-1 has been divided into smaller sections for ease of use. Versions prior to 4/1/07 and rule history are located in the first section, 6 CCR 1007-1. Prior versions can be accessed from the History link that appears above the text in 6 CCR 1007-1. To view versions effective on or after 4/1/07, Select the desired part of the rule, for example 6 CCR 1007-1 Part 1 or 6 CCR 1007-1 Parts 8 - 10.

## **History**

*[For history of this section, see Editor's Notes in the first section, 6 CCR 1007-1]*