Conference of Radiation Control Program Directors, Inc.

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December 11, 2009

Rob Lewis, Deputy Director
Division of Materials Safety and State Agreements
US Nuclear Regulatory Commission
Two White Flint North
11545 Rockville Pike
Rockville, MD 20852

Dear Mr. Lewis:

Please find enclosed the finished copy of the latest revision to the *Suggested State Regulations for Control of Radiation* from the Conference of Radiation Control Program Directors, Inc. (CRCPD):

Part F – Diagnostic X-Rays and Imaging Systems in the Healing Arts

2009 Rationale for Part F

On December 9, 2009, the CRCPD Board of Directors approved the publication of SSR Part F. CRCPD now requests concurrence from your agency. CRCPD requests that a written response relative to federal concurrence by your agency be submitted within 60 days of receipt of this correspondence.

Thank you for your attention to this important matter.

Sincerely,

Ruth E. McBurney

Ruth E. McBurney, CHP
Executive Director

Enclosure

cc: CRCPD Board of Directors
Kathleen Schneider, NRC
Russell Takata (HI), Chair, SR-F
Bruce Hirschler (CRCPD) SSRCR Publication Manager

PART F

DIAGNOSTIC X-RAYS AND IMAGING SYSTEMS IN THE HEALING ARTS

Sec. F.1 - Purpose and Scope. This Part establishes requirements, for which a registrant [licensee] is responsible, for use of diagnostic x-ray equipment and imaging systems by, or under the supervision of, an individual authorized by and licensed in accordance with State statutes to engage in the healing arts or veterinary medicine. The provisions of this Part are in addition to, and not in substitution for, other applicable provisions of Parts A, B, D, G and J of these regulations. Some registrants [licensees] may also be subject to the requirements of Parts I ~~and~~ , X, and Z of these regulations.

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

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

"Accessory component" means:

(1) A component used with diagnostic x-ray systems, such as a cradle or film changer, that is not necessary for the compliance of the system with applicable provisions of this ~~p~~Part but which requires an initial determination of compatibility with the system; or

(2) A component necessary for compliance of the system with applicable provisions of this ~~p~~Part but which may be interchanged with similar compatible components without affecting the system's compliance, such as one of a set of interchangeable beam-limiting devices; or

(3) A component compatible with all x-ray systems with which it may be used and that does not require compatibility or installation instructions, such as a tabletop cassette holder.

~~"Added filtration" means any filtration which is in addition to the inherent filtration.~~

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

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

"Aluminum equivalent" means the thickness of type 1100 aluminum alloy[1/] affording the same attenuation, under specified conditions, as the material in question.

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

[1/] *The nominal chemical composition of type 1100 aluminum is 99.00 percent minimum aluminum, 0.12 percent copper.*

"Assembler" means any person engaged in the business of assembling, replacing, or installing one or more components into an x-ray system or subsystem. The term includes the owner of an x-ray system or his or her employee or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.

"Attenuation block" means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy[1/] or other materials having equivalent attenuation.

"Automatic exposure control (AEC)" means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation (Includes devices such as phototimers and ion chambers).

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

"Barrier" (See "Protective barrier").

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

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

"Bone densitometry system" means a medical device which uses electronically-produced ionizing radiation to determine the density of bone structures of 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 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.]~~
"C-arm fluoroscope" means a fluoroscopic x-ray system in which the image receptor and the x-ray tube housing assembly are connected or coordinated to maintain a spatial relationship. Such a system allows a change in the direction of the beam axis with respect to the patient without moving the patient.

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

"Cassette holder" means a device, other than a spot-film device, that supports and/or fixes the position of an x-ray film [imaging] cassette during an x-ray exposure.
~~"Cephalometric device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.~~
~~"Certified components" means components of x-ray systems which are subject to regulations promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968, the Food and Drug Administration.~~
~~"Certified system" means any x-ray system which has one or more certified component(s)."Changeable filters" means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical, or physical process.~~

"Coefficient of variation (C)" means the ratio of the standard deviation to the mean value of a ~~[set]~~ population of observations. It is estimated using the following equation:

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

where:

s	=	Estimated ~~[S]~~standard deviation of the ~~[observed values;]~~ population.
$\bar{x}$	=	Mean value of observations in sample;
x_i	=	i_{th} observation in sample;
n	=	Number of observations ~~[in]~~ sampled.

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

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

"Cooling curve" means the graphical relationship between heat units stored and cooling time.

"Cradle" means:

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

(2) A device;

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

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

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

"CT" (See "Computed tomography").

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

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

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

"Detector" (See "Radiation detector")
~~"Diagnostic imaging system" means an assemblage of components for the generation, emission, reception, transformation, storage and visual display of the resultant image.~~

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

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

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

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

~~"Entrance exposure rate" means the exposure free in air per unit time.~~

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

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

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

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

"Fluoroscopic air kerma display devices" means separate devices, subsystems, or components that provide the display of AKR and cumulative air kerma, respectively, required by Section F.5. They include 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 fluoroscopic images or radiographic images recorded from the fluoroscopic ~~[visible]~~ image receptor. It includes the image receptor(s) ~~[such as the image intensifier and spot-film device]~~, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

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

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

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

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

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

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

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

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

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

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

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

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

"Image receptor support device" means, for mammography x-ray systems, that part of the system designed to support the image receptor during a mammographic examination and 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.

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

"Kerma" means the quantity defined by the International Commission on Radiation Units and Measurements. The kerma, K, is the quotient of dEtr by dm, where dEtr is the sum of the initial kinetic energies of all the charged participles liberated by uncharged particles in a mass dm of material; thus K=dEtr/dm, in units of J/kg, where the special name for the unit of kerma is gray (Gy). When the material is air, the quantity is referred to as "air kerma."

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

"kV" means kilovolts.

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

"kWs" means kilowatt second.

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

"Lateral fluoroscope" means the x-ray tube and image receptor combination in a biplane system dedicated to the lateral projection. It consists of the lateral x-ray tube housing assembly and the lateral image receptor that are fixed in position relative to the table with the x-ray beam axis parallel to the plane of the table.

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

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

(1) T~~t~~he useful beam; and

(2) R~~r~~adiation produced when the exposure switch or timer is not activated.

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

(1) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge

per exposure being 10 millicoulombs~~[, i.e., 10 milliampere seconds,]~~ (or 10 mAs) or the minimum obtainable from the unit, whichever is larger;

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

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

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

"Line-voltage regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential~~.~~ , as follows: ~~[It is calculated using the following equation:] that is,~~

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

where:

V_n = No-load line potential; and
V_l = Load line potential.

"mA" means milliampere.

"mAs" means milliampere second.

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

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

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

"Movable tabletop" means a tabletop which, when assembled for use, is capable of movement with respect to its supporting structure within the plane of the tabletop.

"Non-image-intensified fluoroscopy" means fluoroscopy using only a fluorescent screen.

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

"PBL" See "Positive beam limitation."

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

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

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

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

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

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

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

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

~~["Protective barrier" means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:~~

~~(1) "Primary protective barrier" means the material, excluding filters, placed in the useful beam;~~

~~(2) "Secondary protective barrier" means the material which attenuates stray radiation.]~~

"Protective glove" means a glove made of radiation absorbing materials used to reduce radiation exposure.

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

"Qualified ~~expert~~ medical physicist" means an individual who meets the requirements specified in Part Z. ~~has demonstrated to the satisfaction of the Agency that such individual possesses the knowledge, training and experience to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs.~~

"Quick change x-ray tube" means an x-ray tube designed for use in its associated tube housing such that:

(1) The tube cannot be inserted in its housing in a manner that would result in noncompliance of the system with the requirements of Section F.6;

(2) The focal spot position will not cause noncompliance with the provisions of this section or;

(3) The shielding within the tube housing cannot be displaced; and

(4) Any removal and subsequent replacement of a beam-limiting device during reloading of the tube in the tube housing will not result in noncompliance of the x-ray system with the applicable field limitation and alignment requirements of Section F.6.

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

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

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

~~"Radiographic imaging system" means any system whereby a permanent or semi-permanent 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 an image(s) after termination of the exposure.

"Rated line voltage" means the range of potentials, in volts, of the supply line specified by the manufacturer at which the x-ray machine is designed to operate.

"Rated output current" means the maximum allowable load current of the x-ray high-voltage generator.

"Rating" means the operating limits ~~[as]~~ specified by the ~~[component]~~ manufacturer.

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

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

"Scan time" means the period of time between the beginning and end of x-ray transmission data accumulation for a single scan.

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

~~["Secondary protective barrier" (See "Protective barrier").]~~

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

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

"Solid state x-ray imaging device" means an assembly, typically in a rectangular panel configuration, 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. The electronic signal is then used to create an image for display and/or storage.

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

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

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

"Spot film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

"Spot-film device" means a device intended to transport and/or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of ~~[an]~~ the fluoroscopic image ~~[intensifier]~~ receptor for the purpose of ~~[making]~~ producing a radiograph.

~~"SSD" means the distance between the source and the skin entrance plane of the patient.]~~

"Stationary tabletop" means a tabletop which, when assembled for use, is incapable of movement with respect to its supporting structure within the plane of the tabletop.

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

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

"Technique factors" means the following conditions of operation:

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

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

(3) For CT ~~[x-ray systems]~~ equipment designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in milliamperes (mA), x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of tube current, x-ray pulse width, and the number of x-ray pulses in mAs;

(4) For CT ~~[x-ray systems]~~ equipment not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and

(5) For all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

~~"Termination of irradiation" means the stopping of irradiation in a fashion which 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.

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

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

"Tube rating chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

"Useful beam" means the radiation ~~[emanating from]~~ which passes through the tube housing port ~~[or]~~ and ~~[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]~~ switch or timer is activated.

"Variable-aperture beam-limiting device" means a beam-limiting device which 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.

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

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

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

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

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

(3) "Stationary x-ray equipment" means x-ray equipment which 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 exposure rate is one-fourth of the maximum in the intersection.~~

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

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

"X-ray subsystem" means any combination of two or more components of an x-ray system for which there are requirements specified in this section and Sec. F.4, F.5, and F.6.

"X-ray system" means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

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

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

Sec. F.3 - General and Administrative Requirements.

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

i. An x-ray system which does not meet the provisions of these regulations shall not be operated for diagnostic purposes.

ii. Individuals who will be operating the x-ray systems ~~shall~~ shall meet the Agency's qualifications to conduct the practice of radiologic technology. ~~be adequately instructed in the safe operating procedures and be competent in the safe use of the equipment. See Appendix A for a list of subject matters pertinent to this requirement. The Agency may use interview, observation and/or testing to determine compliance.~~

iii. A chart shall be provided in the vicinity of the diagnostic x-ray system's control panel which specifies, for all examinations performed with that system, the following information:

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

(2) Type and size of the ~~film or film-screen combination~~ image receptor to be used;

(3) Type and ~~focal distance of the grid~~ size of the image receptor combination to be used, if any;

(4) Source to image receptor distance to be used (except for dental intraoral radiography);

(5) Type and location of placement of patient shielding (e.g., gonad, etc.) to be used; and

(6) For mammography, indication of kVp/target/filter combination.

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

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

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

(2) The x-ray operator, other staff, ancillary personnel, and other persons required for the medical procedure shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent material;

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

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

vii. Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:

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

(2) Exposure of an individual for the purpose of healing arts screening except as authorized by F.3a.xi.

viii. When a patient or ~~film~~ image receptor must be provided with auxiliary support during a radiation exposure:

(1) Mechanical holding devices shall be used when the technique permits. The written safety procedures, required by F.3a.iv., shall list individual projections where holding devices cannot be utilized;

(2) Written safety procedures, as required by F.3a.iv., shall indicate the requirements for selecting a holder and the procedure the holder shall follow;

(3) The human holder shall be instructed in personal radiation safety and protected as required by F.3a.v.;

(4) No individual shall be used routinely to hold ~~film~~ image receptor or patients;

(5) In those cases where the patient must hold the ~~film~~ image receptor, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material; and

(6) Each facility shall have leaded aprons and gloves available in sufficient numbers to provide protection ~~to~~ for all personnel who are involved with x-ray operations and who are otherwise not shielded.

ix. Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.

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

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

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

(4) X-ray systems subject to F.6 shall not be utilized in procedures where the source to patient distance is less than 30 centimeters, except for veterinary systems.

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

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

(b) If the grid is of the focused type, be of the proper focal distance for the SIDs being used.

x. All individuals who are associated with the operation of an x-ray system are subject to the requirements of ~~D.201, D.205, D.207 and D.208~~ D.1201, D.1207 and D.1208 of these regulations.

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

xii. Information and Maintenance Record and Associated Information. The registrant [licensee] shall maintain the following information for each x-ray system for inspection by the Agency:

(1) Model and serial numbers of all major components, and user's manuals for those components;

(2) Tube rating charts and cooling curves;

(3) Records of surveys, calibrations, maintenance, and modifications performed on the x-ray system(s); and

(4) A copy of all correspondence with this Agency regarding that x-ray system.

xiii. X-Ray Utilization Log. Except for veterinary facilities, each facility shall maintain a record containing the patient's name, the type of examinations, and the dates the examinations were performed. When the patient or film must be provided with human auxiliary support, the name of the human holder shall be recorded.

b. X-Ray Film Processing Facilities and Practices.

i. Each installation using a radiographic x-ray system and using analog image receptors (e.g. radiographic film) shall have available suitable equipment for handling and processing radiographic film in accordance with the following provisions:

(1) Manually developed film:

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

(b) The temperature of solutions in the tanks shall be maintained within the range of 60° F to 80° F (16° C to 27° C). Film shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer, or, in the absence of such recommendations, with the following time-temperature chart:

Time-Temperature Chart		
Thermometer Reading (Degrees)		Minimum Developing Time (Minutes)
°C	°F	
26.7	80	2
26.1	79	2
25.6	78	2½
25.0	77	2½
24.4	76	3
23.9	75	3
23.3	74	3½
22.8	73	3½
22.2	72	4
21.7	71	4
21.1	70	4½
20.6	69	4½
20.0	68	5
19.4	67	5½
18.9	66	5½
18.3	65	6
17.8	64	6½
17.2	63	7
16.7	62	8
16.1	61	8½
15.6	60	9½

(c) Devices shall be utilized which will indicate the actual temperature of the developer and signal the passage of a preset time appropriate to the developing time required.

(2) Automatic processors and other closed processing systems: ~~(a)~~ Films shall be developed in accordance with the time-temperature relationships recommended

by the film manufacturer; in the absence of such recommendations, the film shall be developed using the following chart:

Developer Temperature		Minimum Immersion Time[a/]
°C	°F	Seconds
35.5	96	19
35	95	20
34.5	94	21
34	93	22
33.5	92	23
33	91	24
32	90	25
31.5	89	26
31	88	27
30.5	87	28
30	86	29
29.5	85	30

[a/] *Immersion time only, no crossover time included.*

~~(b) The specified developer temperature and immersion time shall be posted in the darkroom or on the automatic processor.~~

(3) Processing deviations from the requirements of F.3b.i. shall be documented by the registrant [licensee] in such manner that the requirements are shown to be met or exceeded (e.g., extended processing, and special rapid chemistry).

ii. Other Requirements.

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

(2) The darkroom shall be light tight and use proper safelighting such that any film type in use exposed in a cassette to x-radiation sufficient to produce an optical density from 1 to 2 when processed shall not suffer an increase in density greater than 0.1 (0.05 for mammography) when exposed in the darkroom for 2 minutes with all safelights on. If used, daylight film handling boxes shall preclude fogging of the film.

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

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

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

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

(7) Film developing solutions shall be prepared in accordance with the directions given by the manufacturer, and shall be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.

Sec. F.4 - General Requirements for All Diagnostic X-Ray Systems. In addition to other requirements of this Part, all diagnostic x-ray systems shall meet the following requirements:

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

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

~~c.~~ b. Leakage Radiation from the Diagnostic Source Assembly. The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source shall not exceed ~~25.8 μC/kg~~ 0.88 milligray (mGy) air kerma (vice 100 milliroentgen ~~roentgens~~ (mR) exposure) in 1 hour when the x-ray tube is operated at its leakage technique factors. If the maximum rated peak tube potential of the tube housing assembly is greater than the maximum rated peak tube potential for the diagnostic source assembly, positive means shall be provided to limit the maximum x-ray tube potential to that of the diagnostic source assembly. Compliance shall be determined by measurements averaged over an area of 100 square ~~centimeters~~ centimeters with no linear dimension greater than 20 centimeters.

~~d.~~ c. Radiation from Components Other Than the Diagnostic Source Assembly. The radiation emitted by a component other than the diagnostic source assembly shall not exceed ~~0.5 μC/kg~~ an air kerma of 18 microgray (vice 2 milliroentgens exposure) in 1 hour at 5 centimeters ~~-~~ from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements

averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

~~e.~~ d. Beam Quality.

i. Half-Value Layer (HVL).

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

~~TABLE I~~			
~~Design Operating Range~~	~~Measured Potential (kVp)~~	~~Half-Value Layer In mm Aluminum~~	
		~~Dental Intra-Oral Manufactured Before Aug. 1, 1974 and On or After Dec. 1, 1980~~	~~All Other Diagnostic X-Ray Systems~~
~~Below 51~~	~~30~~	~~N/A~~	~~0.3~~
	~~40~~	~~N/A~~	~~0.4~~
	~~50~~	~~1.5~~	~~0.5~~
~~51 to 70~~	~~51~~	~~1.5~~	~~1.2~~
	~~60~~	~~1.5~~	~~1.3~~
	~~70~~	~~1.5~~	~~1.5~~
~~Above 70~~	~~71~~	~~2.1~~	~~2.1~~
	~~80~~	~~2.3~~	~~2.3~~
	~~90~~	~~2.5~~	~~2.5~~
	~~100~~	~~2.7~~	~~2.7~~
	~~110~~	~~3.0~~	~~3.0~~
	~~120~~	~~3.2~~	~~3.2~~
	~~130~~	~~3.5~~	~~3.5~~
	~~140~~	~~3.8~~	~~3.8~~
	~~150~~	~~4.1~~	~~4.1~~

TABLE 1

X-Ray Tube Voltage (kilovolt peak)				
Design Operating Range	Measured Operating Potential	Minimum HVL (mm in Aluminum)		
		Specified Dental Systems \1\	Other X-Ray Systems\2\	Other X-Ray Systems\3\
Below 51	30	1.5	0.3	0.3
	40	1.5	0.4	0.4
	50	1.5	0.5	0.5
51 to 70	51	1.5	1.2	1.3

	60	1.5	1.3	1.5
	70	1.5	1.5	1.8
Above 70	71	2.1	2.1	2.5
	80	2.3	2.3	2.9
	90	2.5	2.5	3.2
	100	2.7	2.7	3.6
	110	3.0	3.0	3.9
	120	3.2	3.2	4.3
	130	3.5	3.5	4.7
	140	3.8	3.8	5.0
	150	4.1	4.1	5.4

\1\ Dental x-ray systems designed for use with intraoral image receptors and manufactured after December 1, 1980.
\2\ Dental x-ray systems designed for use with intraoral image receptors and manufactured before or on December 1, 1980, and all other x-ray systems
subject to this section and manufactured before June 10, 2006.
\3\ All x-ray systems, except dental x-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after June 10, 2006.

~~\1\ Dental x-ray systems designed for use with intraoral image receptors and manufactured after December 1, 1980.~~
~~\2\ Dental x-ray systems designed for use with intraoral image receptors and manufactured before or on December 1, 1980, and all other x-ray systems~~
~~subject to this section and manufactured before June 10, 2006.~~
~~\3\ All x-ray systems, except dental x-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after~~
~~June 10, 2006.~~

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

~~(2)~~(3) Measuring compliance. For capacitor energy storage equipment, compliance ~~with the requirements of F.4e.i.~~ shall be determined with the maximum selectable quantity of charge per ~~system fully charged and a setting of 10 mAs for each~~ exposure.

e. Aluminum equivalent of material between patient and image receptor. Except when used in a CT x-ray system, the aluminum equivalent of each of the items listed in Table 2 in this paragraph, which are used between the patient and the image receptor, may not exceed the indicated limits. Compliance shall be determined by x-ray measurements made at a potential of

100 kilovolts peak and with an x-ray beam that has an HVL specified in Table 1 of this section for the potential. This requirement applies to front panel(s) of cassette holders and film changers provided by the manufacturer for patient support or for prevention of foreign object intrusions. It does not apply to screens and their associated mechanical support panels or grids. Table 2 follows:

TABLE 2

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

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

~~(3) The required minimal half-value layer of the useful beam shall include the filtration contributed by all materials which are permanently between the source and the patient.~~

~~ii. Filtration Controls. For x-ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) and shall prevent an exposure unless the minimum amount of filtration necessary to produce the HVL required by F.4e.i. is in the useful beam for the given kVp which has been selected.~~

g. Modification of certified diagnostic x-ray components and systems.

i. Diagnostic x-ray components and systems certified in accordance with 21 CFR Part 1020 shall not be modified such that the component or system fails to comply with any applicable provision of this Part.

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

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

~~g.~~i. Mechanical Support of Tube Head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the x-ray system.

~~h.~~j. Technique Indicators.

i. For x-ray equipment capable of displaying technique factors, ~~T~~the technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated.

ii. The requirement of ~~F.4h.i.~~ F.4j.i. may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

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

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

Sec. F.5 - Fluoroscopic ~~X-Ray Systems~~ Equipment. ~~. All fluoroscopic x-ray systems used shall be image intensified and meet the following requirements:~~ The provisions of this Part apply to equipment for fluoroscopic imaging or for recording images from the fluoroscopic image receptor, except computed tomography x-ray systems manufactured on or after November 29, 1984.

a. Primary Protective Barrier

i. Limitation of useful beam. The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID. The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam. The AKR due to transmission through the barrier with the attenuation block in the useful beam combined with radiation from the fluoroscopic imaging receptor shall not exceed 3.34×10^{-3} percent of the entrance AKR, at a distance of 10 cm from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor. Radiation therapy simulation systems shall be exempt from this requirement provided the systems are intended only for remote control operation.

ii. Measuring compliance. The AKR shall be measured in accordance with subsection d. of this section. The AKR due to transmission through the primary barrier combined with radiation from the fluoroscopic image receptor shall be determined by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 cm above the tabletop. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 cm. Movable grids and compression devices shall be removed from the useful beam during the measurement. For all measurements, the attenuation block shall be positioned in the useful beam 10 cm from the point of measurement of entrance AKR and between this point and the input surface of the fluoroscopic imaging assembly.

~~a.~~ b. Field Limitation ~~of Useful Beam~~.

i. Angulation. For fluoroscopic equipment manufactured after February 25, 1978, when the angle between the image receptor and the beam axis of the x-ray beam is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor. Compliance with F.5b. iv. and v. shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

ii. Further means for limitation. Means shall be provided to permit further limitation of the x-ray field to sizes smaller than the limits of F.5b.iv. and v. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID and/or capability of a visible area of greater than 300 square cm, shall be provided with means for stepless adjustment of the x-ray field. Equipment with a fixed SID and the capability of a visible area of no greater than 300 square cm shall be provided with either stepless adjustment of the x-ray field or with a means to further limit the x-ray field size at the plane of the image receptor to 125 square cm or less. Stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size containable in a square of 5 cm by 5 cm. This paragraph does not apply to non-image-intensified fluoroscopy.

iii. Non-image-intensified fluoroscopy. The x-ray field produced by non-image-intensified fluoroscopic equipment shall not extend beyond the entire visible area of the image receptor. Means shall be provided for stepless adjustment of field size. The minimum field size, at the greatest SID, shall be containable in a square of 5 cm by 5 cm.

iv. Fluoroscopy and radiography using the fluoroscopic imaging assembly with inherently circular image receptors.

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

(a) Neither the length nor width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID.

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

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

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

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

v. Fluoroscopy and radiography using fluoroscopic imaging assembly with inherently rectangular image receptors. For x-ray systems manufactured on or after June 10, 2006, the following applies:

(1) Neither the length nor width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID.

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

~~i. Primary Barrier.~~

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

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

~~ii. Fluoroscopic Beam Limitation.~~

~~(1) For certified fluoroscopic systems with or without a spot film device, 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 per cent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID.~~

~~(2) For uncertified fluoroscopic systems with a spot film device, the x-ray beam with the shutters fully opened (during fluoroscopy or spot filming) shall be no larger than the largest spot film size for which the device is designed. Measurements shall be made at the maximum SID available but at no less than 20 centimeters table top to the film plane distance.~~

~~(3) For uncertified fluoroscopic systems without a spot film device, the requirements of F.5a.ii.(1) apply.~~

~~(4) Other requirements for fluoroscopic beam limitation:~~

~~(a) Means shall be provided to permit further limitation of the field. 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 centimeters 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 centimeters 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 centimeters or less;~~

~~(c) If provided, stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum attainable to a field size of 5 centimeters by 5 centimeters or less;~~

~~(d) For equipment manufactured after February 25, 1978, when the angle between 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;~~

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

~~iii. Spot-film Beam Limitation. Spot-film devices shall meet the following requirements:~~

~~(1) Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot-film selector. Such adjustment shall be automatically accomplished except when the x-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot film devices manufactured after June 21, 1979, if the x-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option;~~

~~(2) 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 3 percent of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences shall not exceed 4 percent of the SID;~~

~~(3) It shall be possible to adjust the x-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to, or less than, 5 centimeters by 5 centimeters;~~

~~(4) The center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within 2 percent of the SID; and~~

~~(5) 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.~~

~~iv.~~ vi. ~~Override Capability. If a means exists to override any of the automatic x-ray field size adjustments required in F.5a.ii. and iii., that means:~~

~~(1) Shall be designed for use only in the event of system failure;~~

~~(2) Shall incorporate a signal visible at the fluoroscopist's position which will indicate whenever the automatic field size adjustment is overridden; and~~

~~(3) Shall be clearly and durably labeled as follows:~~

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

FOR X-RAY FIELD

—LIMITATION SYSTEM FAILURE

~~b.~~ c. Activation of ~~the Fluoroscopic~~ Tube. X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the ~~fluoroscopist~~ operator for the entire time of any exposure. When recording serial radiographic images from the fluoroscopic image receptor, ~~fluoroscopic images,~~ the ~~fluoroscopist~~ 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.

d. Air Kerma Rates. For fluoroscopic equipment, the following requirements apply:

i. Fluoroscopic equipment manufactured before May 19, 1995.

(1) Equipment provided with automatic exposure rate control (AERC) shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (vice 10 R/min exposure rate) at the measurement point specified in paragraph iii. in this subsection, except as specified in F.5d.i.(5).

(2) Equipment provided without AERC shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 44 mGy per minute (vice 5 R/min exposure rate) at the measurement point specified in paragraph iii. in this subsection, except as specified in F.5d.i.(5).

(3) Equipment provided with both an AERC mode and a manual mode shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (vice 10 R/min exposure rate) in either mode at the measurement point specified in paragraph iii. in this subsection, except as specified in F.5d.i.(5).

(4) Equipment may be modified in accordance with this Part to comply with F.5d.ii.. When the equipment is modified, it shall bear a label indicating the date of the modification and the statement:

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

(5) Exceptions:

(a) During recording of fluoroscopic images, or

(b) When a mode of operation has an optional high-level control, in which case that mode shall not be operable at any combination of tube potential and current that will result in an AKR in excess of the rates specified in paragraphs (1), (2) and (3) at the measurement point specified in paragraph iii. of this subsection, unless the high-level control is activated.

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

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

(1) Shall be equipped with AERC if operable at any combination of tube potential and current that results in an AKR greater than 44 mGy per minute (vice 5 R/min exposure rate) at the measurement point specified in F.5d.iii.~~.~~ Provision for manual selection of technique factors may be provided.

(2) Shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (vice 10 R/min exposure rate) at the measurement point specified in paragraph iii. of this subsection, except as specified in F.5d.ii.(3).

(3) Exceptions:

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

(b) For equipment manufactured on or after June 10, 2006, during the recording of images from the fluoroscopic image receptor for the purpose of providing the user with a recorded image(s) after termination of the exposure. Such recording does not include images resulting from a last-image-hold feature that are not recorded.

(c) When a mode of operation has an optional high-level control and the control is activated, in which case the equipment shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 176 mGy per minute (vice 20 R/min exposure rate) at the measurement point specified in paragraph iii. of this subsection. Special means of activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is employed.

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

(1) If the source is below the x-ray table, the AKR shall be measured at 1 cm above the tabletop or cradle.

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

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

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

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

iv. Exemptions. Fluoroscopic radiation therapy simulation systems are exempt from the requirements set forth in this subsection when used for therapy simulation purposes.

e. Reserved.

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

g. Source-skin distance.

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

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

h. Fluoroscopic irradiation time, display, and signal.

i. Fluoroscopic equipment manufactured before June 10, 2006

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

Modified to comply with 21 CFR 1020.32(h)(2)

(2) As an alternative to the requirements of this paragraph, radiation therapy simulation systems may be provided with a means to indicate the total cumulative exposure time during which x-rays were produced, and which is capable of being reset between x-ray examinations.

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

(1) A display of the fluoroscopic irradiation time at the fluoroscopist's working position. This display shall function independently of the audible signal described in this subsection. The following requirements apply:

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

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

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

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

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

j. Display of last-image-hold (LIH). Fluoroscopic equipment manufactured on or after June 10, 2006, shall be equipped with means to display LIH image following termination of the fluoroscopic exposure.

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

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

iii. Means shall be provided to clearly indicate to the user whether a displayed image is the LIH radiograph or fluoroscopy. Display of the LIH radiograph shall be replaced by the fluoroscopic image concurrently with re-initiation of fluoroscopic exposure, unless separate displays are provided for the LIH radiograph and fluoroscopic images.

k. Displays of values of AKR and cumulative air kerma. Fluoroscopic equipment manufactured on or after June 10, 2006, shall display at the fluoroscopist's working position the AKR and cumulative air kerma. The following requirements apply for each x-ray tube used during an examination or procedure:

i. When the x-ray tube is activated and the number of images produced per unit time is greater than six images per second, the AKR in mGy/min shall be continuously displayed and updated at least once every second.

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

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

iv. The AKR and cumulative air kerma shall represent the value for conditions of free-in-ar irradiation at one of the following reference locations specified according to the type of fluoroscope.

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

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

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

vi. The displayed AKR and cumulative air kerma shall not deviate from the actual values by more than ±35 percent over the range of 6 mGy/min and 100 mGy to the maximum indication of AKR and cumulative air kerma, respectively. Compliance shall be determined with an irradiation time greater than 3 seconds.

~~e. Exposure Rate Limits.~~

~~i. Entrance Exposure Rate Allowable Limits.~~

~~(1) Fluoroscopic equipment which is provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 2.6 mC/kg (10 roentgens) per minute at the point where the center of the useful beam enters the patient, except:~~

~~(a) During recording of fluoroscopic images; or~~

~~(b) When an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 1.3 mC/kg (5 roentgens) per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.~~

~~(2) Fluoroscopic equipment which is not provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in a exposure rate in excess of 1.3 mC/kg (5 roentgens) per minute at the point where the center of the useful beam enters the patient, except:~~

~~(a) During recording of fluoroscopic images; or~~

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

~~(3)Fluoroscopic equipment which is provided with both automatic exposure rate control mode and a manual mode shall not be operable at any combination of tube potential and current which shall result in an exposure rate in excess of 2.6 mC/kg (10 roentgens) per minute in either mode at the point where the center of the useful beam enters the patient, except:~~

~~(a)During recording of fluoroscopic images; or~~

~~(b)When the mode or modes have an optional high level control, in which case that mode or modes shall not be operable at any combination of tube potential and current which shall result in an exposure rate in excess of 1.3 mC/kg (5 roentgens) per minute at the point where the center of the useful beam enters the patient, unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.~~

~~(4) Any fluoroscopic equipment manufactured after May 19, 1995 which can exceed 1.3 mC/kg (5 roentgens) per minute shall be equipped with an automatic exposure rate control. All entrance exposure rate limits shall be 2.6 mC/kg (10 roentgens) per minute with an upper limit of 5.2 mC/kg (20 roentgens) per minute when high level control is activated~~

~~(5) Compliance with the requirements of F.5c. shall be determined as follows:~~

~~(a) If the source is below the x-ray table, the exposure rate shall be measured 1 centimeter above the tabletop or cradle;~~

~~(b) If the source is above the x-ray table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement;~~

~~(c) For a C-arm type of fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly;~~

~~(d) For a lateral type fluoroscope, the exposure rate shall be measured at a point 15 centimeters from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than 15 centimeters to the centerline of the x-ray table.~~

~~ii. Periodic measurement of entrance exposure rate shall be performed by a qualified expert for both typical and maximum values as follows:[2]~~

[2] *Materials should be placed in the useful beam to protect the imaging system when conducting these periodic measurements.*

~~(1) Such measurements shall be made annually or after any maintenance of the system which might affect the exposure rate;~~

~~(2) Results of these measurements shall be posted where any fluoroscopist may have ready access to such results while using the fluoroscope and in the record required in F.3a.xii.(3). The measurement results shall be stated in coulombs per kilogram (roentgens) per minute and include the technique factors used in determining such results. The name of the individual performing the measurements and the date the measurements were performed shall be included in the results;~~

~~(3) Conditions of periodic measurement of typical entrance exposure rate are as follows:~~

~~(a) The measurement shall be made under the conditions that satisfy the requirements of F.5e.i.(5);~~

~~(b) The kVp, mA, and/or other selectable parameters shall be adjusted to those settings typical of clinical use on a 23 cm thick abdominal patient;~~

~~(c) The x-ray system that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce a milliamperage and/or kilovoltage to satisfy the conditions of F.5e.ii.(3)(b);~~

~~(4) Conditions of periodic measurement of maximum entrance exposure rate are as follows:~~

~~(a) The measurement shall be made under the conditions that satisfy the requirements of F.5e.i.(5);~~

~~(b) The kVp, mA and/or other selectable parameters shall be adjusted to those settings which give the maximum entrance exposure rate;~~

~~(c) The x-ray system(s) that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce the maximum entrance exposure rate of the system.~~

~~d. Barrier Transmitted Radiation Rate Limits.~~

~~i. The exposure rate 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 0.5 μC/kg (2 milliroentgens) per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each mC/kg (roentgen) per minute of entrance exposure rate.~~

~~ii. Measuring Compliance of 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 centimeters with no linear dimension greater than 20 centimeters.~~

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

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

~~e. Indication of Potential and Current. During fluoroscopy and cinefluorography the kV and the mA shall be continuously indicated.~~

~~f. Source-to-Skin Distance. The SSD shall not be less than:~~

~~i. 38 centimeters on stationary fluoroscopic systems manufactured on or after August 1, 1974;~~

~~ii. 35.5 centimeters on stationary fluoroscopic systems manufactured prior to August 1, 1974;~~

~~iii. 30 centimeters on all mobile fluoroscopes; or~~

~~iv. 20 centimeters for all mobile fluoroscopes when used for specific surgical applications.~~

~~g. Fluoroscopic Timer.~~

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

~~ii. A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while x rays are produced until the timing device is reset.~~

~~h.~~ l. Control of Scattered Radiation.

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

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

(1) Is at least 120 centimeters from the center of the useful beam; or

(2) The radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, drapes, Bucky-slot cover panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in F.3a.v.

iii. The Agency may grant exemptions to ~~F.5h.ii.~~ F.5l.ii., where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the Agency shall not permit such exemption. See Appendix C for a suggested list of fluoroscopic procedures where such exemptions will be automatically granted.

~~i. Spot Film Exposure Reproducibility. Fluoroscopic systems equipped with spot film (radiographic) mode shall meet the exposure reproducibility requirements of F.6d. when operating in the spot film mode.~~

~~j. Radiation Therapy Simulation Systems. Radiation therapy simulation systems shall be exempt from all the requirements of F.5c. In addition, these systems shall be exempt from:~~

~~i. The requirements of F.5a. and F.5d. provided such systems are designed and used in such a manner that no individual other than the patient is in the x-ray room during periods of time when the system is producing x-rays; and~~

~~ii. The requirements of F.5g. if such systems are 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.~~

~~k.~~ m. Operator Qualifications.

~~i.~~ j. The facility shall ensure that only a licensed practitioner of the healing arts or a radiologic technologist [or equivalent] ~~who is trained in the safe use of~~ be allowed to operate fluoroscopic x-ray systems. ~~shall be allowed to operate these systems. All persons using fluoroscopic x-ray operating these systems shall have, at a minimum, additional completed training as specified in F.5k.ii..~~

ii. All persons operating fluoroscopic x-ray systems shall have completed at least the following training before using fluoroscopy independently: ~~Training to meet the requirements of F.5k.i.~~ F.5l.i.
~~shall include, but is not limited to the following:~~

~~(1) Principles and operation of the fluoroscopic x-ray system;~~

~~(2)~~(1) Biological effects of x-ray;

~~(3)~~(2) Principles of radiation protection;

~~(4)~~(3) Factors affecting ~~F~~fluoroscopic outputs;

~~(5) High level control options;~~

~~(6)~~(4) Dose reduction techniques for fluoroscopic x-ray systems; ~~and~~

(5) Principles and operation of the specific fluoroscopic x-ray system(s) to be used;

(6) Fluoroscopic and fluorographic outputs of each mode of operation on the system(s) to be used clinically; and

~~(7)~~(7) Applicable requirements of these regulations.

iii. The facility shall either provide annual in-service training for all operators of fluoroscopic x-ray systems used for high dose, high risk procedures, or require evidence of annual continuing medical education~~,~~ in fluoroscopic radiation safety and patient dose management.

iv. Documentation pertaining to the requirements of ~~F.5k.i. and F.5kii~~ F.5m.ii. and F.5m.iii. shall be maintained for review for ~~[ ]~~ three years.

~~l.~~ n. Equipment Operation.

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

ii. The ~~use~~ operation of fluoroscopic x-ray systems by radiologic technologists [or equivalent] shall be performed under the direct supervision of a licensed practitioner of the healing arts ~~for the purpose of localization to obtain images for diagnostic purposes.~~ who meets the requirements of ~~F.5k.i.~~ F.5m.i.~~.~~

iii. Radiologic technology students shall not be allowed to operate fluoroscopic x-ray systems unless directly supervised by a licensed practitioner of the healing arts or radiologic technologist as specified in ~~F.5k.i.~~ F.5m.i.~~.~~

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

v. Facilities ~~that use fluoroscopic x-ray systems~~ shall maintain a record of the cumulative fluoroscopic exposure time used and the number of ~~spot films~~ fluorographic images recorded for each examination. This record shall ~~indicate~~ include patient identification, type and date of examination, ~~date of examination,~~ the fluoroscopic system used, and operator's name.

Sec. F.6 - Radiographic ~~Systems Other Than Fluoroscopic, Dental Intraoral, Bone Densitometry or Computed Tomography X-Ray Systems.~~ Equipment.

a. Control and indication of technique factors.

i. Visual indication. The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls are used, in which case the technique factors which are set prior to the exposure shall be indicated. On equipment having fixed technique factors, this requirement may be met by permanent markings. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

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

(1) Except during serial radiography, the operator shall be able to terminate the exposure at any time during an exposure of greater than one-half second. Except during panoramic dental radiography, termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero. It shall not be possible to make an exposure when the timer is set to a zero or off position if either position is provided.

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

iii. Automatic exposure controls. When an automatic exposure control is provided:

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

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

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

(4) A visible signal shall indicate when an exposure has been terminated at the limits described in F.6a.iii.(3), and manual resetting shall be required before further automatically timed exposures can be made.

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

b. Reproducibility. The following requirements shall apply when the equipment is operated on an adequate power supply as specified by the manufacturer:

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

ii. Measuring compliance. Determination of compliance shall be based on 10 consecutive measurements taken within a time period of 1 hour. Equipment manufactured after September 5, 1978, shall be subject to the additional requirement that all variable controls for technique factors shall be adjusted to alternate settings and reset to the test setting after each measurement. The percent line-voltage regulation shall be within ±1 of the mean value for all measurements. For equipment having automatic exposure controls, compliance shall be determined with a sufficient thickness of attenuating material in the useful beam such that the technique factors can be adjusted to provide individual exposures of a minimum of 12 pulses on field emission equipment rated for pulsed operation or no less than one-tenth second per exposure on all other equipment.

c. Linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer in accordance with 21 CFR Part 1020 for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rated.

i. Equipment having independent selection of x-ray tube current (mA). The average ratios of air kerma to the indicated milliampere-seconds product (mGy/mAs) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum. This is: $|X_1 - X_2| < 0.10(X_1 + X_2)$; where X_1 and X_2 are the average mGy/mAs values

obtained at each of two consecutive mAs selector settings or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

ii. Equipment having selection of x-ray tube current-exposure time product (mAs). For equipment manufactured after May 3, 1994, the average ratios of air kerma to the indicated milliampere-seconds product (mGy/mAs) obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum. This is: $|X_1 - X_2| \leq 0.10(X_1 + X_2)$; where X_1 and X_2 are the average mGy/mAs values obtained at each of two consecutive mAs selector settings or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

iii. Measuring compliance. Determination of compliance will be based on 10 exposures, made within 1 hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 mm and the other is greater than 0.45 mm. For purposes of this requirement, focal spot size is the focal spot size specified by the x-ray tube manufacturer. The percent line-voltage regulation shall be determined for each measurement. All values for percent line-voltage regulation at any one combination of technique factors shall be within ±1 of the mean value for all measurements at these technique factors.

d. Field limitation and alignment for mobile, portable, and stationary general purpose x-ray systems. Except when spot-film devices are in service, mobile, portable, and stationary general purpose radiographic x-ray systems shall meet the following requirements:

i. Variable x-ray field limitation. A means for stepless adjustment of the size of the x-ray field shall be provided. Each dimension of the minimum field size at an SID of 100 cm shall be equal to or less than 5 cm.

ii. Visual definition.

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

(2) When a light localizer is used to define the x-ray field, it shall provide an average illuminance of not less than 160 lux (15 footcandles) at 100 cm or at the maximum SID, whichever is less. The average illuminance shall be based on measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems are exempt from this requirement.

(3) The edge of the light field at 100 cm or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than 4 in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than 3 in the case of beam-limiting devices designed for

use on mobile and portable equipment. The contrast ratio is defined as I_1/I_2, where I_1 is the illuminance 3 mm from the edge of the light field toward the center of the field; and I_2 is the illuminance 3 mm from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring aperture of 1 mm.

e. Field indication and alignment on stationary general purpose x-ray equipment. Except when spot-film devices are in service, stationary general purpose x-ray systems shall meet the following requirements in addition to those prescribed in F.6d:

i. Means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within 2 percent of the SID, and to indicate the SID to within 2 percent;

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

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

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

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

i. Equipment for use with intraoral image receptors. Radiographic equipment designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that:

(1) If the minimum source-to-skin distance (SSD) is 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

(2) 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.

ii. X-ray systems designed for one image receptor size. Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image

receptor, and to align the center of the x-ray field with the center of image receptor to within 2 percent of the SID, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond the edge of the image receptor.

iii. Systems designed for mammography.

(1) Radiographic systems designed only for mammography and general purpose radiography systems, when special attachments for mammography are in service, manufactured on or after November 1, 1977, and before September 30, 1999, shall be provided with means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated SID except the edge of the image receptor designed to be adjacent to the chest wall where the x-ray field may not extend beyond this edge by more than 2 percent of the SID. This requirement can be met with a system that performs as prescribed in F.6f.iv.(1), (2), and (3). When the beam-limiting device and image receptor support device are designed to be used to immobilize the breast during a mammographic procedure and the SID may vary, the SID indication specified in F.6fiv.(2) and (3) shall be the maximum SID for which the beam-limiting device or aperture is designed.

(2) Mammographic beam-limiting devices manufactured on or after September 30, 1999, shall be provided with a means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor by more than 2 percent of the SID. This requirement can be met with a system that performs as prescribed in F.6fiv.(1), (2), and (3). For systems that allow changes in SID, the SID indication specified in F.6fiv.(2) and (3) shall be the maximum SID for which the beam-limiting deviced or aperture is designed.

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

iv. Other x-ray systems. Radiographic systems not specifically covered in F.6d, e, f.ii., f.iii., h, and systems covered in F.6f.i., which are also designed for use with extraoral image receptors and when used with an extraoral image receptor, shall be provided with means to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2 percent of the SID, when the axis of the x-ray beam is perpendicular to the plane of the image receptor. In addition, means shall be provided to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or means shall be provided to both size and alignment the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. These requirements may be met with:

(1) A system which performs in accordance with F.6d. and e.; or when alignment means are also provided, may be met with either;

(2) An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Each such device shall have clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

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

g. Positive beam limitation (PBL). The requirements of this subsection shall apply to radiographic systems which contain PBL.

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

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

(2) The sum of the length and width differences stated in F.6g.i.(1) without regard to sign exceeds 4 percent of the SID.

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

ii. Conditions for PBL. When provided, the PBL system shall function as described in F.6g.i. whenever all the following conditions are met:

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

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

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

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

(5) Neither tomographic nor stereoscopic radiography is being performed.

iii. Measuring compliance. Compliance with the requirements of F.6g.i. shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the

image receptor and the provisions of F.6g.ii. are met. Compliance shall be determined no sooner than 5 second after insertion of the image receptor.

iv. Operator initiated undersizing. The PBL system shall be capable of operating such that, at the discretion of the operator, the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. Each dimension of the minimum field size at an SID of 100 cm shall be equal to or less than 5 cm. Return to PBL function as described in F.6g.i. shall occur automatically upon any change of image receptor size or SID.

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

For X-Ray Field Limitation System Failure

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

h. Field limitation and alignment for spot-film devices. The following requirements shall apply to spot-film devices, except when the spot-film device is provided for use with a radiation therapy simulation system:

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

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

iii. The center of the x-ray field in the plane of the image receptor shall be aligned with the center of the selected portion of the image receptor to within 2 percent of the SID.

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

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

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

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

For X-ray Field Limitation System Failure

i. Source-skin distance.

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

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

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

ii. Mobile and portable x-ray systems other than dental shall be provided with means to limit the source-skin distance to not less than 30 cm.

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

k. Reserved.

l. Radiation from capacitor energy storage equipment. Radiation emitted from the x-ray tube shall not exceed:

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

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

m. Primary protective barrier for mammography x-ray systems.

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

ii. For mammographic x-ray systems manufactured on or after September 30, 1999:

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

(2) The x-ray system shall not permit exposure unless the appropriate barrier is in place to intercept the useful beam as required in F.6m.ii.(1).

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

iii. Compliance with the requirements of F.6m.i. and F.6m.ii.(3) for transmission shall be determined with the x-ray system operated at the minimum SID for which it is designed, at maximum rated peak tube potential, at the maximum rated product of x-ray tube current and exposure time (mAs) for the maximum rated peak tube potential, and by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm. The sensitive volume of the radiation measuring instrument shall not be positioned beyond the edge of the primary protective barrier along the chest wall side.

~~a.~~o. Beam Limitation, Except Mammographic Systems. The useful beam shall be limited to the area of clinical interest. This shall be deemed to have been met if a positive beam limiting device meeting manufacturer's specifications and the requirements of ~~F.6h.ii.~~ F.6g. ~~has~~ have been properly used or if evidence of collimation is shown on at least three sides or three corners of the film (for example, projections from the shutters of the collimator, cone cutting at the corners, or borders at the film's edge).

~~i. General Purpose Stationary and Mobile X-Ray Systems, Including Veterinary Systems (Other than Portable) Installed After the Effective Date of These Regulations.~~

~~(1) Only x-ray systems provided with means for independent stepless adjustment of at least two dimensions of the x-ray field shall be used.~~

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

~~(3) The Agency may grant an exemption on non-certified x-ray systems to F.6a.i.(1) and (2) provided the registrant makes a written application for such exemption and in that application:~~

~~(a) Demonstrates it is impractical to comply with F.6a.i.(1) and (2); and~~

~~(b) The purpose of F.6a.i.(1) and (2) will be met by other methods.~~

~~ii. Additional Requirements for Stationary General Purpose X-Ray Systems. In addition to the requirements of F.6a.i., stationary general purpose x-ray systems, both certified and noncertified, shall meet the following requirements:~~

~~(1) A method shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within 2 percent of the SID, and to indicate the SID to within 2 percent;~~

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

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

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

~~iv. X-Ray Systems Other Than Those Described in F.6a.i., ii., and iii., and Veterinary Systems Installed Prior to the Effective Date of These Regulations and all Portable Veterinary X-Ray Systems.~~

~~(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 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 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. Compliance shall be determined with the axis of the x-ray beam perpendicular to the plane of the image receptor.~~

~~(3) F.6a.iv.(1) and (2) may be met with a system that meets the requirements for a general purpose x-ray system as specified in F.6a.i. 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.~~

~~b.~~ p. Radiation Exposure Control.

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

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

~~iii. Exposure Termination. 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. Except for dental panoramic systems, termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero." It shall not be possible to make an exposure when the timer is set to a zero or off position if either position is provided.~~

~~(1) Manual Exposure Control. An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time except for:~~

~~(a) Exposure of ½ second or less; or~~

~~(b) During serial radiography when means shall be provided to permit completion of any single exposure of the series in process.~~

~~(2) Automatic Exposure Controls. When an automatic exposure control is provided:~~

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

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

~~(c) The minimum exposure time for all equipment other than that specified in F.6b.ii.(2)(b) shall be equal to or less than one-sixtieth (1/60) second or a time interval required to deliver 5 mAs, whichever is greater;~~

~~(d) Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kWs per exposure, or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except that, when the x-ray tube potential is less than 50 kVp, the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and~~

~~(e) A visible signal shall indicate when an exposure has been terminated at the limits required by F.6b.ii.(2)(d), and manual resetting shall be required before further automatically timed exposures can be made.~~

~~iv. Exposure Duration (Timer) Linearity. For systems having independent selection of exposure time settings, the average ratios (X_i) of exposure to the indicated timer setting, in units of C $kg^{-1}s^{-1}$ (mR/s), obtained at any two clinically used timer settings shall not differ by more than 0.10 times their sum. This is written as:~~

$$(X_1 - X_2) \leq 0.1\,(X_1 + X_2)$$

~~where X_1 and X_2 are the average C kg^{-1}s^{-1} (mR/s) values.~~

~~v. Exposure Control Location. The x-ray exposure control shall be so placed that the operator can view the patient while making any exposure.~~

~~vi.~~iii. Operator Protection, Except Veterinary Systems.

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

(2) Mobile and Portable Systems. Mobile and portable x-ray systems which are:

(a) Used continuously for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of ~~F.6b.vi.(1)~~ F.6o.iii.(1);

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

~~vii.~~iv. Operator Protection for Veterinary Systems. All stationary, mobile or portable x-ray systems used for veterinary work shall be provided with either a 2 meter (6.5 feet) high protective barrier for operator protection during exposures, or shall be provided with means to allow the operator to be at least 2.7 meters (9 feet) from the tube housing assembly during exposures. Refer to Appendix B for hand-held intraoral dental radiographic units used in veterinary practice.

~~c. Source-to-Skin Distance. All mobile or portable radiographic systems shall be provided with means to limit the source-to-skin distance to equal to or greater than 30 centimeters, except for veterinary systems.~~

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

~~e. Radiation from Capacitor Energy Storage Equipment in Standby Status. Radiation emitted from the x-ray tube when the system is fully charged and the exposure switch or timer is not activated shall not exceed a rate of 0.5 μC/kg (2 milliroentgens) per hour at 5 centimeters from any accessible surface of the diagnostic source assembly, with the beam limiting device fully open.~~

~~f. Accuracy. Deviation of measured technique factors from indicated values of kVp and exposure time shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed 10 percent of the indicated value for kVp and 20 percent for time.~~

~~g. mA/mAs Linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rated:~~

~~i. Equipment Having Independent Selection of X-Ray Tube Current (mA). The average ratios (X_i) of exposure to the indicated milliampere-seconds product ($C\ kg^{-1}\ mAs^{-1}$ (or mR/mAs)) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum:~~

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

~~where X_1 and X_2 are the average values obtained at each of two consecutive tube current settings, or at two settings differing by no more than a factor of 2 where the tube current selection is continuous.~~

~~ii. Equipment Having a Combined X-Ray Tube Current-Exposure Time Product (mAs) Selector, But Not a Separate Tube Current (mA) Selector. The average ratios (X_i) of exposure to the indicated milliampere-seconds product, in units of $C\ kg^{-1}\ mAs^{-1}$ (or mR/mAs), obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum:~~

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

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

~~iii. Measuring Compliance. Determination of compliance shall be based on 10 exposures taken within a time period of one hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the x-ray tube manufacturer.~~

~~h. Additional Requirements Applicable to Certified Systems Only. Diagnostic x-ray systems incorporating one or more certified component(s) shall be required to comply with the following additional requirement(s) which relate to that certified component(s).~~

~~i. Beam Limitation for Stationary and Mobile General Purpose X-Ray Systems.~~

~~(1) There shall be provided a means of stepless adjustment of the size of the x-ray field. The minimum field size at an SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters.~~

~~(2) When a light localizer is used to define the x-ray field, it shall provide an average illumination of not less than 160 lux or 15 foot-candles at 100 centimeters or at~~

~~the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems manufactured on and after May 27, 1980, are exempt from this requirement.~~

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

~~ii. Beam Limitation and Alignment on Stationary General Purpose X-Ray Systems Equipped with PBL. If PBL is being used, the following requirements shall be met:~~

~~(1) PBL shall prevent the production of x-rays when:~~

~~(a) Either the length or width of the x-ray field in the plane of the image receptor differs, except as permitted by F.6h.ii.(3), from the corresponding image receptor dimensions by more than 3 percent of the SID; or~~

~~(b) The sum of the length and width differences as stated in F.6h.ii.(1)(a) without regard to sign exceeds 4 percent of the SID;~~

~~(2) Compliance with F.6h.ii.(1) shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor. Compliance shall be determined no sooner than 5 seconds after insertion of the image receptor;~~

~~(3) 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. The minimum field size at an SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters;~~

~~(4) 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 F.6h.ii.(1), then any change of image receptor size or SID must cause the automatic return.~~

~~iii. Beam Limitation for Portable X-Ray Systems. Beam limitation for portable x-ray systems shall meet the beam limitation requirements of F.6a.i. or F.6h.ii.~~

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

Sec. F.7 - Intraoral Dental Radiographic ~~Systems~~ Equipment. In addition to the applicable provisions of F.3, ~~and~~ F.4, and F.6, the requirements of F.7 apply to x-ray equipment and associated facilities used for dental intraoral radiography. Requirements for extraoral dental radiographic systems are covered in F.6. ~~Only systems meeting the requirements of F.7 shall be used.~~

~~a. Source-to-Skin Distance (SSD). X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit SSD, to not less than:~~

~~i. 18 centimeters if operable above 50 kVp; or~~

~~ii. 10 centimeters if operable at 50 kVp only.~~

~~b. Beam Limitation. Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that the beam at the minimum SSD shall be containable in a circle having a diameter of no more than 7 centimeters.~~

~~c.~~a. Radiation Exposure Control.

~~i. Exposure Initiation.~~

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

~~(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.~~

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

~~iii. Exposure Termination.~~

~~(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) An x-ray exposure control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time, except for exposures of 1/2 second or less.~~

~~(3) Termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero."~~

~~iv. Exposure Duration (Timer) Linearity. For systems having independent selection of exposure time settings, the average ratios (X_i) of exposure to the indicated timer setting, in units of C kg^{-1} s^{-1} (mR/s), obtained at any two clinically used timer settings shall not differ by more than 0.10 times their sum. This is written as:~~

$$\cancel{(X_1 - X_2) \leq 0.1\,(X_1 + X_2)}$$

~~where X_1 and X_2 are the average values.~~

~~v.~~ b. Exposure Control Location and Operator Protection.

(1) Stationary x-ray systems shall be required to have the x-ray exposure control permanently mounted in a protected area, so that the operator is required to remain in that protected area during the entire exposure; and

(2) Mobile and portable x-ray systems which are:

(a) Used for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of ~~F.7e.v.(1)~~ F.7a.(1);

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

~~d. Reproducibility. When the equipment is operated on an adequate power supply as specified by the manufacturer, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05, for any specific combination of selected technique factors.~~

~~e. mA/mAs Linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rated.~~

~~i. Equipment Having Independent Selection of X-Ray Tube Current (mA). The average ratios (X_i) of exposure to the indicated milliampere-seconds product, in units of C kg^{-1} mAs^{-1} (or mR/mAs), obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum:~~

$$\cancel{X_1 - X_2 \leq 0.10\,(X_1 + X_2)}$$

~~where X_1 and X_2 are the average values obtained at each of two consecutive tube current settings, or at two settings differing by no more than a factor of 2 where the tube current selection is continuous.~~

~~ii. Equipment Having a Combined X-Ray Tube Current-Exposure Time Product (mAs) Selector, But Not a Separate Tube Current (mA) Selector. The average ratios (X_i) of exposure to the indicated milliampere-seconds product, in units of C kg^{-1} mAs^{-1} (or mR/mAs), obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum:~~

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

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

~~iii. Measuring Compliance. Determination of compliance shall be based on 10 exposures taken within a time period of one hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the x-ray tube manufacturer.~~

~~f. Accuracy. Deviation of technique factors from indicated values for kVp and exposure time (if time is independently selectable) shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications the deviation shall not exceed 10 percent of the indicated value for kVp and 20 percent for time.~~

~~g.~~ c. kVp Limitations. Dental x-ray machines with a nominal fixed kVp of less than 50 kVp shall not be used to make diagnostic dental radiographs of humans.

~~h.~~ d. Administrative Controls.

i. Patient and film holding devices shall be used when the techniques permit.

ii. The tube housing and the PID for a permanently mounted intraoral dental system shall not be hand-held during an exposure. Appendix B specifies requirements for the use of intraoral dental radiographic units designed to be hand-held during patient examination.

~~iii. The x-ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements of F.7b.~~

~~iv.~~ iii. Dental fluoroscopy without image intensification shall not be used.

Sec. F.11 - Computed Tomography Equipment ~~X-Ray Systems.~~

a. Definitions. In addition to the definitions provided in A.2 and F.2 of these regulations, the following definitions shall be applicable to F.11:

"Computed tomography dose index" (CTDI) means the integral ~~from -7T to +7T~~ of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan, that is:

$$\overline{CTDI} = \frac{1}{n\,T}\int_{-7T}^{+7T} D(z)\,dz$$

where:

z	=	Position along a line perpendicular to the tomographic plane;
~~D(z)~~	~~=~~	~~Dose at position z;~~
T	=	Nominal tomographic section thickness;
n	=	Number of tomograms produced in a single scan.

This definition assumes that the dose profile is centered around z=0 and that, for a multiple tomogram system, the scan increment between adjacent scans is nT.

"Contrast scale" means the change in the linear attenuation coefficient per CTN relative to water, that is:

$$\overline{CS} = \frac{\mu_x - \mu_w}{\overline{CTN}_x - \overline{CTN}_w}$$

where:

μ_x	=	Linear attenuation coefficient of the material of interest;
μ_w	=	Linear attenuation coefficient of water;
$\overline{CTN}_x$	=	of the material of interest;
$\overline{CTN}_w$	=	of water.

~~"CS" (See "Contrast scale").~~

"CT conditions of operation" means all selectable parameters governing the operation of a CT x-ray system including, ~~but not limited to,~~ nominal tomographic section thickness, filtration, and the technique factors as defined in F.2.

"CT dosimetry phantom" means the phantom used for determination of the dose delivered by a CT x-ray system. The phantom shall be a right circular cylinder of polymethl-methacrylate of density 1.19±0.01 grams per cubic centimeter. The phantom shall be at least 14 centimeters in length and shall have

diameters of 32.0 centimeters for testing any CT system designed to image any section of the body (whole body scanners) and 16.0 centimeters for any system designed to image the head (head scanners) or for any whole body scanner operated in the head scanning mode. The phantom shall provide means for the placement of a dosimeter(s) along its axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. Means for the placement of a dosimeter(s) or alignment device at other locations may be provided for convenience. Any effect on the doses measured due to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom.

~~"CTDI" (See "Computed tomography dose index").~~

~~"CT gantry" means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames which hold these components.~~

~~"CTN" (See "CT number").~~

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

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

where:

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

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

~~"Elemental area" means the smallest area within a tomogram for which the x-ray attenuation properties of a body are depicted. (See also "Picture element").~~

"Modulation transfer function" means the modulus of the Fourier transform of the impulse response of the system.

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

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

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

where:

$\overline{CS}$	=	Linear attenuation coefficient of the material of interest.
μ_w	=	Linear attenuation coefficient of water.
s	=	Standard deviation of the CTN of picture elements in a specified area of the CT image.

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

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

"Reference plane" means a plane which is displaced from and parallel to the tomographic plane.

"Remanufacturing" means modifying a CT system in such a way that the resulting dose and imaging performance become substantially equivalent to any CT x-ray system manufactured by the original manufacturer on or after November 29, 1984. Any reference in this subsection to "manufacture," "manufacturer," or -"manufacturing" includes remanufacture, remanufacturing, respectively.

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

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

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

~~"Scan time" means the period of time between the beginning and end of x-ray transmission data accumulation for a single scan.~~

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

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

"Tomographic plane" means that geometric plane which the manufacturer identified ~~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.

b. Requirements for Equipment.

i. Termination of Exposure.

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

(2) A visible signal shall indicate when the x-ray exposure has been terminated through the means required by Subdivision F.11b.i.(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.

ii. Tomographic Plane Indication and Alignment.

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

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

(3) If a device using a light source is used to satisfy the requirements of Subdivisions F.11b.ii.(1) or (2), 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.

iii. 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.

iv. Indication of CT Conditions of Operation. The CT x-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

v. Extraneous Radiation. When data are not being collected for image production, the radiation adjacent to the tube port shall not exceed that permitted by F.4c.

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

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

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

(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 kilograms resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel.

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

c. Facility Design Requirements.

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

ii. Viewing Systems.

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

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

d. Surveys, Calibrations, Spot Checks, and Operating Procedures.

i. Surveys.

(1) All CT x-ray systems installed after [insert the effective date of the regulations] and those systems not previously surveyed shall have a survey made by, or under the direction of, a qualified ~~expert~~ medical physicist. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

(2) The registrant [licensee] shall obtain a written report of the survey from the qualified ~~expert~~ medical physicist, and a copy of the report shall be made available to the Agency upon request.

ii. Radiation Calibrations.

(1) The calibration of the radiation output of the CT x-ray system shall be performed by, or under the direction of, a qualified ~~expert~~ medical physicist who is physically present at the facility during such calibration.

(2) The calibration of a CT x-ray system shall be performed after initial installation and before use on human patients, annually or at intervals specified by a qualified ~~expert~~ medical physicist, and after any change or replacement of components which, in the opinion of the qualified ~~expert~~ medical physicist, could cause a change in the radiation output.

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

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

(a) CT dosimetry phantom(s) shall be right circular cylinders of polymethyl methacrylate of density 1.19 plus or minus 0.01 grams per cubic centimeter. The phantom(s) shall be at least 14 centimeters in length and shall have diameters of 32.0 centimeters for testing CT x-ray systems designed to image any section of the body and 16.0 centimeters for systems designed to image the head or for whole body scanners operated in the head scanning mode;

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

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

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

(5) The calibration shall be required for each type of head, body, or whole-body scan performed at the facility.

(6) Calibration shall meet the following requirements:

(a) The dose profile along the center axis of the CT dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the registrant shall be measurable. Where less than 3 nominal tomographic thicknesses can be selected, the dose profile determination shall be performed for each available nominal tomographic section thickness;

(b) The CTDI[3/] along the two axes specified in Subdivision F.11d.ii.(4)(b) shall be measured. The CT dosimetry phantom shall be oriented so that the measurement point 1.0 centimeter from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface CTDI identified. The CT conditions of operation shall correspond to typical values used by the registrant;

(c) The spot checks specified in F.11d.iii. shall be made.

(7) Calibration procedures shall be in writing. Records of calibrations performed shall be maintained for inspection by the Agency.

iii. Spot Checks.

(1) The spot-check procedures shall be in writing and shall have been developed by a qualified ~~expert~~ medical physicist.

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

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

(3) All spot checks shall be included in the calibration required by F.11d.ii. and at time intervals and under system conditions specified by a qualified ~~expert~~ medical physicist.

(4) Spot checks shall include acquisition of images obtained with the CT dosimetry phantom(s) using the same processing mode and CT conditions of operation as are used to perform calibrations required by F.11d.ii. The images shall be retained, until a new calibration is performed, in two forms as follows:

(a) Photographic copies of the images obtained from the image display device; and

(b) Images stored in digital form on a storage medium compatible with the CT x-ray system.

(5) Written records of the spot checks performed shall be maintained for inspection by the Agency.

iv. Operating Procedures.

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

(2) Information shall be available at the control panel regarding the operation and calibration of the system. Such information shall include the following:

(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 dosimetry 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) The distance in millimeters between the tomographic plane and the reference plane if a reference plane is utilized; and

(d) A current technique chart available at the control panel which specifies for each routine examination the CT conditions of operation and the number of scans per examination.

(3) If the calibration or spot check of the CT x-ray system identifies that a system operating parameter has exceeded a tolerance established by the qualified ~~expert~~ medical physicist, use of the CT x-ray system on patients shall be limited to those uses permitted by established written instructions of the qualified ~~expert~~ medical physicist.

Sec. F.12 - Mammography Requirements for States Without FDA Certifying Authority.

Requirements for Certification.

a. Only x-ray systems, pursuant to the Mammography Quality Standards Reauthorization Act of 1998, Public Law 105-248, and 21 C.F.R. Part 900, shall be used for screening and diagnostic mammography.

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

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

~~Sec. F.13 - Mammography Definitions for States With Certifying Authority.~~

~~"Accreditation body" means an entity that has been approved by FDA to accredit mammography facilities~~

~~"Action limits" means the minimum and maximum values of a quality assurance measurement that can be interpreted as representing acceptable performance with respect to the parameter being tested. Values less than the minimum or greater than the maximum action limit or level indicate that corrective action must be taken by the facility. Action limits or levels are also sometimes called control limits or levels.~~

~~"Action levels" (See "Action limits").~~

~~"Adverse event" means an undesirable experience associated with mammography activities that include but are not limited to:~~

~~(1) Poor image quality;~~

~~(2) Failure to send mammography reports within thirty days to the referring physician or in a timely manner to the self-referred patient; and~~

~~(3)Use of personnel that do not meet the applicable requirements of F.14b.i..~~

~~"Air kerma" means kerma in a given mass of air. The unit used to measure the quantity of air kerma~~

~~is the Gray (Gy). For X-rays with energies less than 300 kiloelectronvolts (keV), 1 Gy = 100 rad. In air, 1 Gy of absorbed dose is delivered by 114 roentgens (R) of exposure.~~

~~"Body" (See "Accreditation body")~~

~~"Breast implant" means a prosthetic device implanted in the breast.~~

~~"Calendar quarter" means any one of the following time periods during a given year: January 1 through March 31, April 1 through June 30, July 1 through September 30, or October 1 through December 31.~~

~~"Category I" means medical education activities that have been designated as Category I by the Accreditation Council for Continuing Medical Education (ACCME), the American Osteopathic Association (AOA), a state medical society, or an equivalent organization.~~

~~"Certificate" means the certificate described in section F.14a.i..~~

~~"Certification" means the process of approval of a facility by the FDA or FDA approved certifying Agency to provide mammography services.~~

~~"Clinical image" means a mammogram.~~

~~"Consumer" means an individual who chooses to comment or complain in reference to a mammography examination, including the patient or representative of the patient (e.g., family member or referring physician).~~

~~"Contact hour" means an hour of training received through direct instruction.~~

~~"Continuing education credit" (See "Continuing education unit").~~

~~"Continuing education unit" means one contact hour of training.~~

~~"Control limits" (See "Action limits").~~

~~"Control levels" (See "Action limits").~~

~~"Direct instruction" means~~

~~(1) Face-to-face interaction between instructor(s) and student(s), as when the instructor provides a lecture, conducts demonstrations, or reviews student performance; or~~

~~(2) The administration and correction of student examinations by an instructor(s) with subsequent feedback to the student(s).~~

~~"Direct supervision" means that:~~

~~(1) During joint interpretation of mammograms, the supervising interpreting physician~~

~~reviews, discusses, and confirms the diagnosis of the physician being supervised and signs the resulting report before it is entered into the patient's records; or~~

~~(2) During the performance of a mammography examination or survey of the facility's equipment and quality assurance program, the supervisor is present to observe and correct, as needed, the performance of the individual being supervised who is performing the examination or conducting the survey.~~

~~"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" means, with reference to mammography, 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, processing of the mammogram, initial interpretation of the mammogram, and maintaining viewing conditions for that interpretation. This does not include VA facilities and federal facilities.~~

~~"FDA" means the Food and Drug Administration.~~

~~"First allowable time" means the earliest time a resident physician is eligible to take the diagnostic radiology boards from an FDA-designated certifying body. The "first allowable time" may vary with the certifying body.~~

~~"Image receptor support device" means, for mammography x-ray systems, that part of the system designed to support the image receptor during a mammographic examination and to provide a primary protective barrier.~~

~~"Interim regulations" means the regulations entitled "Requirements for Accrediting Bodies of Mammography Facilities (58 FR 67558-67565) and "Quality Standards and Certification Requirements for Mammography Facilities" (58 FR 67565-67572), published by FDA on December 21, 1993, and amended on September 30, 1994 (59FR 49808-49813). These regulations established the standards that had to be met by mammography facilities in order to lawfully operate between October 1, 1994, and April 28, 1999.~~

~~"Interpreting physician" means a licensed physician who interprets mammograms and who meets the requirements set forth in section F.14b.i.(1).~~

~~"Kerma" means the sum of the initial energies of all charged particles liberated by uncharged ionizing particles in a material of given mass.~~

~~"Laterality" means the designation of either the right or left breast.~~

~~"Lead interpreting physician" means the interpreting physician assigned the general responsibility for ensuring that a facility's quality assurance program meets all of the requirements of F.14b.iv. through vi.. The administrative title and other supervisory responsibilities of the individual, if any, are left to the discretion of the facility.~~

~~"Mammogram" means a radiographic image of the breast produced through mammography.~~

~~"Mammographic Modality" means a technology for radiography of the breast. Examples are digital mammography, screen-film mammography, and xeromammography.~~

~~"Mammography" means radiography of the breast, but does not include: (1) Radiography of the breast performed during invasive interventions for localization or biopsy procedures; or (2) radiography of the breast performed with an investigational mammography device as part of a scientific study conducted in accordance with FDA's investigational device exemption regulations.~~

~~"Mammography equipment evaluation" means an onsite assessment of mammography unit or image processor performance by a medical physicist for the purpose of making a preliminary determination as to whether the equipment meets all of the applicable standards in F.14b.ii.(1) through (10).~~

~~"Mammography medical outcomes audit" means a systematic collection of mammography results and the comparison of those results with outcomes data.~~

~~"Mammography unit(s)" means an assemblage of components for the production of x-rays for use during mammography, including, at a minimum: an x-ray generator, an x-ray control, a tube housing assembly, a beam limiting device, and the supporting structures for these components.~~

~~"Mean optical density" means the average of the optical densities measured using phantom thicknesses of 2, 4, and 6 centimeters with values of kilovolt peak (kVp) clinically appropriate for those thicknesses.~~

~~"Medical physicist" means a person trained in evaluating performance of mammography equipment and facility quality assurance programs and who meets the qualifications for a medical physicist set forth in F.14b.i.(3).~~

~~"MQSA" means the Mammography Quality Standards Act of 1992.~~

~~"MQSRA" means the Mammography Quality Standards Reauthorization Act of 1998.~~

~~"Multi-reading" means two or more physicians, at least one of whom is an interpreting physician, interpreting the same mammogram.~~

~~"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.~~

~~"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.~~

~~"Phantom image" means a radiographic image of a phantom.~~

~~"Physical science" means physics, chemistry, radiation science (including medical physics and health physics), and engineering.~~

~~"Positive mammogram" means a mammogram that has an overall assessment of findings that are either "suspicious" or "highly suggestive of malignancy."~~

~~"Provisional certificate" means the provisional certificate described in F.14a.ii.(2).~~

~~"Qualified instructor" means an individual whose training and experience adequately prepared him or her to carry out specified training assignments. Interpreting physicians, radiologic technologists, or medical physicists who meet the requirements of F.14b.i. would be considered qualified instructors in their respective areas of mammography. Other examples of individuals who may be qualified instructors for the purpose of providing training to meet the regulations of this part include, but are not limited to, instructors in a post-high school training institution and manufacturer's representatives.~~

~~"Quality control technologist" means an individual meeting the requirements of F.14b.i.(2) who is responsible for those quality assurance responsibilities not assigned to the lead interpreting physician or to the medical physicist.~~

~~"Radiologic technologist" means an individual specifically trained in the use of radiographic equipment and the positioning of patients for radiographic examinations and when performing mammography without direct supervision, also meets the requirements set forth in F.14b.i.(2).~~

~~"Screening mammography" means mammography performed on an asymptomatic patient to detect the presence of breast cancer at an early stage.~~

~~"Serious adverse event" means an adverse event that may significantly compromise clinical outcomes, or an adverse event for which a facility fails to take appropriate corrective action in a timely manner.~~

~~"Serious complaint" means a report of a serious adverse event.~~

~~"Standard breast" means a 4.2 centimeter (cm) thick compressed breast consisting of 50 percent glandular and 50 percent adipose tissue.~~

~~"Survey" means an onsite physics consultation and evaluation of a facility quality assurance program performed by a medical physicist.~~

~~"Time cycle" means the film development time.~~

~~"Traceable to a national standard" means an instrument is calibrated at either the National Institute of Standards and Technology (NIST) or at a calibration laboratory that participates in a proficiency program with NIST at least once every two years and the results of the proficiency test conducted within 24 months of calibration show agreement within ± 3 percent of the national standard in the mammography energy range.~~

Sec. F.14 — Mammography Requirements for States With Certifying Authority.

[Current] federal regulations, 21 CFR Part 900, [dated] referring to states with certifying authority, is incorporated in its entirety in Part F.

~~a. Requirements for Certification.~~

~~i. General. After the effective date of these regulations, a certificate issued by the Agency under FDA authority is required for lawful operation of all mammography facilities subject to the provisions of this section. To obtain a certificate from the Agency, facilities are required to meet the quality standards in F.14b. and to be accredited by an approved accreditation body.~~

~~ii. Application.~~

~~(1) Certificates.~~

~~(a) In order to qualify for a certificate, a facility must apply to an FDA-approved accreditation body or to another entity designated by FDA. The facility shall submit to such body or other entity the information required in 42 U.S.C. 263b(d)(1).~~

~~(b) Following the Agency's receipt of the accreditation body's decision to accredit a facility, the Agency may issue a certificate to the facility, or renew an existing certificate, if the Agency determines that the facility has satisfied the requirements for certification or recertification.~~

~~(2) Provisional certificates.~~

~~(a) A new facility is eligible to apply for a provisional certificate. The provisional certificate will allow the facility to perform mammography and to obtain clinical images needed to complete the accreditation process. To receive a provisional certificate, a facility must apply and submit the required information to an FDA-approved accreditation body or other entity.~~

~~(b) Following the Agency's receipt of the accreditation body's decision that a facility has submitted the required information, the Agency may issue a provisional certificate to a facility upon determination that the facility has satisfied the requirements for provisional certification. A provisional certificate shall be effective for up to six months from the date of issuance. A provisional certificate cannot be renewed, but a facility may apply for a 90-day extension of the provisional certificate.~~

~~(3) Extension of provisional certificate.~~

~~(a) To apply for a 90-day extension to a provisional certificate, a facility shall submit to its accreditation body a statement of what the facility is doing to obtain certification and evidence that there would be a significant adverse impact on access to mammography in the geographic area served if such facility did not obtain an extension.~~

~~(b) Following the Agency's receipt of the accreditation body's decision that a facility has submitted the required information in F.14a.ii(3)(a), the Agency may issue a 90-day extension of the provisional certificate upon determination that the facility has satisfied the requirements for the 90-day extension.~~

~~(c) There can be no renewal of a provisional certificate beyond the 90-day extension.~~

~~iii. Reinstatement Policy. A previously certified facility that has allowed its certificate to expire, that has been refused a renewal of its certificate by FDA or the Agency, or that has had its certificate suspended or revoked by FDA or the Agency, may apply to have the certificate reinstated so that the facility may be considered to be a new facility and thereby be eligible for a provisional certificate.~~

~~(1) Unless prohibited from reinstatement under F.14a.iii.(4), a facility applying for reinstatement shall:~~

~~(a) Contact an FDA-approved accreditation body to determine the requirements for reapplication for accreditation;~~

~~(b) Fully document its history as a previously provisionally certified or certified mammography facility, including the following information:~~

~~1. Name and address of the facility under which it was previously provisionally certified or certified;~~

~~2. Name of previous owner/lessor;~~

~~3. Agency facility identification number assigned to the facility under its previous certification; and~~

~~4. Expiration date of the most recent Agency provisional certificate or certificate; and~~

~~(c) Justify application for reinstatement of accreditation by submitting to the accreditation body or other entity designated by the Agency, a corrective action plan that details how the facility has corrected deficiencies that contributed to the lapse of, denial of renewal, or revocation of its certificate.~~

~~(2) The Agency may issue a provisional certificate to the facility if:~~

~~(a) Following the Agency's receipt of the accreditation body's decision that a facility has adequately corrected, or is in the process of correcting, pertinent deficiencies; and~~

~~(b) The Agency determines that the facility has taken sufficient corrective action since the lapse of, denial or renewal, or revocation of its previous certificate.~~

~~(3) After receiving the provisional certificate, the facility may lawfully resume performing mammography services while completing the requirements for certification.~~

~~(4) If a facility's certificate was revoked on the basis of an act described in F.14d., no person who owned or operated that facility at the time the act occurred may own or operate a mammography facility within two years of the date of revocation.~~

~~iv. Fees. Each certified mammography facility shall pay a certification fee. Failure to pay the required fee shall be grounds for suspension or revocation of the certificate.~~

~~b. Quality Standards.~~

~~i. Personnel. The following requirements apply to all personnel involved in any aspect of mammography, including the production, processing, and interpretation of mammograms and related quality assurance activities:~~

~~(1) Interpreting physicians. All physicians interpreting mammograms shall meet the following qualifications:~~

~~(a) Initial qualifications. Unless the exemption in F.14b.i.(1)(c)1. of this subsection applies, before beginning to interpret mammograms independently, the interpreting physician shall:~~

~~1. Be licensed to practice medicine in this State;~~

~~2. Meet the following requirements:~~

~~(A) Be certified in an appropriate specialty area by a body determined by FDA to have procedures and requirements adequate to ensure that physicians certified by the body are competent to interpret radiological procedures, including mammography; or~~

~~(B) Have a minimum of sixty hours of documented medical education in mammography, which shall include: instruction in the interpretation of mammograms and education in basic breast anatomy, pathology, physiology, technical aspects of mammography, and quality assurance and quality control in mammography. All sixty of these hours shall be Category I and at least~~

~~fifteen of the Category I hours shall have been acquired with the three years immediately prior to the date that the physician qualifies as an interpreting physician. Hours spent in residency specifically devoted to mammography will be considered as equivalent to Category I continuing education credits and shall be accepted if documented in writing by the appropriate representative of the training institution; and~~

~~(C) Unless the exemption in F.14b.i.(1)(c)2. applies, have interpreted or multi-read at least 240 mammographic examinations within the six-month period immediately prior to the date that the physician qualifies as an interpreting physician. This interpretation or multi-reading shall be under the direct supervision of an interpreting physician.~~

~~(b) Continuing experience and education. All interpreting physicians shall maintain their qualifications by meeting the following requirements:~~

~~1. Following the second anniversary date of the end of the calendar quarter in which the requirements of F.14b.i.(1)(a) were completed, the interpreting physician shall have interpreted or multi-read at least 960 mammographic examinations during the twenty-four months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in-between the two. The facility shall choose one of these dates to determine the 24-month period.~~

~~2. Following the third anniversary date of the end of the calendar quarter in which the requirements of F.14b.i.(1)(a) were completed, the interpreting physician shall have taught or completed at least fifteen Category I continuing medical education units in mammography during the thirty-six months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility shall choose one of these dates to determine the 36-month period. This training shall include at least six Category I continuing medical education credits in each mammographic modality used by the interpreting physician in his or her practice; and~~

~~3. Before an interpreting physician may begin independently interpreting mammograms produced by a new mammographic modality, that is, a mammographic modality in which the physician has not previously been trained, the interpreting~~

~~physician shall have at least eight hours of training in the new mammographic modality.~~

~~4. Units earned through teaching a specific course can be counted only once towards the fifteen required by F.14b.i.(1)(b)2., even if the course is taught multiple times during the previous thirty-six months.~~

~~(c) Exemptions.~~

~~1. Those physicians who qualified as interpreting physicians under FDA's interim regulations prior to April 28, 1999 are considered to have met the initial requirements of F.14b.i.(1)(a). They may continue to interpret mammograms provided they continue to, meet the licensure requirement of F.14b.i.(1)(a)1. and the continuing experience and education requirements of F.14b.i.(1)(b).~~

~~2. Physicians who have interpreted or multi-read at least 240 mammographic examinations under the direct supervision of an interpreting physician in any six-month period during the last two years of a diagnostic radiology residency and who become appropriately board certified at the first allowable time, as defined by an eligible certifying body, are otherwise exempt from F.14b.i.(1)(a)4.. F.14b.i.(1)(a)2.(C).~~

~~(d) Reestablishing qualifications. Interpreting physicians who fail to maintain the required continuing experience or continuing education requirements shall reestablish their qualifications before resuming the independent interpretation of mammograms, as follows:~~

~~1. Interpreting physicians who fail to meet the continuing experience requirements of F.14b.i.(1)(b)1. shall:~~

~~(A) Interpret or multi-read at least 240 mammographic examinations under the direct supervision of an interpreting physician, or~~

~~(B) Interpret or multi-read a sufficient number of mammographic examinations under the direct supervision of an interpreting physician, to bring the physician's total up to 960 examinations for the prior twenty-four months, whichever is less.~~

~~(C) The interpretations required under F.14b.i.(1)(d)1.(A) or F.14b.i.(1)(d)1.(B) shall be done within the six months immediately prior to resuming independent~~

~~interpretation.~~

~~2. Interpreting physicians who fail to meet the continuing education requirements of F.14b.i.(1)(b)2. shall obtain a sufficient number of additional Category I continuing medical education credits in mammography to bring their total up to the required fifteen credits in the previous thirty-six months before resuming independent interpretation.~~

~~(2) Radiologic technologists. All mammographic examinations shall be performed by radiologic technologists who meet the following general requirements, mammography requirements, and continuing education and experience requirements:~~

~~(a) General requirements.~~

~~1. Be licensed to perform general radiographic procedures in this State; or~~

~~2. Be certified and registered in active status with one of the bodies approved by FDA to certify radiologic technologists in the field of radiography; and~~

~~(b) Mammography requirements. Have, prior to April 28, 1999 qualified as a radiologic technologist under Section 900.12, paragraph (a)(2), of FDA's interim regulations of December 21, 1993 or completed at least forty contact hours of documented training specific to mammography under the supervision of a qualified instructor. The hours of documented training shall include, but not necessarily be limited to:~~

~~1. Training in breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, imaging of patients with breast implants;~~

~~2. The performance of a minimum of twenty-five examinations under the direct supervision of an individual qualified under F.14b.i.(2); and~~

~~3. At least eight hours of training in each mammography modality to be used by the technologist in performing mammography exams; and~~

~~(c) Continuing education requirements.~~

~~1. Following the third anniversary date of the end of the calendar quarter in which the requirements of F.14b.i.(2)(a) and F.14b.i.(2)(b) were completed, the radiologic technologist shall~~

~~have taught or completed at least fifteen continuing education units in mammography during the thirty-six months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility shall choose one of these dates to determine the 36-month period.~~

~~2. Units earned through teaching a specific course can be counted only once towards the fifteen required in F.14b.i.(2)(c)1., even if the course is taught multiple times during the previous thirty-six months.~~

~~3. At least six of the continuing education units required in F.14b.i.(2)(c)1. shall be related to each mammographic modality used by the technologist.~~

~~4. Requalification. Radiologic technologists who fail to meet the continuing education requirements of F.14b.i.(2)(c)1. shall obtain a sufficient number of continuing education units in mammography to bring their total up to at least fifteen in the previous three years, at least six of which shall be related to each modality used by the technologist in mammography. The technologist may not resume performing unsupervised mammography examinations until the continuing education requirements are completed.~~

~~5. Before a radiologic technologist may begin independently performing mammographic examinations using a mammographic modality other than one of those for which the technologist received training under F.14b.i.(2)(b)3., the technologist shall have at least eight hours of continuing education units in the new modality.~~

~~(d) Continuing experience requirements.~~

~~1. Following the second anniversary date of the end of the calendar quarter in which the requirements of F.14b.i.(2)(a) and F.14b.i.(2)(b) were completed or of April 28, 1999, whichever is later, the radiologic technologist shall have performed a minimum of two hundred mammography examinations during the twenty-four months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter or any date in between the two. The facility shall choose one of these dates to determine the 24-month period.~~

~~2. Requalification. Radiologic technologists who fail to meet the~~

~~continuing experience requirements of F.14b.i.(2)(d)1. shall perform a minimum of twenty-five mammography examinations under the direct supervision of a qualified radiologic technologist, before resuming the performance of unsupervised mammography examinations.~~

~~(3) Medical physicists. All medical physicists conducting surveys of mammography facilities and providing oversight of the facility quality assurance program shall meet the following:~~

~~(a) Initial qualifications.~~

~~1.Have the following credentials:~~

~~(A) Be licensed or approved to practice in this State; or~~

~~(B) Have certification in diagnostic radiological physics or radiological physics by either the American Board of Radiology (ABR), the American Board of Medical Physics (ABMP), or any entity approved by FDA.~~

~~2. Meet the following requirements:~~

~~(A) Have a masters degree or higher in a physical science from an accredited institution, with no less than twenty semester hours or equivalent (e.g., thirty quarter hours) of college undergraduate or graduate level physics;~~

~~(B) Have twenty contact hours of documented specialized training in conducting surveys of mammography facilities; and~~

~~(C) Have the experience of conducting surveys of at least one mammography facility and a total of at least ten mammography units. No more than one survey of a specific unit within a period of sixty days can be counted towards the total mammography unit survey requirement. After April 28, 1999 experience conducting surveys shall be acquired under the direct supervision of a medical physicist who meets all the requirements of F.14b.i.(3)(a) or.F.14b.i.(3)(c); or~~

~~(b) Alternative initial qualifications.~~

~~1. Have qualified as a medical physicist under FDA's interim regulations and retained that qualification by maintenance of active status of any licensure, approval, or certification required~~

~~under the interim regulations; and~~

~~2. Prior to the April 28, 1999 have:~~

~~(A) A bachelor's degree or higher in a physical science from an accredited institution with no less than ten semester hours or equivalent of college undergraduate or graduate level physics;~~

~~(B) Forty contact hours of documented specialized training in conducting surveys of mammography facilities; and~~

~~(C) Have the experience of conducting surveys of at least one mammography facility and a total of at least twenty mammography units. No more than one survey of a specific unit within a period of sixty days can be counted towards the total mammography unit survey requirement. The training and experience requirements shall be met after fulfilling the degree requirement.~~

~~(e) Continuing qualifications.~~

~~1. Continuing education. Following the third anniversary date of the end of the calendar quarter in which the requirements of F.14b.i.(3)(a) and or F.14b.i.(3)(b) were completed, the medical physicist shall have taught or completed at least fifteen continuing education units in mammography during the thirty-six months immediately preceding the date of the facility's annual inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility shall choose one of these dates to determine the 36-month period. This continuing education shall include hours of training appropriate to each mammographic modality evaluated by the medical physicist during his or her surveys or oversight of quality assurance programs. Units earned through teaching a specific course can be counted only once towards the required fifteen units in a 36-month period, even if the course is taught multiple times during the thirty-six months.~~

~~2. Continuing experience. Following the second anniversary date of the end of the calendar quarter in which the requirements of F.14b.i.(3)(a) or F.14b.i.(3)(b) were completed or of April 28, 1999 whichever is later, the medical physicist shall have surveyed at least two mammography facilities and a total of at least six mammography units during the twenty-four months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter or any date in-~~

~~between the two. The facility shall choose one of these dates to determine the 24-month period. No more than one survey of a specific facility within a 10-month period or a specific unit within a period of sixty days can be counted towards the total mammography unit survey requirement.~~

~~3. Before a medical physicist may begin independently performing mammographic surveys of a new mammographic modality, that is, a mammographic modality other than one for which the physicist received training to qualify under F.14b.i.(3)(a) or F.14b.i.(3)(b), the physicist shall receive at least eight hours of training in surveying units of the new mammographic modality.~~

~~(d) Reestablishing qualifications. Medical physicists who fail to maintain the required continuing qualifications of F.14b.i.(3)(c) may not perform the MQSA surveys without the supervision of a qualified medical physicist. Before independently surveying another facility, medical physicists shall reestablish their qualifications, as follows:~~

~~1. Medical physicists who fail to meet the continuing educational requirements of F.14b.i.(3)(c)1. shall obtain a sufficient number of continuing education units to bring their total units up to the required fifteen in the previous three years.~~

~~2. Medical physicists who fail to meet the continuing experience requirement of F.14b.i.(3)(c)2. shall complete a sufficient number of surveys under the direct supervision of a medical physicist who meets the qualifications of F.14b.i.(3)(a) and F.14b.i.(3)(c) to bring their total surveys up to the required two facilities and six units in the previous twenty-four months. No more than one survey of a specific unit within a period of sixty days can be counted towards the total mammography unit survey requirement.~~

~~(4) Retention of personnel records. Facilities shall maintain records to document the qualifications of all personnel who worked at the facility as interpreting physicians, radiologic technologists, or medical physicists. These records must be available for review by Agency inspectors. Records of personnel no longer employed by the facility shall not be discarded until the next annual inspection has been completed and the Agency has determined that the facility is in compliance with the MQSA personnel requirements.~~

~~ii. Equipment.~~

~~(1) Prohibited equipment. Radiographic equipment designed for general purpose or special nonmammography procedures shall not be used for mammography.~~

~~This prohibition includes systems that have been modified or equipped with special attachments for mammography.~~

~~(2) General. All radiographic equipment used for mammography shall be specifically designed for mammography and shall be certified pursuant to 21 C.F.R., Section 1010.2 as meeting the applicable requirements of 21 C.F.R., 1020.30 and 1020.31, in effect at the date of manufacture.~~

~~(3) Motion of tube-image receptor assembly.~~

~~(a) The assembly shall be capable of being fixed in any position where it is designed to operate. Once fixed in any such position, it shall not undergo unintended motion.~~

~~(b) The mechanism ensuring compliance with F.14b.ii.(3)(a) shall not fail in the event of power interruption.~~

~~(4) Image receptor sizes.~~

~~(a) Systems using screen-film image receptors shall provide, at a minimum, for operation with image receptors of eighteen centimeters (cm) by twenty-four cm and twenty-four cm x thirty cm.~~

~~(b) Systems using screen-film image receptors shall be equipped with moving grids matched to all image receptor sizes provided.~~

~~(c) Systems used for magnification procedures shall be capable of operation with the grid removed from between the source and image receptor.~~

~~(5) Light fields. For any mammography system with a light beam that passes through the x-ray beam-limiting device, the light shall provide an average illumination of not less than one hundred sixty lux (fifteen foot candles) at one hundred cm or the maximum source-image receptor distance (SID), whichever is less.~~

~~(6) Magnification.~~

~~(a) Systems used to perform noninterventional problem solving procedures shall have radiographic magnification capability available for use by the operator.~~

~~(b) Systems used for magnification procedures shall provide, at a minimum, at least one magnification value within the range of 1.4 to 2.0.~~

~~(7) Focal spot selection.~~

~~(a) When more than one focal spot is provided, the system shall indicate, prior to exposure, which focal spot is selected.~~

~~(b) When more than one target material is provided, the system shall indicate, prior to exposure, the preselected target material.~~

~~(c) When the target material and/or focal spot is selected by a system algorithm that is based on the exposure or on a test exposure, the system shall display, after the exposure, the target material and/or focal spot actually used during the exposure.~~

~~(8) Compression. All mammography systems shall incorporate a compression device.~~

~~(a) Application of compression. Effective October 28, 2002, each system shall provide:~~

~~1. An initial power-driven compression activated by hands-free controls operable from both sides of the patient; and~~

~~2. Fine adjustment compression controls operable from both sides of the patient.~~

~~(b) Compression paddle.~~

~~1. Systems shall be equipped with different sized compression paddles that match the size of all full-field image receptors provided for the system. Compression paddles for special purposes, including those smaller than the full size of the image receptor (for "spot compression") may be provided. Such compression paddles for special purposes are not subject to the requirements of F.14b.ii.(8)(b)4. and F.14b.ii.(8)(b)5..~~

~~2. Except as provided in F.14b.ii.(8)(b)3., the compression paddle shall be flat and parallel to the breast support table and shall not deflect from parallel by more than 1.0 cm at any point on the surface of the compression paddle when compression is applied.~~

~~3. Equipment intended by the manufacturer's design to not be flat and parallel to the breast support table during compression shall meet the manufacturer's design specifications and maintenance requirements.~~

~~4. The chest wall edge of the compression paddle shall be straight and parallel to the edge of the image receptor.~~

~~5. The chest wall edge may be bent upward to allow for patient comfort but shall not appear on the image.~~

~~(9) Technique factor selection and display.~~

~~(a) Manual selection of milliampere seconds (mAs) or at least one of its component parts (milliampere (mA) and/or time) shall be available.~~

~~(b) The technique factors (peak tube potential in kilovolt (kV) and either tube current in mA and exposure time in seconds or the product of tube current and exposure time in mAs) to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls (AEC) are used, in which case the technique factors that are set prior to the exposure shall be indicated.~~

~~(c) Following AEC mode use, the system shall indicate the actual kilovoltage peak (kVp) and mAs used during the exposure. The mAs may be displayed as mA and time.~~

~~(10) Automatic exposure control.~~

~~(a) Each screen-film system shall provide an AEC mode that is operable in all combinations of equipment configuration provided, e.g., grid, nongrid; magnification, nonmagnification; and various target-filter combinations.~~

~~(b) The positioning or selection of the detector shall permit flexibility in the placement of the detector under the target tissue.~~

~~1. The size and available positions of the detector shall be clearly indicated at the x-ray input surface of the breast compression paddle.~~

~~2. The selected position of the detector shall be clearly indicated.~~

~~(c) The system shall provide means for the operator to vary the selected optical density from the normal (zero) setting.~~

~~(11) X-ray film. The facility shall use x-ray film for mammography that has been designated by the film manufacturer as appropriate for mammography.~~

~~(12) Intensifying screens. The facility shall use intensifying screens for mammography that have been designated by the screen manufacturer as appropriate for mammography and shall use film that is matched to the screen's spectral output as specified by the manufacturer.~~

~~(13) Film processing solutions. For processing mammography films, the facility shall use chemical solutions that are capable of developing the films used by the facility in a manner equivalent to the minimum requirements specified by the film manufacturer.~~

~~(14) Lighting. The facility shall make special lights for film illumination, i.e., hot-lights, capable of producing light levels greater than that provided by the view box, available to the interpreting physicians.~~

~~(15) Film masking devices. Facilities shall ensure that film masking devices that can limit the illuminated area to a region equal to or smaller than the exposed portion of the film are available to all interpreting physicians interpreting for the facility.~~

~~iii. Medical records and mammography reports.~~

~~(1) Contents and terminology. Each facility shall prepare a written report of the results of each mammography examination performed under its certificate. The mammography report shall include the following information:~~

~~(a) The name of the patient and an additional patient identifier;~~

~~(b) Date of examination;~~

~~(c) The name of the interpreting physician who interpreted the mammogram;~~

~~(d) Overall final assessment of findings, classified in one of the following categories:~~

~~1. "Negative:" Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained);~~

~~2. "Benign:" Also a negative assessment;~~

~~3. "Probably Benign:" Finding(s) has a high probability of being benign;~~

~~4. "Suspicious:" Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probably of being malignant;~~

~~5. "Highly suggestive of malignancy:" Finding(s) has a high probability of being malignant.~~

~~(e) In cases where no final assessment category can be assigned due to~~

~~incomplete work-up, "Incomplete: Need additional imaging evaluation" shall be assigned as an assessment and reasons why no assessment can be made shall be stated by the interpreting physician; and~~

~~(f) Recommendations made to the health care provider about what additional actions, if any, should be taken. All clinical questions raised by the referring health care provider shall be addressed in the report to the extent possible. even if the assessment is negative or benign.~~

~~(2) Communication of mammography results to the patient. Each facility shall send each patient a summary of the mammography report written in lay terms within 30 days of the mammographic examination. If assessments are "Suspicious" or "Highly suggestive of malignancy," the facility shall make reasonable attempts to ensure that the results are communicated to the patient as soon as possible.~~

~~(a) Patients who do not name a health care provider to receive the mammography report shall be sent the report described in F.14b.iii.(1) within 30 days, in addition to the written notification of results in lay terms.~~

~~(b) Each facility that accepts patients who do not have a health care provider shall maintain a system for referring such patients to a health care provider when clinically indicated.~~

~~(3) Communication of mammography results to health care providers. When the patient has a health care provider or the patient has named a health care provider, the facility shall:~~

~~(a) Provide a written report of the mammography examination, including the items listed in F.14b.iii.(1), to that health care provider as soon as possible, but no later than thirty days from the date of the mammography examination; and~~

~~(b) If the assessment is "Suspicious" or "Highly suggestive of malignancy," make reasonable attempts to communicate with the health care provider as soon as possible, or if the health care provider is unavailable, to a responsible designee of the health care provider.~~

~~(4) Recordkeeping. Each facility that performs mammograms:~~

~~(a) Shall (except as provided in F.14b.iii.(4)(b)) maintain mammography films and reports in a permanent medical record of the patient for a period of not less than five years, or not less than ten years if no additional mammograms of the patient are performed at the facility; and~~

~~(b) Shall upon request by, or on behalf of, the patient, permanently or temporarily transfer the original mammograms and copies of the patient's reports to a medical institution, or to a physician or health care provider of the patient, or to the patient directly;~~

~~(c) Any fee charged to the patients for providing the services in F.14b.iii.(4)(b) shall not exceed the documented costs associated with this service.~~

~~(5) Mammographic image identification. Each mammographic image shall have the following information indicated on it in a permanent, legible, and unambiguous manner and placed so as not to obscure anatomic structures:~~

~~(a) Name of patient and an additional patient identifier.~~

~~(b) Date of examination.~~

~~(c) View and laterality. This information shall be placed on the image in a position near the axilla. Standardized codes specified by the accreditation body shall be used to identify view and laterality.~~

~~(d) Facility name and location. At a minimum, the location shall include the city, State, and zip code of the facility.~~

~~(e) Technologist identification.~~

~~(f) Cassette/screen identification.~~

~~(g) Mammography unit identification, if there is more than one unit in the facility.~~

~~iv. Quality assurance general. Each facility shall establish and maintain a quality assurance program to ensure the safety, reliability, clarity, and accuracy of mammography services performed at the facility.~~

~~(1) Responsible individuals. Responsibility for the quality assurance program and for each of its elements shall be assigned to individuals who are qualified for their assignments and who shall be allowed adequate time to perform these duties.~~

~~(a) Lead interpreting physician. The facility shall identify a lead interpreting physician who shall have the general responsibility of ensuring that the quality assurance program meets all requirements of F.14b.iv. through vi.. No other individual shall be assigned or shall retain responsibility for quality assurance tasks unless the lead interpreting physician has determined that the individual's~~

~~qualifications for, and performance of, the assignment are adequate.~~

~~(b) Interpreting physicians. All interpreting physicians interpreting mammograms for the facility shall:~~

~~1. Following the facility procedures for corrective action when the images they are asked to interpret are of poor quality, and~~

~~2.Participate in the facility's medical outcomes audit program.~~

~~(c) Audit interpreting physician. Each facility shall designate at least one interpreting physician to review the medical outcomes audit data at least once every twelve months. This individual shall record the dates of the audit period(s) and shall be responsible for analyzing results based on this audit. This individual shall also be responsible for documenting the results and notifying other interpreting physicians of their results and the facility aggregate results. If follow-up actions are taken, the audit interpreting physician shall also be responsible for documenting the nature of the follow-up.~~

~~(d) Medical physicist. Each facility shall have the services of a medical physicist available to survey mammography equipment and oversee the equipment-related quality assurance practices of the facility. At a minimum, the medical physicist(s) shall be responsible for performing the surveys and mammography equipment evaluations and providing the facility with the reports described in F.14b.v.(9) and F.14b.v.(10).~~

~~(e) Quality control technologist. Responsibility for all individual tasks within the quality assurance program not assigned to the lead interpreting physician or the medical physicist shall be assigned to a quality control technologist(s). The tasks are to be performed by the quality control technologist or by other personnel qualified to perform the tasks. When other personnel are utilized for these tasks, the quality control technologist shall ensure that the tasks are completed in such a way as to meet the requirements of F.14b.v..~~

~~(2) Quality assurance records. The lead interpreting physician, quality control technologist, and medical physicist shall ensure that records concerning mammography technique and procedures, quality control (including monitoring data, problems detected by analysis of that data, corrective actions, and the effectiveness of the corrective actions), safety, protection and employee qualification to meet assigned quality assurance tasks are properly maintained and updated. These quality control records shall be kept for each test specified in F.14b.v. and F.14b.vi. until the next annual inspection has been completed and the Agency has determined that the facility is in compliance with the quality assurance requirements or until the test has been performed two additional times at the required frequency, whichever is longer.~~

~~v. Quality assurance - equipment~~

~~(1) Daily quality control tests. Film processors used to develop mammograms shall be adjusted and maintained to meet the technical development specifications for the mammography film in use. A processor performance test shall be performed on each day that clinical films are processed before any clinical films are processed that day. The test shall include an assessment of base plus fog density, mid-density, and density difference, using the mammography film used clinically at the facility.~~

~~(a) The base plus fog density shall be within ±0.03 of the established operating level.~~

~~(b) The mid-density shall be within ±0.15 of the established operating level.~~

~~(c) The density difference shall be within ±0.15 of the established operating level.~~

~~(2) Weekly quality control tests. Facilities within screen-film systems shall perform an image quality evaluation test, using an FDA-approved phantom, at least weekly.~~

~~(a) The optical density of the film at the center of an image of the phantom shall be at least 1.20 when exposed under a typical clinical condition.~~

~~(b) The optical density of the film at the center of the phantom image shall not change by more than ±0.20 from the established level.~~

~~(c) The phantom image shall achieve at least the minimum score established by the accreditation body.~~

~~(d) The density difference between the background of the phantom and an added test object, used to assess image contrast, shall be measured and shall not vary by more than ±0.05 from the established operating level.~~

~~(3) Quarterly quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least quarterly:~~

~~(a) Fixer retention in film. The residual fixer shall be no more than five micrograms per square cm.~~

~~(b) Repeat analysis. If the total repeat or reject rate changes from the previously determined rate by more than 2.0 percent of the total films included in the analysis, the reason(s) for the change shall be determined. Any corrective actions shall be recorded and the results of~~

~~these corrective actions shall be assessed.~~

~~(4) Semiannual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least semiannually:~~

~~(a) Darkroom fog. The optical density attributable to darkroom fog shall not exceed 0.05 when a mammography film of the type used in the facility, which has a mid-density of no less than 1.20 OD, is exposed to typical darkroom conditions for two minutes while such film is placed on the counter top emulsion side up. If the darkroom has a safelight used for mammography film, it shall be on during this test.~~

~~(b) Screen-film contact. Testing for screen-film contact shall be conducted using the appropriate size forty mesh copper screen. All cassettes used in the facility for mammography shall be tested.~~

~~(c) Compression device performance.~~

~~1. A compression force of at least one hundred eleven newtons (twenty-five pounds) maintained for at least fifteen seconds shall be provided.~~

~~2. Effective October 28, 2002, the maximum compression force for the initial power drive shall be between one hundred eleven newtons (twenty-five pounds) and two hundred newtons (forty-five pounds).~~

~~(5) Annual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least annually:~~

~~(a) Automatic exposure control performance.~~

~~1. The AEC shall be capable of maintaining film optical density within ±0.30 of the mean optical density when thickness of a homogeneous material is varied over a range of two to six cm and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility. If this requirement cannot be met, a technique chart shall be developed showing appropriate techniques (kVp and density control settings) for different breast thicknesses and compositions that must be used so that optical densities within ±0.30 of the average under phototimed conditions can be produced.~~

~~2. After October 28, 2002, the AEC shall be capable of maintaining film optical density (OD) within ±0.15 of the mean optical density when thickness of a homogeneous material is varied over a range of two to six cm and the kVp is varied~~

~~appropriately for such thicknesses over the kVp range used clinically in the facility.~~

~~3. The optical density of the film in the center of the phantom image shall not be less than 1.20.~~

~~(b) Kilovoltage peak (kVp) accuracy and reproducibility.~~

~~1. The kVp shall be accurate within ±five percent of the indicated or selected kVp at:~~

~~(A) The lowest clinical kVp than can be measured by a kVp test device;~~

~~(B) The most commonly used clinical kVp;~~

~~(C) The highest available clinical kVp, and~~

~~2. At the most commonly used clinical settings of kVp, the coefficient of variation of reproducibility of the kVp shall be equal to or less than 0.02.~~

~~(c) Focal spot condition. Until October 28, 2002, focal spot condition shall be evaluated either by determining system resolution or by measuring focal spot dimensions. After October 28, 2002, facilities shall evaluate focal spot condition only by determining the system resolution.~~

~~1. System resolution.~~

~~(A) Each x-ray system used for mammography, in combination with the mammography screen-film combination used in the facility, shall provide a minimum resolution of eleven cycles per millimeters (mm) (line-pairs/mm) when a high contrast resolution bar test pattern is oriented with the bars perpendicular to the anode-cathode axis, and a minimum resolution of thirteen line-pairs/mm when the bars are parallel to that axis.~~

~~(B) The bar pattern shall be placed 4.5 cm above the breast support surface, centered with respect to the chest wall edge of the image receptor, and with the edge of the pattern within one cm of the chest wall edge of the image receptor.~~

~~(C) When more than one target material is provided, the~~

~~measurement in F.14b.v.(5)(e)1. shall be made using the appropriate focal spot for each target material.~~

~~(D) When more than one SID is provided, the test shall be performed at the SID most commonly used clinically.~~

~~(E) Test kVp shall be set at the value used clinically by the facility for a standard breast and shall be performed in the AEC mode, if available. If necessary, a suitable absorber may be placed in the beam to increase exposure times. The screen-film cassette combination used by the facility shall be used to test for this requirement and shall be placed in the normal location used for clinical procedures.~~

~~2. Focal spot dimensions. Measured values of the focal spot length (dimension parallel to the anode cathode axis) and width (dimension perpendicular to the anode cathode axis) shall be within the tolerance limits specified in Appendix D.~~

~~(d) Beam quality and half value layer (HVL). The HVL shall meet the minimum HVL specified in Appendix E. Values not shown in Appendix E may be determined by linear interpolation or extrapolation.~~

~~(e) Breast entrance air kerma and AEC reproducibility. The coefficient of variation for both air kerma and mAs shall not exceed 0.05.~~

~~(f) Dosimetry. The average glandular dose delivered during a single craniocaudal view of an FDA-accepted phantom simulating a standard breast shall not exceed 3.0 milliGray (mGy) (0.3 rad) per exposure. The dose shall be determined with technique factors and conditions used clinically for a standard breast.~~

~~(g) X-ray field/light field/image receptor/compression paddle alignment.~~

~~1. All systems shall have beam-limiting devices that allow the entire chest wall edge of the x-ray field to extend to the chest wall edge of the image receptor and provide means to assure that the x-ray field does not extend beyond any edge of the image receptor by more than two percent of the SID.~~

~~2. If a light field that passes through the x-ray beam limitation device is provided, it shall be aligned with the x-ray field so that the total of any misalignment of the edges of the light field and the x-ray field along either the length or the width of the visually defined field at the plane of the breast support surface~~

~~shall not exceed two percent of the SID.~~

~~3. The chest wall edge of the compression paddle shall not extend beyond the chest wall edge of the image receptor by more than one percent of the SID when tested with the compression paddle placed above the breast support surface at a distance equivalent to standard breast thickness. The shadow of the vertical edge of the compression paddle shall not be visible on the image.~~

~~(h) Uniformity of screen speed. Uniformity of screen speed of all the cassettes in the facility shall be tested and the difference between the maximum and minimum optical densities shall not exceed 0.30. Screen artifacts shall also be evaluated during this test.~~

~~(i) System artifacts. System artifacts shall be evaluated with a high-grade, defect-free sheet of homogeneous material large enough to cover the mammography cassette and shall be performed for all cassette sizes used in the facility using a grid appropriate for the cassette size being tested. System artifacts shall also be evaluated for all available focal spot sizes and target filter combinations used clinically.~~

~~(j) Radiation output.~~

~~1. The system shall be capable of producing a minimum output of 4.5 mGy air kerma per second (five hundred thirteen milliroentgen (mR) per second) when operating at twenty-eight kVp in the standard mammography (moly/moly) mode at any SID where the system is designed to operate and when measured by a detector with its center located 4.5 cm above the breast support surface with the compression paddle in place between the source and the detector. After October 28, 2002, the system, under the same measuring conditions shall be capable of producing a minimum output of 7.0 mGy air kerma per second (eight hundred mR per second) when operating at twenty-eight kVp in the standard (moly/moly) mammography mode at any SID where the system is designed to operate.~~

~~2. The system shall be capable of maintaining the required minimum radiation output averaged over a 3.0 second period.~~

~~(k) Decompression. If the system is equipped with a provision for automatic decompression after completion of an exposure or interruption of power to the system, the system shall be tested to confirm that it provides:~~

~~1. An override capability to allow maintenance of compression;~~

~~2. A continuous display of the override status; and~~

~~3. A manual emergency compression release that can be activated in the event of power or automatic release failure.~~

~~(6) Quality control tests - other modalities. For systems with image receptor modalities other than screen-film, the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems in F.14b.v.(5)(f).~~

~~(7) Mobile units. The facility shall verify that mammography units used to produce mammograms at more than one location meet the requirements in F.14b.v.(1) through v.(6). In addition, at each examination location, before any examinations are conducted, the facility shall verify satisfactory performance of such units using a test method that establishes the adequacy of the image quality produced by the unit.~~

~~(8) Use of test results.~~

~~(a) After completion of the tests specified in F.14b.v.(1) through v.(7), the facility shall compare the test results to the corresponding specified action limits; or, for non-screen-film modalities, to the manufacturer's recommended action limits; or, for post-move, preexamination testing of mobile units, to the limits established in the test method used by the facility.~~

~~(b) If the test results fall outside of the action limits, the source of the problem shall be identified and corrective actions shall be taken:~~

~~1. Before any further examinations are performed or any films are processed using the component of the mammography system that failed any of the tests described in F.14b.v.(1), v.(2), v..(4)(a), v.(4)(b), v.(4)(c), v.(5)(f), v.(6), or v.(7);~~

~~2. Within thirty days of the test date for all other tests described in F.14b.v.~~

~~(9) Surveys.~~

~~(a) At least once a year, each facility shall undergo a survey by a medical physicist or by an individual under the direct supervision of a medical physicist. At a minimum, this survey shall include the performance of tests to ensure that the facility meets the quality assurance requirements of the annual tests described in F.14b.v.(5) and~~

~~F.14b.v.(6) and the weekly phantom image quality test described in F.14b.v.(2).~~

~~(b) The results of all tests conducted by the facility in accordance with F.14b.v.(1) through v.(7), as well as written documentation of any corrective actions taken and their results, shall be evaluated for adequacy by the medical physicist performing the survey.~~

~~(c) The medical physicist shall prepare a survey report that includes a summary of this review and recommendations for necessary improvements.~~

~~(d) The survey report shall be sent to the facility within thirty days of the date of the survey.~~

~~(e) The survey report shall be dated and signed by the medical physicist performing and/or supervising the survey. If the survey was performed entirely or in part by another individual under the direct supervision of the medical physicist, that individual and the part of the survey that individual performed shall also be identified in the survey report.~~

~~(10) Mammography equipment evaluations. Additional evaluations of mammography units or image processors shall be conducted whenever a new unit or processor is installed, a unit or processor is disassembled and reassembled at the same or a new location, or major components of a mammography unit or processor equipment are changed or repaired. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in F.14b.ii. and F.14b.v.. All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing. The mammography equipment evaluation shall be performed by a medical physicist or an individual under the direct supervision of a medical physicist.~~

~~(11) Facility cleanliness.~~

~~(a) The facility shall establish and implement protocols for maintaining darkroom, screen, and viewbox cleanliness.~~

~~(b) The facility shall document that all cleaning procedures are performed at the frequencies specified in the protocols.~~

~~(12) Calibration of air kerma measuring instruments. Instruments used by medical physicists in their annual survey to measure the air kerma or air kerma rate from a mammography unit shall be calibrated at least once every two years and each time the instrument is repaired. The instrument calibration must be traceable to a national standard and calibrated with an accuracy of ± six percent (ninety-five percent confidence level) in the mammography energy~~

~~range.~~

~~(13) Infection control. Facilities shall establish and comply with a system specifying procedures to be followed by the facility for cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials. This system shall specify the methods for documenting facility compliance with the infection control procedures established and shall:~~

~~(a)Comply with all applicable federal, state, and local regulations pertaining to infection control;~~

~~(b)Comply with the manufacturer's recommended procedures for the cleaning and disinfection of the mammography equipment used in the facility; and~~

~~(c)If adequate manufacturer's recommendations are not available, comply with generally accepted guidance on infection control, until such recommendations become available.~~

~~vi. Quality assurance - mammography medical outcomes audit. Each facility shall establish and maintain a mammography medical outcomes audit program to follow-up positive mammographic assessments and to correlate pathology results with the interpreting physician's findings. This program shall be designed to ensure the reliability, clarity, and accuracy of the interpretation of mammograms.~~

~~(1) General requirements. Each facility shall establish a system to collect and review outcome data for all mammograms performed, including follow-up on the disposition of all positive mammograms and correlation of pathology results with the interpreting physician's mammography report. Analysis of these outcome data shall be made individually and collectively for all interpreting physicians at the facility. In addition, any cases of breast cancer among women imaged at the facility that subsequently become known to the facility shall prompt the facility to initiate follow-up on surgical and/or pathology results and review of the mammograms taken prior to the diagnosis of a malignancy.~~

~~(2) Frequency of audit analysis. The facility's first audit analysis shall be initiated no later than twelve months after the date the facility becomes certified, or twelve months after April 28, 1999 whichever date is the latest. This audit analysis shall be completed within an additional twelve months to permit completion of diagnostic procedures and data collection. Subsequent audit analyses will be conducted at least once every twelve months.~~

~~(3) Reviewing Audit interpreting physician. Each facility shall designate at least one interpreting physician to review the medical outcomes audit data at once every twelve months. This individual shall record the dates of the audit~~

~~period(s) and shall be responsible for analyzing results based on this audit. This individual shall also be responsible for documenting the results and for notifying other interpreting physicians of their results and the facility aggregate results. If follow-up actions are taken, the reviewing interpreting physician shall also be responsible for documenting the nature of the follow-up.~~

~~vii. Mammographic procedure and techniques for mammography of patients with breast implants.~~

~~(1) Each facility shall have a procedure to inquire whether or not the patient has breast implants prior to the actual mammographic exam.~~

~~(2) Except where contraindicated, or unless modified by a physician's directions, patients with breast implants undergoing mammography shall have mammographic views to maximize the visualization of breast tissue.~~

~~viii. Consumer complaint mechanism. Each facility shall:~~

~~(1) Establish a written and documented system for collecting and resolving consumer complaints;~~

~~(2) Maintain a record of each serious complaint received by the facility for at least three years from the date the complaint was received;~~

~~(3) Provide the consumer with adequate directions for filing serious complaints with the facility's accreditation body if the facility is unable to resolve a serious complaint to the consumer's satisfaction;~~

~~(4) Report unresolved serious complaints to the accreditation body in a manner and time frame specified by the accreditation.~~

~~ix. Clinical image quality. Clinical images produced by any certified facility must continue to comply with the standards for clinical image quality established by that facility's accreditation body.~~

~~x. Additional mammography review and patient notification.~~

~~(1) If the Agency believes that mammography quality at a facility has been compromised and may present a serious risk to human health, the facility shall provide clinical images and other relevant information, as specified by the Agency, for review by the accreditation body or other entity designated by FDA. This additional mammography review will help the Agency to determine whether the facility is in compliance with this section and if not, whether there is a need to notify affected patients, their physicians, or the public that the reliability, clarity, and accuracy of interpretation of mammograms has been compromised.~~

~~(2)If the Agency determines that the quality of mammography performed by a facility, whether or not certified under F.14a., was so inconsistent with the quality standards established in this section as to present a significant risk to individual or public health, the Agency may require such facility to notify patients who received mammograms at such facility, and their referring physicians, of the deficiencies presenting such risk, the potential harm resulting, appropriate remedial measures, and such other relevant information as the Agency may require.~~

~~xi.Alternative requirements for F.14b.~~

~~(1) All mammography facilities seeking alternative requirements for F.14b. shall notify the Agency in writing of such intent.~~

~~(2) Mammography facilities shall have written Agency and FDA approval before implementing alternative requirements for F.14b.~~

~~c. Revocation of Accreditation.~~

~~If a facility's accreditation is revoked by an accreditation body, the Agency may conduct an investigation into the reasons for the revocation. Following such investigation, the Agency may suspend or revoke the facility's certificate and take whatever other action or combination of actions to protect public health, including requiring the establishment and implementation of a corrective plan of action that shall permit the certificate to continue in effect while the facility seeks reaccreditation. A facility whose certificate is suspended or revoked because it has lost its accreditation may not practice mammography.~~

~~d. Suspension or Revocation of Certificates.~~

~~i. Except as provided in F.14d.ii., the Agency may suspend or revoke a certificate if the Agency finds, after providing the owner or operator of the facility with notice and opportunity for an informal hearing in accordance with Agency procedures, that the owner, operator, or any employee of the facility:~~

~~(1) Has been guilty of misrepresentation in obtaining the certificate;~~

~~(2) Has failed to comply with the standards of F.14b;~~

~~(3) Has failed to comply with reasonable requests of the Agency or the accreditation body for records, information, reports, or materials that the Agency believes are necessary to determine the continued eligibility of the facility for a certificate or continued compliance with the standards of F.14b.;~~

~~(4) Has refused a reasonable request of a duly designated FDA inspector, Agency inspector, or accreditation body representative for permission to inspect the facility or the operations and pertinent records of the facility;~~

~~(5) Has violated or aided and abetted in the violation of any provision of this regulation;~~

~~(6)Has failed to comply with prior sanctions imposed by the Agency; or~~

~~(7) Has failed to pay any required fees.~~

~~ii. The Agency may suspend the certificate of a facility before holding a hearing if the Agency makes a finding described in F.14d.i. and also determines that:~~

~~(1) The failure to comply with required standards presents a serious risk to human health;~~

~~(2) The refusal to permit inspection makes immediate suspension necessary; or~~

~~(3) There is reason to believe that the violation or aiding and abetting of the violation was intentional or associated with fraud.~~

~~iii. If the Agency suspends a certificate in accordance with F.14d.ii:~~

~~(1) The Agency shall provide the facility with an opportunity for an informal hearing under Agency procedures not later than thirty days from the effective date of this suspension;~~

~~(2) The suspension shall remain in effect until the Agency determines that:~~

~~(a) Allegations of violations or misconduct were not substantiated;~~

~~(b) Violations of required standards have been corrected to the Agency's satisfaction; or~~

~~(c) The facility's certificate is revoked in accordance with F.14d.iv;~~

~~iv. After providing a hearing in accordance with F.14d.iii.(1), the Agency may revoke the facility's certificate if the Agency determines that the facility:~~

~~(1) Is unwilling or unable to correct violations that were the basis for suspension; or~~

~~(2) Has engaged in fraudulent activity to obtain or continue certification.~~

~~e. Appeals of Adverse Accreditation or Reaccreditation Decisions That Preclude Certification or Recertification.~~

~~i. The appeals procedures described are available only for adverse accreditation or reaccreditation decisions that preclude certification or recertification by the Agency.~~

~~Agency decisions to suspend or revoke certificates that are already in effect shall be conducted in accordance with F.14d.~~

~~ii. Upon learning that a facility has failed to become accredited or reaccredited, the Agency will notify the facility that the Agency is unable to certify that facility without proof of accreditation.~~

~~iii. A facility that has been denied accreditation or reaccreditation is entitled to an appeals process from the accreditation body. A facility shall avail itself of the accreditation body's appeal process before requesting an appeal from the Agency.~~

~~iv. A facility that cannot achieve satisfactory resolution of an adverse accreditation decision through the accreditation body's appeal process may request a review by the Agency. This request shall be submitted in writing to the Agency within sixty days after the accreditation body's adverse decision.~~

~~v. A facility cannot perform mammography services while an adverse accreditation decision is being appealed.~~

Sec. F.15 - Bone Densitometry.

a. Bone densitometry systems shall be:

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

ii. Registered [licensed] in accordance with Part B of these regulations; and

iii. Maintained and operated in accordance with the manufacturer's specifications.

b. Equipment Requirements. Systems with stepless collimators shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond 2 percent of the SID.

c. Operators of bone densitometry systems shall be:

i. Licensed, certified, or permitted as a radiologic technologist [by the Agency]; or

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

iii. Permitted, certified, or approved [by the Agency] as a bone densitometry operator; or

iv. Complete a training course on bone densitometry which is approved by the Agency. The training course shall include:

(1) Basic radiation protection;

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

(3) Patient positioning for the types of examinations performed.

d. During the operation of any bone densitometry system:

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

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

e. The registrant [licensee] shall keep maintenance records for bone densitometry systems as prescribed by ~~F.13a.iii~~ F.15a.iii.. These records shall be maintained for inspection by the Agency [insert Agency recordkeeping timelines as appropriate].

f. Bone densitometry on human patients shall be conducted only:

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

ii. Under a screening program approved by the Agency.

g. Any person proposing to conduct a bone densitometry screening program shall submit the information outlined in Appendix ~~B~~ A of this Part with the exception of g, h, i, j, k, and m, and include the name and address of the individual who will interpret the screening results.

Sec. F.16 - Quality Assurance Program.

a. All registrants [licensees] of diagnostic x-ray imaging equipment shall establish and maintain a quality assurance program consisting of quality control assessments addressing at least the following items:

i. Administration:

(1) Written standard operating procedures on radiation protection and the practice of radiologic technology reviewed and updated annually by management;

(2) Employee review and written acknowledgement of standard operating procedures and policies on radiation protection and the practice of radiologic technology;

(3) Credentialling of practitioners, medical physicists, and x-ray equipment operators; and

(4) Record retention in accordance with state statutes, regulations, but in no case less than three years.

ii. Film Processing equipment

(1) Compliance with Section F.3;

(2) Film processor performance to include medium density, density difference, and base + fog;

(3) Darkroom fog;

iii. Radiographic equipment

(1) Compliance with performance standards in Sections F.4 and F.6;

(2) Entrance skin exposure rates of selected patient examinations;

(3) Image printing and viewing equipment;

(4) Measurement of low and high contrast resolution; and

(5) Radiation protection.

iv. Fluoroscopic equipment

(1) Compliance with performance standards in Sections F.4 and F.5;

(2) Entrance skin exposure rates of selected patient examinations;

(3) Image printing and viewing equipment;

(4) Measurement of low and high contrast resolution; and

(5) Radiation protection.

v. Computerized tomography equipment

(1) Compliance with performance standards in Section F.11;

(2) CT number;

(3) Low contrast and high contrast resolution;

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

(5) Image printing and viewing equipment; and

(6) Radiation protection.

vi. Bone densitometry equipment

Compliance with requirements in Section F.15.

vii. Structural shielding for new facilities with x-ray equipment.

(1) Pre-construction shielding design and evaluation; and

(2) Post-construction radiation protection survey.

viii. Structural shielding for modifying use or equipment in existing facility

(1) Re-evaluation of shielding design; and

(2) Post-modification radiation protection survey.

b. The registrant [licensee] shall assign qualified personnel to fully implement the quality assurance program.

c. Quality control assessments for Section F.16a.i., ii., iii., and vi. may be assigned to qualified personnel who possess the requisite training and/or experience.

d. Quality control assessments for Section F.16a.iv., v., vii., and viii shall be conducted by, or under the direction of, a qualified medical physicist.

e. The registrant [licensee] and/or qualified medical physicist shall determine the frequency of quality control tests.

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

g. Equipment used for compliance with the provisions of this section shall be properly calibrated and maintained in accordance with accepted professional standards.

This Section does not pertain to quality assurance for mammography equipment.

~~PART F~~

~~APPENDIX A~~

~~DETERMINATION OF COMPETENCE~~

~~The following are areas in which the agency considers it important that an individual have expertise for the competent operation of x-ray equipment:~~

~~(a) Familiarization with equipment~~
- ~~(1) Identification of controls~~
- ~~(2) Function of each control~~
- ~~(3) How to use a technique chart~~

~~(b) Radiation Protection~~
- ~~(1) Collimation~~
- ~~(2) Filtration~~
- ~~(3) Gonad shielding and other patient protection devices if used~~
- ~~(4) Restriction of x-ray tube radiation to the image receptor~~
- ~~(5) Personnel protection~~
- ~~(6) Grids~~

~~(c) Film Processing~~
- ~~(1) Film speed as related to patient exposure~~
- ~~(2) Film processing parameters~~
- ~~(3) Quality assurance program~~

~~(d) Emergency Procedures~~
- ~~(1) Termination of exposure in event of automatic timing device failure~~

~~(e) Proper Use of Personnel Dosimetry, if Required~~

~~(f) Understanding Units of Radiation~~

PART F

APPENDIX ~~B~~ A

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

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

a. Name and address of the applicant and, where applicable, the names and addresses of agents within this State;

b. Diseases or conditions for which the x-ray examinations are to be used in diagnoses;

c. A ~~detailed~~ description of the x-ray examinations proposed in the screening program i.e., type and number of views;

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

e. [An evaluation of any known alternate methods not involving ionizing radiation that ~~which~~ could achieve the goals of the screening program and why these methods are not used instead of the x-ray examinations;]

f. An evaluation by a qualified medical physicist ~~expert~~ of the x-ray system(s) to be used in the screening program. The evaluation ~~by the qualified expert~~ shall ~~show~~ include the following:

1. Documentation that such system(s) ~~do~~ satisfy all requirements of these regulations; ~~and~~. ~~The evaluation shall include a~~

2. Measurement of patient exposures from the x-ray examinations to be performed;

g. [A description of the diagnostic x-ray quality control program;]

h. A copy of the technique chart for the x-ray examination procedures to be used;

i. The qualifications of each individual who will be operating the x-ray system(s);

j. The qualifications of the individual who will be supervising the operators of the x-ray system(s). The extent of supervision and the method of work performance evaluation shall be specified;

k. The name and address of the practitioner licensed in the state ~~individual~~ who will

interpret the radiograph(s);

l. ~~A description of the procedures~~ Procedures to be used in advising the individuals screened and their ~~private~~ practitioners of the healing arts or health care provider of the results of the screening procedure and any further medical needs indicated;

m. ~~A description of the procedures~~ Procedures for the retention or disposition of the radiographs and other records pertaining to the x-ray examinations;

n. ~~An indication of the frequency~~ Frequency of screening of individuals; and ~~the duration of the entire screening program.~~

o. The duration of the screening program.

PART F

APPENDIX B

HAND-HELD INTRAORAL DENTAL RADIOGRAPHIC UNIT

REQUIREMENTS FOR USE

The Agency may specify any of, but not be limited to, the following requirements for intraoral dental radiographic units designed to be operated as a hand-held unit:

1. For all uses:

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

   b) When operating a hand-held intraoral dental radiographic unit, operators shall wear a lead apron and thyroid collar, unless otherwise authorized by the Agency or a qualified health or medical physicist.

   c) A hand-held intraoral dental radiographic unit shall be held without any motion during a patient examination. A tube stand may be utilized to immobilize a hand-held intraoral dental radiographic unit during patient examination.

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

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

2. Additional requirements for operatories in permanent facilities:

   a) Hand-held intraoral dental radiographic units shall be used for patient examinations in dental operatories that meet the structural shielding requirements specified by the Agency or by a qualified health or medical physicist.

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

~~PART F~~

~~APPENDIX C~~

~~EXEMPTIONS FROM SHIELDING~~
~~FOR CERTAIN FLUOROSCOPIC PROCEDURES~~

~~a. Angiograms~~

~~b. Arthrograms~~

~~c. Biliary drainage procedures~~

~~d. Fluoroscopic biopsy procedures~~

~~e. Myelograms~~

~~f. Percutaneous cholangiograms~~

~~g. Percutaneous nephrostomies~~

~~h. Sinograms or fistulograms~~

~~i. T-tube cholangiograms~~

~~APPENDIX D~~

~~FOCAL SPOT TOLERANCE LIMIT~~

~~Nominal Focal Sport Size (mm)~~	~~Maximum Measured Dimensions~~	
	~~Width (mm)~~	~~Length (mm)~~
~~0.10~~	~~0.15~~	~~0.15~~
~~0.15~~	~~0.23~~	~~0.23~~
~~0.20~~	~~0.30~~	~~0.30~~
~~0.30~~	~~0.45~~	~~0.65~~
~~0.40~~	~~0.60~~	~~0.85~~
~~0.60~~	~~0.90~~	~~1.30~~

~~APPENDIX E~~

~~X-RAY TUBE VOLTAGE (KILOVOLT PEAK) AND MINIMUM HVL~~

~~Designed Operating Range (kV)~~	~~Measured Operating Voltage(kV)~~	~~Minimum VL (mm Al)~~
~~Below 50~~	~~20~~	~~0.20~~
	~~25~~	~~0.25~~
	~~30~~	~~0.30~~

2009
RATIONALE FOR REVISIONS

PART F
DIAGNOSTIC X-RAYS AND IMAGING SYSTEMS IN THE HEALING ARTS

Introduction

This amendment to Part F includes the addition of revised performance standards specified in Title 21, Code of Federal Regulations (CFR), Part 1020, effective June 10, 2006, quality assurance program requirements, and hand-held dental units. In addition, Sections F.13, Mammography Definitions for States with Certifying Authority, and F.14, Mammography Requirements for States with Certifying Authority, have been deleted.

Specific Provisions:

Part F – Diagnostic X-Rays and Imaging Systems in the Healing Arts

Throughout Part F, "license," "licensee," and "licensed," have been added alongside "registration," "registrant," and "registered," respectively, as an optional term. State radiation control programs differ in the regulation of diagnostic and imaging systems by utilizing registration or licensure of machines and/or facilities.

In addition, "qualified expert" has been replaced by "qualified medical physicist."

Section F.1 – Purpose and Scope.

Part Z is added to recognize medical credentialing of operators utilizing diagnostic x-ray and imaging systems.

Section F.2 – Definitions.

The following definitions were added, revised, or replaced in accordance with the changes specified in 21 CFR Part 1020, effective June 10, 2006:

"Accessory component" - Added
"Air kerma" -Added
"Air kerma rate" -Added
"Articulated joint" -Added
"Automatic exposure rate control" -Added
"C-arm x-ray system" –Replaced with "C-arm fluoroscope"
"Cantilevered tabletop" -Added
"Cassette holder" –Added w/option for computed radiography (CR)
"Coefficient of variation (C)" -Amended
"Computed tomography (CT)" -Amended

"Cradle"-Added
"CT gantry" -Added
"Cumulative air kerma" -Added
"Dose" -Added
"Exposure (X)" -Added
"Fluoroscopic air kerma display device" -Added
"Fluoroscopic imaging assembly" -Amended
"Fluoroscopic irradiation time" -Added
"Fluoroscopy" -Added
"Half-value layer (HVL)" -Amended
"Image receptor" -Amended
"Image receptor support device" -Added
"Isocenter" -Added
"Kerma" -Added
"Last image hold (LIH) radiograph" -Added
"Lateral fluoroscope" -Added
"Leakage technique factors" -Amended
"Line-voltage regulation" -Amended
"Mode of operation" -Amended
"Movable tabletop" -Amended
"Non-image-intensified fluoroscopy" -Amended
"Primary protective barrier" –Added with clarification
"Protective barrier" -Deleted
"Pulsed mode" -Added
"Quick change x-ray tube" -Added
"Radiography" -Added
"Rated line voltage" -Added
"Rated output current" -Added
"Rating" -Amended
"Recording" -Amended
"Scan" -Added
"Scan time" -Added
"Secondary protective barrier" -Deleted
"Solid state x-ray imaging device" -Added
"Source-skin distance (SSD)" -Added
"Spot film device" -Amended
"SSD" -Deleted
"Stationary tabletop" -Added
"Technique factors" -Amended
"Useful beam" -Amended
"X-ray control" -Added
"X-ray field" -Added
"X-ray subsystem" -Added
"X-ray table" -Amended
"X-ray tube" -Amended

The following definitions were added or changed for clarification:

"Diagnostic x-ray system" –Option added for veterinary use
"Hand-held x-ray equipment" –Added
"Qualified expert" replaced with "Qualified medical physicist"

Editorial change was made in the following definition:

"Leakage radiation"

The following definitions were deleted because they are not used in Part F:

"Added filtration"
"Cephalometric device"
"Certified components"
"Certified system"
"Changeable filters"
"Dead-man switch"
"Diagnostic imaging system"
"Entrance exposure rate"
"Inherent filtration"
"Maximum line current"
"Radiographic imaging system"
"Termination of irradiation"

Section F.3 – General and Administrative Requirements.

Changes are as follows:

F.3a.ii.: Changed to reflect the upcoming Part Z – Medical Credentialing.
F.3a.iii.(3): Changed to recognize CR systems.
F.3a.viii.: Changed to recognize CR systems.
F.3a.viii.(6): Editorial correction.
F.3a.ix(1): Changed to recognize CR systems.
F.3a.xi.: Editorial correction.

Section F.4 – General Requirements for All Diagnostic X-Ray Systems.

The entire Section F.4 was amended in accordance with the changes specified in 21 CFR Part 1020, effective June 10, 2006.

F.4a.: Updated.
F.4b.: Deleted.
F.4c.: Redesignated F.4b. and updated.
F.4d.: Redesignated F.4c. and updated.
F.4e.: Redesignated F.4d. and updated.

New F.4e.: Added.
New F.4f.: Added.
New F.4g.: Added.
F.4f.: Redesignated F.4h.
F.4g.: Redesignated F.4i.
F.4h.: Redesignated F.4j.
F.4i.: Redesignated F.4k.
F.4j.: Redesignated F.4l.

Section F.5 – Fluoroscopic X-Ray Systems.

Section F.5, including title, was amended in accordance with the changes specified in 21 CFR Part 1020, effective June 10, 2006.

New F.5a.: Added.
F.5a.: Redesignated F.5b.
F.5a.i thru iii: Deleted.
F.5a.iv.: Amended.
F.5b.: Redesignated F.5c. and amended.
New F.5d.: Added.
New F.5e.: Added.
New F.5f.: Added.
New F.5g.: Added.
New F.5h.: Added.
New F.5i.: Added.
New F.5j.: Added.
New F.5k.: Added.
F.5c.: Deleted.
F.5d.: Deleted.
F.5e.: Deleted.
F.5f.: Deleted.
F.5g.: Deleted.
F.5h.: Redesignated F.5l and amended.
F.5i.: Deleted.
F.5j.: Deleted.
F.5k.: Redesignated F.5m.
F.5l.: Redesignated F.5n.

The following were amended to reflect recommendations from the Task Force on Fluoroscopic Use:

F.5m.
F.5n.

Section F.6 – Radiographic Systems Other than Fluoroscopic, Dental Intraoral, Bone Densitometry or Computed Tomography X-Ray Systems.

Section F.6, including title, was amended in accordance with the changes specified in 21 CFR Part 1020, effective June 10, 2006.

New F.6a.: Added.
New F.6b.: Added.
New F.6c.: Added.
New F.6d.: Added.
New F.6e.: Added.
New F.6f.: Added.
New F.6g.: Added.
New F.6h.: Added.
New F.6i.: Added.
New F.6j.: Added.
New F.6k.: Added.
New F.6l.: Added.
New F.6m.: Added.
F.6a.: Redesignated F.6o. and amended.
F.6a.i. thru iv.: Deleted.
F.6b.: redesignated F.6p.
F.6b.iii. thru v.: Deleted.
F.6b.vi.: Redesignated F.6.p.iii.
F.6b.vii.: Redesignated F.6.p.iv.; added reference to hand-held radiographic devices.
F.6c.: Deleted.
F.6d.: Deleted.
F.6e.: Deleted.
F.6f.: Deleted.
F.6g.: Deleted.
F.6h.: Deleted.
F.6i.: Redesignated F.6q.

Section F.7 – Intraoral Dental Radiographic Systems.

Title was changed to reflect categorical change from "x-ray systems" in Sections F.5 and F.6 to "equipment."

Performance standards for intraoral equipment are now specified in Section F.6. This will facilitate future revisions of 21 CFR Part 1020. Therefore, Section F.7 only includes requirements not specifically identified as performance standards.

F.7a.: Deleted.
F.7b.: Deleted.
F.7c.i.(2): Deleted.
F.7c.ii. thru iv.: Deleted.
F.7c.v.: Redesignated F.7b.

F.7d.: Deleted.
F.7e.: Deleted.
F.7f.: Deleted.
F.7g.: Redesignated F.7c.
F.7h.: Redesignated F.7d.
F.7h.ii.: Redesignated as F.7d.ii.; specifies Appendix B for hand-held dental radiographic units.
F.7h.iii: Deleted since beam limitation requirements are in Section F.6.
F.7h.iv.: Redesignated F.7d.iii.

Section F.11 – Computed Tomography X-Ray Systems.

Section F.11, including title, was modified in accordance with the changes specified in 21 CFR Part 1020, effective June 10, 2006.

F.11d.ii.(2): Amended to clarify the necessity for appropriate and timely calibration.

Section F.13 – Mammography Definitions for States with Certifying Authority.

This section was deleted in conjunction with the deletion of text in Section F.14.

Section F.14 – Mammography Requirements for States with Certifying Authority.

The text in this section was deleted and replaced by a statement incorporating 21 CFR Part 900 in F.14. Incorporation can include the "current" version or a "dated" version. The inclusion of the full text in Part F in 2001 resulted in the adoption of a version which was outdated when adopted. This was due to periodic changes to 21 CFR Part 900 which could not be included during the adoption process. States desiring to have certifying authority should develop rules or regulations directly from 21 CFR Part 900.

Section F.15 – Bone Densitometry.

Changes are as follows:

F.15c.iii.: Amended to recognize certification.
F.15e.: Editorial correction.
F.15g.: Editorial correction.

Section F.16 – Quality Assurance Program.

This section was added to address the necessity for quality assurance programs in facilities with diagnostic x-ray and imaging systems. General requirements are specified in accordance with type of x-ray equipment, mode of imaging processing, and radiation protection practices. The text was developed generically to assure current and future application for all types of facilities, programs, and use. This precludes the use of overly prescriptive requirements which may be outdated upon adoption.

Appendix A – Determination of Competence

This appendix was deleted in deference to the anticipated Part Z – Medical Credentialing.

Appendix B – Information to be Submitted by Persons Proposing to Conduct Healing Arts Screening

This appendix was redesignated Appendix A. In addition, changes were made to clarify paragraphs c., d., f., k., l., m., and n. Paragraphs e. and g. were designated optional. Paragraph o. was added to specify program duration.

Appendix B (New)– Hand-Held Intraoral Dental Radiographic Unit Requirements for Use

This appendix was added to provide guidance to states on the use of hand-held dental radiographic units.

Appendix C – Exemptions from Shielding for Certain Fluoroscopic Procedures

This appendix is now inappropriate, and therefore, deleted in its entirety.

Appendix D – Focal Spot Tolerance Limit

This appendix is now inappropriate, and therefore, deleted in its entirety.

Appendix E – X-Ray Tube Voltage (Kilovolt Peak) and Minimum HVL

This appendix is now inappropriate, and therefore, deleted in its entirety.