Draft Amendments to the Federal Performance Standard for Diagnostic X-ray Systems and their Major Components

(Fluoroscopic x-ray systems and other requirements)

For discussion at the

Technical Electronic Product Radiation Safety Standards Committee

Meeting on September 23, 1998

Center for Devices and Radiological Health
Food and Drug Administration

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Sections 1020.30 through 1020.32 are provided with the changes (deletions and additions) indicated as follows:

Additions - Shown with underline of new text.

Deletions - Shown with strike through of deleted text.

Concepts for Proposed Amendments to the Performance Standard for Diagnostic X-Ray Systems

§1020.30 Diagnostic x-ray systems and their major components.

(a) *Applicability*--(1) The provisions of this section are applicable to:

(i) The following components of diagnostic x-ray systems:

(A) Tube housing assemblies, x-ray controls, x-ray high-voltage generators, x-ray tables, cradles, film changers, vertical cassette holders mounted in a fixed location and cassette holders with front panels, and beam-limiting devices manufactured after August 1, 1974.

(B) Fluoroscopic imaging assemblies manufactured after August 1, 1974, and before April 26, 1977.

(C) Spot-film devices manufactured after April 26, 1977 and image intensifiers manufactured after April 26, 1977, and before (insert date 1 year after publication of final rule in the Federal register).

(D) Cephalometric devices manufactured after February 25, 1978.

(E) Image receptor support devices for mammographic x-ray systems manufactured after September 5, 1978.

(F) Image receptors which are electrically powered or connected with the x-ray system manufactured on or after (insert date 1 year after publication of final rule in the Federal register).

(ii) Diagnostic x-ray systems, except computed tomography x-ray systems, incorporating one or more of such components; however, such x-ray systems shall be required to comply only with those provisions of this section and §§1020.31 and 1020.32 which relate to the components certified in accordance with paragraph (c) of this section and installed into the systems.

(iii) Computed tomography (CT) x-ray systems manufactured before November 29, 1984.

(iv) CT gantries manufactured after September 3, 1985.

(2) The following provisions of this section and §1020.33 are applicable to CT x-ray systems manufactured or remanufactured on or after November 29, 1984:

(i) Section 1020.30(a);

(ii) Section 1020.30(b) “Technique factors”;

(iii) Section 1020.30(b) “CT,” “Dose,” “Scan,” “Scan time,’’ and “Tomogram”;

(iv) Section 1020.30 (h)(3)(vi) through (h)(3)(viii);

(v) Section 1020.30(n);

(vi) Section 1020.33 (a) and (b);

(vii) Section 1020.33(c)(1) as it affects Sec. 1020.33(c)(2); and

(viii) Section 1020.33(c)(2).

(3) The provisions of this section and §1020.33 in its entirety including those provisions in paragraph (a)(2) of this section, are applicable to CT x-ray systems manufactured or remanufactured on or after September 3, 1985. The date of manufacture of the CT system is the date of manufacture of the CT gantry.

(b) *Definitions.* As used in this section and §§1020.31, 1020.32, and 1020.33, the following definitions apply:

Accessible surface means the external surface of the enclosure or housing 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 subchapter 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 subchapter 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.

Aluminum equivalent means the thickness of aluminum (type 1100 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 for one of the sections to pivot on the line segment along which the sections join.

Assembler means any person engaged in the business of assembling, replacing, or installing one or more components into a diagnostic 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 of type 1100 aluminum alloy or aluminum alloy having equivalent attenuation with dimensions 20 centimeters by 20 centimeters by 3.8 centimeters.

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[1] The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0.12 percent copper, as given in “Aluminum Standards and Data” (1969). Copies may be obtained from: The Aluminum Association, New York, NY.

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

Automatic exposure rate control 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.

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.

Cantilevered tabletop means a tabletop designed such that the unsupported portion can be extended at least 100 centimeters 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 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.

Coefficient of variation means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

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

where

s = Estimated standard deviation of the population.

X = Mean value of observations in sample.

X_i = ith observation sampled.

n = Number of observations 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 gantry means tube housing assemblies, beam-limiting devices, detectors, and the supporting structures, frames, and covers which hold and/or enclose these components.

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 body for the purpose of diagnosis or visualization.

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 by ionizing radiation to matter of mass dm.

Equipment means x-ray equipment.

Exposure 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 (negatrons and positrons) liberated by photons in a volume element of air having mass dm are completely stopped in air.

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

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

Fluoroscopy means a technique for generating x-ray images and presenting them instantaneously and continuously as visible images for the purpose of providing the user with a visual display of dynamic processes.

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

Half-value layer (HVL) means the thickness of specified material which attenuates the beam of radiation to an extent such that the ~~exposure~~ air kerma rate is reduced to 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.

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

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

Image receptor means any device, such as a fluorescent screen, radiographic film, 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 means, for mammographic systems, that part of the system designed to support the image receptor in a horizontal plane during a mammographic examination.

Isocenter means the center of a sphere described by the beam axis of a C-arm gantry moving through a full range of rotations.

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

(1) The useful beam; and

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

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

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

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

(3) For all other diagnostic source assemblies, the maximum-rated continuous tube current for 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 illuminance is one-fourth of the maximum in the intersection.

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

$$= \frac{100(V_n - V_i)}{V_i}$$

where:

V_n = No-load line potential and

V_i = Load line potential.

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

Mode of operation for fluoroscopic systems means a distinct method of fluoroscopy or radiography selected with a set of technique factors or other control settings uniquely associated with the mode. Examples of distinct modes of operation include normal fluoroscopy (analog or digital), high-level control fluoroscopy, cineradiography, digital cine radiography, digital subtraction angiography, electronic radiography using the fluoroscopic image receptor, and

photospot recording. In a specific mode of operation, certain system variables affecting air kerma, air kerma rate, or image quality, such as image magnification, x-ray field size, pulse rate, pulse duration, number of pulses per exposure series, SID, or optical aperture, may be adjustable or may vary; their variation per se does not comprise a mode of operation different than the one that had 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.

Nonimage-intensified fluoroscopy means fluoroscopy using only a fluorescent screen.

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

Primary protective barrier means the material, excluding filters, placed in the useful beam to reduce the radiation exposure for protection purposes.

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.

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 paragraphs (k) and (m) of this section;

(2) The focal spot position will not cause noncompliance with the provisions of this section or §1020.31 or §1020.32;

(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 §§1020.31 and 1020.32.

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.

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.

Rated output voltage means the allowable peak potential, in volts, at the output terminals of the x-ray high-voltage generator.

Rating means the operating limits specified by the manufacturer.

Recording means producing a ~~permanent~~ retrievable form of an image resulting from x-ray photons ~~(e.g., film, videotape)~~.

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.

Solid state x-ray imaging device means an array of small transducer elements, typically in a flat rectangular panel configuration, that intercepts x-ray photons, and through a single or multistage process converts the x-ray photon energy into a modulated electrical signal representative of the x-ray image. The output electrical signals may undergo analog-to-digital conversion before leaving the device to provide either a fluoroscopic or radiographic image.

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

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

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

Spot-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 image intensifier for the purpose of a radiograph.

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.

Technique factors means the following conditions of operation:

(1) For capacitor energy storage equipment, peak tube potential in kilovolts (kV) and quantity of charge in milliamperes-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 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 the tube current, x-ray pulse width, and the number of x-ray pulses in mAs;

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

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

Tomogram means the depiction of the x-ray attenuation properties of a section through a 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 they 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 which passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated.

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

Visible area means the 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 equipment means an x-ray system, subsystem, or component thereof. Types of x-ray equipment are as follows:

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

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

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

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~~ air kerma rate is one-fourth of the maximum in the intersection.

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

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

X-ray subsystem means any combination of two or more components of an x-ray system for which there are requirements specified in this section and §§1020.31 and 1020.32.

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, image intensifier, or spot-film device beneath the tabletop.

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

(c) *Manufacturers' responsibility*. Manufacturers of products subject to §§1020.30 through 1020.33 shall certify that each of their products meet all applicable requirements when installed into a diagnostic x-ray system according to instructions. This certification shall be made under the format specified in §1010.2 of this chapter. Manufacturers may certify a combination of two or more components if they obtain prior authorization in writing from the Director of the Office of Compliance and Surveillance of the Center for Devices and Radiological Health. Manufacturers shall not be held responsible for noncompliance of their products if that noncompliance is due solely to the improper installation or assembly of that product by another person; however, manufacturers are responsible for providing assembly instructions adequate to assure compliance of their components with the applicable provisions of §§1020.30 through 1020.33.

(d) *Assemblers' responsibility*. An assembler who installs one or more components certified as required by paragraph (c) of this section shall install certified components that are of the type required by §§1020.31, 1020.32, or 1020.33 and shall assemble, install, adjust, and test the certified components according to the instructions of their respective manufacturers. Assemblers shall not be liable for noncompliance of a certified component if the assembly of that component was according to the component manufacturer's instruction.

(1) Reports of assembly. All assemblers who install certified components shall file a report of assembly, except as specified in paragraph (d)(2) of this section. The report will be construed

as the assembler's certification and identification under §§1010.2 and 1010.3 of this chapter. The assembler shall affirm in the report that the manufacturer's instructions were followed in the assembly or that the certified components as assembled into the system meet all applicable requirements of §§1020.30 through 1020.33. All assembler reports must be on a form prescribed by and available from the Director, Center for Devices and Radiological Health, 5600 Fishers Lane, Rockville, MD 20857. Completed reports must be submitted to the Director, the purchaser, and, where applicable, to the State agency responsible for radiation protection within 15 days following completion of the assembly.

(2) Exceptions to reporting requirements. Reports of assembly need not be submitted for any of the following:

(i) Reloaded or replacement tube housing assemblies that are reinstalled in or newly assembled into an existing x-ray system;

(ii) Certified accessory components that have been identified as such to the Center for Devices and Radiological Health in the report required under §1002.10 of this chapter;

(iii) Repaired components, whether or not removed from the system and reinstalled during the course of repair, provided the original installation into the system was reported; or

(iv) Components installed temporarily in an x-ray system in place of components removed temporarily for repair, provided the temporarily installed component is identified by a tag or label bearing the following information:

Temporarily Installed Component

This certified component has been assembled, installed, adjusted, and tested by me according to the instructions provided by the manufacturer.

Signature

Company Name

Street Address, P.O. Box

City, State, Zip Code

Date of Installation

The replacement of the temporarily installed component by a component other than the component originally removed for repair shall be reported as specified in paragraph (d)(1) of this section.

(e) *Identification of x-ray components*. In addition to the identification requirements specified in §1010.3 of this chapter, manufacturers of components subject to this section and §§1020.31, 1020.32, and 1020.33, except high-voltage generators contained within tube housings and beam-limiting devices that are integral parts of tube housings, shall permanently inscribe or affix thereon the model number and serial number of the product so that they are legible and accessible to view. The word “model” or “type” shall appear as part of the manufacturer's required identification of certified x-ray components. Where the certification of a system or subsystem, consisting of two or more components, has been authorized pursuant to paragraph (c) of this section, a single inscription, tag, or label bearing the model number and serial number may be used to identify the product.

(1) *Tube housing assemblies*. In a similar manner, manufacturers of tube housing assemblies shall also inscribe or affix thereon the name of the manufacturer, model number, and serial number of the x-ray tube which the tube housing assembly incorporates.

(2) *Replacement of tubes*. Except as specified in paragraph (e)(3) of this section, the replacement of an x-ray tube in a previously manufactured tube housing assembly certified pursuant to paragraph (c) of this section constitutes manufacture of a new tube housing assembly, and the manufacturer is subject to the provisions of paragraph (e)(1) of this section. The manufacturer shall remove, cover, or deface any previously affixed inscriptions, tags, or labels, that are no longer applicable.

(3) *Quick-change x-ray tubes*. The requirements of paragraph (e)(2) of this section shall not apply to tube housing assemblies designed and designated by their original manufacturer to contain quick change x-ray tubes. The manufacturer of quick-change x-ray tubes shall include with each replacement tube a label with the tube manufacturer's name, the model, and serial number of the x-ray tube. The manufacturer of the tube shall instruct the assembler who installs the new tube to attach the label to the tube housing assembly and to remove, cover, or deface the previously affixed inscriptions, tags, or labels that are described by the tube manufacturer as no longer applicable.

(f) [Reserved]

(g) *Information to be provided to assemblers*. Manufacturers of components listed in paragraph (a)(1) of this section shall provide to assemblers subject to paragraph (d) of this section and, upon request, to others at a cost not to exceed the cost of publication and distribution, instructions for assembly, installation, adjustment, and testing of such components adequate to assure that the products will comply with applicable provisions of this section and §§1020.31,

1020.32, and 1020.33, when assembled, installed, adjusted, and tested as directed. Such instructions shall include specifications of other components compatible with that to be installed when compliance of the system or subsystem depends on their compatibility. Such specifications may describe pertinent physical characteristics of the components and/or may list by manufacturer model number the components which are compatible. For x-ray controls and generators manufactured after May 3, 1994, manufacturers shall provide:

(1) A statement of the rated line voltage and the range of line-voltage regulation for operation at maximum line current;

(2) A statement of the maximum line current of the x-ray system based on the maximum input voltage and current characteristics of the tube housing assembly compatible with rated output voltage and rated output current characteristics of the x-ray control and associated high-voltage generator. If the rated input voltage and current characteristics of the tube housing assembly are not known by the manufacturer of the x-ray control and associated high-voltage generator, ~~he~~ the manufacturer shall provide information necessary to allow the assembler to determine the maximum line current for the particular tube housing assembly(ies);

(3) A statement of the technique factors that constitute the maximum line current condition described in paragraph (g)(2) of this section.

(h) *Information to be provided to users*. Manufacturers of x-ray equipment shall provide to purchasers and, upon request, to others at a cost not to exceed the cost of publication and distribution, manuals or instruction sheets which shall include the following technical and safety information:

(1) All x-ray equipment. For x-ray equipment to which this section and §§1020.31, 1020.32, and 1020.33 are applicable, there shall be provided:

(i) Adequate instructions concerning any radiological safety procedures and precautions which may be necessary because of unique features of the equipment; and

(ii) A schedule of the maintenance necessary to keep the equipment in compliance with this section and §§1020.31, 1020.32, and 1020.33.

(2) Tube housing assemblies. For each tube housing assembly, there shall be provided:

(i) Statements of the leakage technique factors for all combinations of tube housing assemblies and beam-limiting devices for which the tube housing assembly manufacturer states compatibility, the minimum filtration permanently in the useful beam expressed as millimeters of aluminum equivalent, and the peak tube potential at which the aluminum equivalent was obtained;

(ii) Cooling curves for the anode and tube housing; and

(iii) Tube rating charts. If the tube is designed to operate from different types of x-ray high-voltage generators (such as single-phase self rectified, single-phase half-wave rectified, single-phase full-wave rectified, 3-phase 6-pulse, 3-phase 12-pulse, constant potential, capacitor energy storage) or under modes of operation such as alternate focal spot sizes or speeds of anode rotation which affect its rating, specific identification of the difference in ratings shall be noted.

(3) *X-ray controls and generators*. For the x-ray control and associated x-ray high-voltage generator, there shall be provided:

(i) A statement of the rated line voltage and the range of line-voltage regulation for operation at maximum line current;

(ii) A statement of the maximum line current of the x-ray system based on the maximum input voltage and output current characteristics of the tube housing assembly compatible with rated output voltage and rated current characteristics of the x-ray control and associated high-voltage generator. If the rated input voltage and current characteristics of the tube housing

assembly are not known by the manufacturer of the x-ray control and associated high-voltage generator, the manufacturer shall provide necessary information to allow the purchaser to determine the maximum line current for his particular tube housing assembly(ies);

(iii) A statement of the technique factors that constitute the maximum line current condition described in paragraph (h)(3)(ii) of this section;

(iv) In the case of battery-powered generators, a specification of the minimum state of charge necessary for proper operation;

(v) Generator rating and duty cycle;

(vi) A statement of the maximum deviation from the preindication given by labeled technique factor control settings or indicators during any radiographic or CT exposure where the equipment is connected to a power supply as described in accordance with this paragraph. In the case of fixed technique factors, the maximum deviation from the nominal fixed value of each factor shall be stated;

(vii) A statement of the maximum deviation from the continuous indication of x-ray tube potential and current during any fluoroscopic exposure when the equipment is connected to a power supply as described in accordance with this paragraph; and

(viii) A statement describing the measurement criteria for all technique factors used in paragraphs (h)(3)(iii), (h)(3)(vi), and (h)(3)(vii) of this section; for example, the beginning and endpoints of exposure time measured with respect to a certain percentage of the voltage waveform.

(4) *Beam-limiting device*. For each variable-aperture beam-limiting device, there shall be provided;

(i) Leakage technique factors for all combinations of tube housing assemblies and beam-limiting devices for which the beam-limiting device manufacturer states compatibility; and

(ii) A statement including the minimum aluminum equivalent of that part of the device through which the useful beam passes and including the x-ray tube potential at which the aluminum equivalent was obtained. When two or more filters are provided as part of the device, the statement shall include the aluminum equivalent of each filter.

(5) *Imaging system information*-- For x-ray systems manufactured on or after (insert date 1 year after publication of final rule in the Federal register) that produce images using the fluoroscopic image receptor, the following information shall be provided in a separate single section of the user's instruction manual or in a separate manual devoted to this information:

(i) For each mode of operation, a description of the mode and detailed instructions on how the mode is engaged and disengaged. This information shall include how the operator can recognize which mode of operation has been selected prior to initiation of x-ray production.

(ii) For each mode of operation, a description of any specific clinical procedure(s) and clinical imaging task(s) for which the mode is recommended or designed to address and how each mode should be used.

(iii) For each mode of operation, the air kerma rate or air kerma per frame, as appropriate, for a specific phantom or specific amount of attenuating material providing x-ray attenuation representative of the attenuation of a typical patient. The system settings or technique factors shall correspond to the settings normally used to image a typical patient. The specifications of the phantom or attenuating material shall also be provided, including the patient size it is intended to simulate.

(iv) For each mode of operation a description, if applicable, of how the operator can change any system technique factor or parameter within the mode and how these changes affect the air kerma rate or the air kerma per frame, including the range over which air kerma rate or air kerma per frame may vary. The requirements of this section can be met with a table, graph, or written explanation.

(v) During measurement of air kerma rate and air kerma per frame, the measurement geometry of §1020.32(d)(7) shall be used with the specified phantom in the beam. Measurements shall be made under conditions approximating free-in-air irradiation, i.e., in ways to preclude significant back-scatter contributions from the phantom. The provided air kerma rate and air kerma per frame values shall include a statement of the maximum deviation of actual values from the values specified.

(6) *Displays of values of air kerma rate and cumulative air kerma*. For x-ray systems manufactured on or after (insert date one year from date of publication of the final rule in the Federal Register) which display values of the air kerma rate and cumulative air kerma according to §1020.32(k), there shall be provided

(i) A statement of the maximum deviations of the air kerma rate and cumulative air kerma from their respective displayed values;

(ii) Instructions for calibrating and maintaining any instrumentation associated with measurement or evaluation of the air kerma rate and cumulative air kerma;

(iii) Identification of the spatial coordinates of the irradiation location(s) to which displayed values of air kerma rate and cumulative air kerma refer according to §1020.32(k)(5);

(iv) A rationale for specification of a reference irradiation location alternative to 15 cm from the isocenter toward the x-ray source along the beam axis when such alternative specification is made according to §1020.32(k)(5)(ii).

(i) [Reserved]

(j) *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 are observed."

(k) *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 ~~2.58 x 10⁵ coulombs per kilogram (C/kg) (100~~ 0.88 mGy air kerma (vice 100 milliroentgen (mR) exposure) ~~milliroentgens (mR))~~ in 1 hour when the x-ray tube is operated at the leakage technique factors. If the maximum rated peak tube potential of the tube housing assembly is greater than the maximum rated peak tube potential for the diagnostic source assembly, positive means shall be provided to limit the maximum x-ray tube potential to that of the diagnostic source assembly. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(l) *Radiation from components other than the diagnostic source assembly*. The radiation emitted by a component other than the diagnostic source assembly shall not exceed ~~5.16 x~~

~~10^{-7} C/kg (2 mR)~~ an air kerma of 18 μGy (vice 2 mR 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.

(m) *Beam quality*--(1) Half-value layer. The half-value layer (HVL) of the useful beam for a given x-ray tube potential shall not be less than the appropriate value shown in Table I under "Specified dental systems," for any dental x-ray system designed for use with intraoral image receptors and manufactured after December 1, 1980; ~~and~~ under "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 or on (insert date 1 year after publication of final rule in the Federal Register); and under "II - Other x-ray systems," for all x-ray systems except dental x-ray systems subject to this section and manufactured after (insert date 1 year after publication of final rule in the Federal Register). If it is necessary to determine such HVL at an x-ray tube potential which is not listed in Table I, linear interpolation or extrapolation may be made. Positive means[2] shall be provided to insure that at least the minimum filtration needed to achieve the above beam quality requirements is in the useful beam during each exposure.

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[2] 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 interlock with the kilovoltage selector which will prevent x-ray emission if the minimum required filtration is not in place.

Table I

X-ray tube voltage (kilovolt peak)			Minimum HVL (millimeters of aluminum)	
Designed operating range		Measured operating potential	Specified dental systems	Other X-ray systems
Below 51.....		30	1.5	0.3
		40	1.5	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

X-ray tube voltage (kilovolt peak)		Minimum HVL (mm of aluminum)		
Designed Operating range	Measured Operating potential	Specified dental systems[1]	I - Other x-ray systems[2]	II – Other x-ray systems except dental[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	2.4
	80	2.3	2.3	2.8
	90	2.5	2.5	3.2
	100	2.7	2.7	3.6
	110	3.0	3.0	4.1
	120	3.2	3.2	4.5
	130	3.5	3.5	5.0
	140	3.8	3.8	5.4
	150	4.1	4.1	5.9

(footnotes to be at bottom of Table)

1 - Dental x-ray system designed for use with intraoral image receptors and manufactured after December 1, 1980.

2 - 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 or on (insert date 1 year after publication of final rule in the Federal Register).

3 - All x-ray systems except dental x-ray systems subject to this section and manufactured after (insert date 1 year after publication of final rule in the Federal Register).

(2) Fluoroscopic systems 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 means to add x-ray filtration to the diagnostic source assembly over and above the amount needed to meet the half-value layer provisions of §1020.30(m)(1).

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

(n) *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 II, which are used between the patient and image receptor, may not exceed the indicated ~~Compliance~~limits. For items manufactured before or on (insert date 1 year after publication of final rule in the Federal Register) compliance shall be determined by x-ray measurements made at a potential of 100 kilovolts peak and with an x-ray beam that has a HVL of 2.7 millimeters of aluminum. For items manufactured after (insert date 1 year after publication of final rule in the Federal Register) compliance shall be determined by x-ray measurements made at a potential of 100 kilovolts peak and with an x-ray beam that has a HVL of 3.6 millimeters of aluminum. 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 II

Item	Aluminum equivalent (millimeters)
Front panel(s) of cassette holder (total of all).....	1.0
Front panel(s) of film changer (total of all).....	1.0
Cradle.....	2.0
Tabletop, stationary, without articulated joint(s).....	1.0
Tabletop, movable, without articulated joint(s) (including stationary subtop).....	1.5
Tabletop, with radiolucent panel having one articulated joint.....	1.5
Tabletop, with radiolucent panel having two or more articulated joints.....	2.0
Tabletop, cantilevered.....	2.0
Tabletop, radiation therapy simulator.....	5.0

(o) *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.

(p) [Reserved]

(q) *Modification of certified diagnostic x-ray components and systems*--(1) Diagnostic x-ray components and systems certified in accordance with §1010.2 of this chapter shall not be modified such that the component or system fails to comply with any applicable provision of this chapter unless a variance in accordance with §1010.4 of this chapter or an exemption under sections 358(a)(5) or 360B(b) of the Public Health Service Act has been granted.

(2) The owner of a diagnostic x-ray system who uses the system in a professional or commercial capacity may modify the system, provided the modification does not result in the failure of the system or component to comply with the applicable requirements of this section or of §1020.31, §1020.32, or §1020.33. The owner who causes such modification need not submit the reports required by subpart B of part 1002 of this chapter, provided the owner records the date and the details of the modification, and provided the modification of the x-ray system does not result in a failure to comply with §§1020.31, 1020.32, or. 1020.33.

§1020.31 Radiographic equipment.

The provisions of this section apply to equipment for the recording of images, except equipment ~~involving use of an image intensifier~~ for fluoroscopic imaging and for radiographic imaging when images are recorded from the fluoroscopic image receptor or computed tomography x-ray systems manufactured on or after November 28, 1984.

(a) *Control and indication of technique factors*--(1) 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.

(2) 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.

(i) 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. 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.

(ii) 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.

(3) Automatic exposure controls. When an automatic exposure control is provided:

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

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

(iii) Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kilowatt-seconds (kW's) 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

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

(4) Accuracy. Deviation of technique factors from indicated values shall not exceed the limits given in the information provided in accordance with §1020.30(h)(3);

(b) *Reproducibility.* The following requirements shall apply when the equipment is operated on an adequate power supply as specified by the manufacturer in accordance with the requirements of §1020.30(h)(3);

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

(2) 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 determined for each measurement. All values for 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 the requirements of §1020.30(h)(3) for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rated.

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

(2) Equipment having selection of x-ray tube current-exposure time product (mAs). For equipment manufactured after May 3, 1994 the average ratios of ~~exposure~~ air kerma to the indicated milliampere-seconds product ~~(C/kg/mAs (or mR/mAs))~~ (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 ~~C/kg/mAs (or mR/mAs)~~ mGy/mAs values obtained at each of two consecutive mAs selector settings or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

(3) Measuring compliance. 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 millimeters and the other is greater than 0.45 millimeters. 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 or special attachments for mammography are in service, mobile, portable, and stationary general purpose radiographic x-ray systems shall meet the following requirements:

(1) 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 centimeters shall be equal to or less than 5 centimeters.

(2) Visual definition. (i) 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.

(ii) 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 centimeters or at the maximum SID, whichever is less. The average illuminance shall be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems are exempt from this requirement.

(iii) 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 and portable equipment. The contrast ratio is defined as I_1 I_2, where I_1 is the illuminance 3 millimeters from the edge of the light field toward the center of the field; and I_2 is the illuminance 3 millimeters from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring aperture of 1 millimeter.

(e) *Field indication and alignment on stationary general purpose x-ray equipment*. Except when spot-film devices or special attachments for mammography are in service, stationary general purpose x-ray systems shall meet the following requirements in addition to those prescribed in paragraph (d) of this section:

(1) 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;

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

(3) Indication of field size dimensions and SID's shall be specified in 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

(4) Compliance measurements will be made at discrete SID's and image receptor dimensions in common clinical use (such as SID's of 100, 150, and 200 centimeters and/or 36, 40, 48, and 72 inches and nominal image receptor dimensions of 13, 18, 24, 30, 35, 40, and 43 centimeters

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*--(1) 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:

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

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

(2) 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.

(3) Systems designed for or provided with special attachments for mammography. Radiographic systems designed only for mammography and general purpose radiographic systems, when special attachments for mammography are in service, 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 which performs as prescribed in paragraphs (f)(4)(i), (f)(4)(ii), and (f)(4)(iii) of this section. 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 paragraphs (f)(4)(ii) and (f)(4)(iii) of this section shall be the maximum SID for which the beam-limiting device or aperture is designed. In addition, each image receptor support intended for installation on a system designed only for mammography shall have clear and permanent markings to indicate the maximum image receptor size for which it is designed.

(4) Other x-ray systems. Radiographic systems not specifically covered in paragraphs (d), (e), (f)(2), (f)(3), and (h) of this section and systems covered in paragraph (f)(1) of this section, 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 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.

These requirements may be met with:

(i) A system which performs in accordance with paragraphs (d) and (e) of this section; or when alignment means are also provided, may be met with either;

(ii) 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

(iii) 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 paragraph shall apply to radiographic systems which contain PBL.

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

(i) 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

(ii) The sum of the length and width differences as stated in paragraph (g)(1)(i) of this section without regard to sign exceeds 4 percent of the SID.

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

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

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

(ii) The image receptor length and width are less than 50 centimeters;

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

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

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

(3) Measuring compliance. Compliance with the requirements of paragraph (g)(1) of this section shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of paragraph (g)(2) of this section are met.

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

(4) Operator initiated undersizing. The PBL system shall be capable of operation 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 centimeters shall be equal to or less than 5 centimeters. Return to PBL function as described in paragraph (g)(1) of this section shall occur automatically upon any change of image receptor size or SID.

(5) 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 SID's 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:

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

(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. 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.

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

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

(i) 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 centimeters; or

(ii) 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 centimeters by 5 centimeters.

(5) 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*--(1) 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:

(i) Eighteen centimeters if operable above 50 kVp; or

(ii) Ten centimeters if not operable above 50 kVp.

(2) 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 centimeters.

(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) *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 before initiation of the exposure.

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

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

(1) ~~8.6×10^{-9} C/kg (0.03 mR)~~ an air kerma of 0.26 µGy (vice 0.03 mR exposure) in 1 minute at 5 centimeters 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 centimeters, with no linear dimension greater than 20 centimeters; and

(2) ~~2.58×10^{-5} C/kg (100 mR)~~ an air kerma of 0.88 mGy (vice 100 mR exposure) in 1 hour at 100 centimeters from the x-ray source, with the 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 ~~exposure~~ 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 centimeters with no linear dimension greater than 20 centimeters.

(m) *Transmission limit for image receptor supporting devices used for mammography*. For x-ray systems manufactured after September 5, 1978, 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 ~~exposure~~ air kerma 5 centimeters from any accessible surface

beyond the plane of the image receptor supporting device does not exceed ~~2.58 x 10^{-8} C/kg (0.1 mR)~~ 0.88 µGy (vice 0.1 mR exposure) for each activation of the tube. ~~Exposure~~ Air kerma shall be measured with the system operated at the minimum SID for which it is designed. Compliance shall be determined at the maximum rated peak tube potential for the system and at the maximum rated product of the tube current and exposure time (mAs) for that peak tube potential. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

§1020.32 Fluoroscopic equipment.

The provisions of this section apply to equipment for ~~fluoroscopy and for the recording of images through an image intensifier~~ fluoroscopic imaging and for radiographic imaging when images are recorded from the fluoroscopic image receptor except computed tomography x-ray systems manufactured on or after November 29, 1984.

(a) *Primary protective barrier*--(1) 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 ~~exposure~~ air kerma rate due to transmission through the barrier with the attenuation block in the useful beam combined with radiation from the image intensifier if provided, shall not exceed 3.34 x 10^{-3} percent of the entrance ~~exposure~~ air kerma rate, at a distance of 10 centimeters 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 and the manufacturer sets forth instructions for assemblers with respect to control location as part of the information required in §1020.30(g). Additionally, the manufacturer shall provide to users, pursuant to §1020.30(h)(1)(i), precautions concerning the importance of remote control operation.

(2) Measuring compliance. The ~~entrance exposure~~ air kerma rate shall be measured in accordance with paragraph (d) of this section. The ~~exposure~~ air kerma rate due to transmission through the primary barrier combined with radiation from the ~~image intensifier~~ fluoroscopic image receptor shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters. 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. 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. 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 centimeters from the point of measurement of entrance ~~exposure~~ air kerma rate and between this point and the input surface of the fluoroscopic imaging assembly.

(b) *Field limitation*--(1) Nonimage-intensified fluoroscopy. (i) The x-ray field produced by nonimage-intensified fluoroscopic equipment shall not extend beyond the entire visible area of the image receptor. Means shall be provided for stepless adjustment of the field size. The minimum field size, at the greatest SID, shall be containable in a square of 5 centimeters by 5 centimeters.

(ii) For 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 paragraph (b)(1)(i) of this section shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(2) Image-intensified fluoroscopy with circular image receptors. (i) For image-intensified fluoroscopic equipment other than radiation therapy simulation systems manufactured before or on (insert date 1 year after publication of final rule in the Federal register), ~~systems, neither~~

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

~~(ii)~~(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.

~~(iii)~~(C) 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. Compliance with paragraph (b)(2)(i) of this section shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

~~(iv)~~(D) 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 the capability of a visible area of greater than 300 square centimeters 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 centimeters 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 centimeters 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 centimeters by 5 centimeters.

(ii) For fluoroscopic equipment other than radiation therapy simulation systems manufactured after (insert date 1 year after publication of final rule in the Federal register), the maximum area of the x-ray field in the plane of the image receptor shall conform with one of the following requirements:

(A) At least 80 percent of the x-ray field overlaps the visible area of the image receptor or;

(B) When the visible area of the image receptor is greater than 34 cm in diameter, the x-ray field measured along a diameter in the direction of greatest misalignment with the visible area of the image receptor shall not extend beyond the visible area of the image receptor by more than 2 cm or;

(C) At least 80 percent of the air kerma integrated over the x-ray field is incident on the visible area of the image receptor.

and, in addition,

(D) 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. Compliance with paragraph (b)(2)(ii) of this section shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(E) Means shall be provided to permit further limitation of the field. Beam-limiting devices incorporated in equipment with a variable SID and/or the capability of a visible area of greater than 300 square centimeters 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 centimeters 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 centimeters 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 centimeters by 5 centimeters.

(3) Fluoroscopy with rectangular image receptors. For x-ray systems manufactured after (insert date 1 year after publication of final rule in the Federal register) (i) When the visible area of the image receptor is rectangular, neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID.

(ii) 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) 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. Compliance with paragraph (b)(3)(i) of this section shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(iv) Means shall be provided to permit further limitation of the field. Beam-limiting devices incorporated in equipment with a variable SID and/or the capability of a visible area of greater than 300 square centimeters 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 centimeters 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 centimeters 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 centimeters by 5 centimeters.

(4) 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

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

(d) ~~*Entrance exposure*~~ *Air kerma rates*. For fluoroscopic equipment, ~~manufactured before May 19, 1995,~~ the following requirements apply:

~~(1) Equipment with automatic exposure rate control (AERC).~~

(1) Fluoroscopic equipment manufactured before May 19, 1995, that is provided with automatic exposure rate control ~~that is provided with AERC~~ (AERC) shall not be operable at any combination of tube potential and current that will result in an ~~exposure~~ air kerma rate in excess of ~~2.58x10^{-3} coulomb per kilogram (C/kg) per minute (10 roentgens per minute (10~~ 88 mGy per

~~R/min)) at the point where the center of the useful beam enters the patient, except:~~ minute (vice 10 R/min exposure rate at the measurement point specified in §1020.32(d)(7), except:

(i) During recording of fluoroscopic images, or

(ii) 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 that will result in an ~~exposure~~ air kerma rate in excess of ~~1.29×10^{-3} C/kg per minute (5 R/min) at the~~ 44 mGy per minute (vice 5 R/min exposure rate) at ~~point where the center of the useful beam enters the patient,~~ the measurement point specified in §1020.32(d)(7), 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.

(2)~~Equipment without AERC (manual mode).~~ Fluoroscopic equipment manufactured before May 19, 1995, that is not provided with AERC shall not be operable at any combination of tube potential and current that will result in an ~~exposure~~ air kerma rate in excess of ~~1.29×10^{-3} C/kg per minute (5~~ 44 mGy per minute (vice 5 R/min exposure ~~R/min) at the point where the center of the useful beam enters the patient,~~ rate) at the measurement point specified in §1020.32(d)(7), except:

(i) During recording of fluoroscopic images, or

(ii) When an optional 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.

(3)~~Equipment with both an AERC mode and a manual mode.~~ Fluoroscopic equipment manufactured before May 19, 1995, that is provided with both an AERC mode and a manual mode shall not be operable at any combination of tube potential and current that will result in an ~~exposure~~ air kerma rate in excess of 88 mGy per minute ~~2.58x10^{-3} C/kg per minute (10 R/min)~~ (vice 10 R/min exposure rate) in either mode at the ~~point where the center of the useful beam enters the patient~~measurement point specified in §1020.32(d)(7), except:

(i) During recording of fluoroscopic images, or

(ii) 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 that will result in an ~~exposure~~ air kerma rate in excess of ~~1.29x10^{-3} C/kg per minute (5~~ 44 mGy per minute (vice 5 R/min ~~R/min) at the point where the center of the useful beam enters the patient,~~ exposure rate) at the measurement point specified in §1020.32(d)(7), 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 is being employed.

~~(4) Measuring compliance. Compliance with paragraph (d) of this section shall be determined as follows:~~

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

~~(ii) 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.~~

~~(iii) In a C-arm type of fluoroscope, the exposure rate shall be measured at 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 imaging assembly.~~

~~(iv) In a lateral type of 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.~~

~~(4) Exemptions. Fluoroscopic radiation therapy simulation systems are exempt from the requirements set forth in paragraph (d) of this section.~~

(4) Fluoroscopic equipment ~~(e) *Entrance exposure rate limits*. For fluoroscopic equipment~~ manufactured on and after May 19, 1995, ~~the following requirements apply:~~

~~(1) Fluoroscopic equipment~~ operable at any combination of tube potential and current that results in an ~~exposure~~ air kerma rate greater than 44 mGy per minute (vice 5 R/min exposure rate) at the measurement point specified ~~1.29×10^{-3} C/kg per minute (5 R/min) at the point where the center of the useful beam enters the patient~~ in §1020.32(d)(7) shall be equipped with AERC. Provision for manual selection of technique factors may be provided.

~~(2)~~(5) Fluoroscopic equipment manufactured on and after May 19, 1995, and before (insert date 1 year after publication of final rule in Federal Register) shall not be operable at any combination of tube potential and current that will result in an ~~exposure~~ air kerma rate in excess of ~~2.58×10^{-3} C/kg per minute (10 R/min) at the point where the center of the useful beam enters~~

~~the patient~~ 88 mGy per minute (vice 10 R/min exposure rate) at the measurement point specified in §1020.32(d)(7), except:

(i) During the recording of images from an x-ray image-intensifier tube using photographic film or a video camera when the x-ray source is operated in a pulsed mode.

(ii) When an optional high-level control is activated. When the high-level control is activated, the equipment shall not be operable at any combination of tube potential and current that will result in an ~~exposure~~ air kerma rate in excess of ~~5.16x10^{-3} C/kg~~ 180 mGy per minute (vice ~~per minute (20 R/min) at the point where the center of the useful beam enters the patient.~~ 20 R/min exposure rate) at the measurement point specified in §1020.32(d)(7). 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.

(6) Fluoroscopic equipment manufactured on and after (insert date 1 year after publication of final rule in Federal Register) shall not be operable at any combination of tube potential and current that will result in an air kerma rate in excess of 88 mGy per minute (vice 10 R/min exposure rate) at the measurement point specified in §1020.32(d)(7), except:

(i) During the recording of images from the fluoroscopic image receptor for the purpose of providing the user with an image(s) after termination of the exposure. However, the archiving of fluoroscopic or radiographic images through the recording of such images in analog format with a video-tape or -disc recorder does not qualify as an exception.

(ii) When an optional high-level control is activated. When the high-level control is activated, the equipment shall not be operable at any combination of tube potential and current that will result in an air kerma rate in excess of 180 mGy per minute (vice 20 R/min exposure

rate) at the measurement point specified in §1020.32(d)(7). 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)~~(7) Measuring compliance. Compliance with paragraph ~~(e)~~(d) of this section shall be determined as follows:

(i) If the source is below the x-ray table, the ~~exposure~~ air kerma rate shall be measured at 1 centimeter above the tabletop or cradle.

(ii) If the source is above the x-ray table, the ~~exposure~~ air kerma 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.

(iii) In a C-arm type of fluoroscope, the ~~exposure~~ air kerma rate shall be measured at 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.

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

(v) In a lateral type of fluoroscope, the ~~exposure~~ air kerma 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.

~~(4)~~ (8) Exemptions. Fluoroscopic radiation therapy simulation systems are exempt from the requirements set forth in paragraph ~~(e)~~ (d) of this section.

(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 values shall not exceed the maximum deviation as stated by the manufacturer in accordance with §1020.30(h)(3).

(g) *Source-skin distance*. (1) Means shall be provided to limit the source-skin distance to not less than 38 centimeters on stationary fluoroscopes and to not less than 30 centimeters on mobile and portable fluoroscopes. In addition, for ~~image-intensified~~ fluoroscopes intended for specific surgical application that would be prohibited at the source-skin distances specified in this paragraph, provisions may be made for operation at shorter source-skin distances but in no case less than 20 centimeters. When provided, the manufacturer must set forth precautions with respect to the optional means of spacing, in addition to other information as required in §1020.30(h).

(2) For mobile or portable C-arm fluoroscopic systems manufactured on or after (insert date one year after date of publication of the final rule in the Federal register) having a maximum source-image receptor distance of less than 45 centimeters, means shall be provided to limit the source-skin distance to not less than 19 centimeters. 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 distances specified in this paragraph, provisions may be made for operation at shorter source-skin distances but in no case less than 10 centimeters. When

provided, the manufacturer must set forth precautions with respect to the optional means of spacing, in addition to other information as required in §1020.30(h).

(h) *Fluoroscopic time and signal*. (1) Fluoroscopic equipment manufactured before (insert date one year from date of publication of the final rule in the Federal Register) shall be provided with means to preset the cumulative on-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 on-time. Such signal shall continue to sound while x-rays are produced until the timing device is reset. 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.

(2) For x-ray controls manufactured on or after (insert date one year from date of publication of the final rule in the Federal Register) there shall be provided for each fluoroscopic tube:

(i) A display of the irradiation time from the beginning of a patient examination or procedure. This display shall be visible throughout the examination or procedure and after it ends. The display shall be able to be reset to zero prior to the commencement of a new examination or procedure, and it shall function independently of the audible signal described in §1020.32(h)(2)(ii).

(ii) A signal audible to the fluoroscopist shall indicate the passage of irradiation time during an examination or procedure. The signal shall sound for at least one second at each interval of 5-minutes duration of irradiation time.

(i) *Mobile and portable fluoroscopes*. In addition to the ~~foregoing~~ other requirements of this section, mobile and portable fluoroscopes shall provide ~~intensified imaging.~~ an image receptor incorporating more than a simple fluorescent screen.

(j) *Display of last fluoroscopic image*. Fluoroscopic equipment manufactured on or after (insert date one year from date of publication of the final rule in the Federal Register) shall be equipped with means to display the last fluoroscopic image obtained prior to termination of fluoroscopic exposure. This image may be one, a sum or other combination of a series of images obtained immediately prior to termination of exposure, provided the number and method of combination is selectable prior to initiation of fluoroscopic exposure. Means shall be provided to clearly indicate to the user whether a displayed fluoroscopic image is from the last-image hold feature or is from live radiation exposure. Display of the held image shall be replaced by the live image concurrently with the reinitiation of fluoroscopic exposure, unless separate displays are provided for the stored and live images. The options for the last image displayed and the impact of the selected option on image characteristics shall be described in the information required by §1020.30(h). If last fluoroscopic image hold is obtained immediately after termination of exposure, by means that continue the exposure to obtain the recorded image(s), then the provisions of §1020.31 (a)(2) shall apply.

(k) *Displays of values of air kerma rate and cumulative air kerma*. Fluoroscopic equipment manufactured on or after (insert date one year after date of the final rule in the Federal Register) shall display at the fluoroscopist's working position values of air kerma rate and cumulative air kerma at reference location(s) specified in §1020.32(k)(5). The following requirements apply for each x-ray tube used during an examination or procedure:

(1) The value displayed for air kerma rate shall be in units of cGy/min and shall represent the air kerma per unit time during fluoroscopy and while recording during fluoroscopy.

(2) The value displayed for cumulative air kerma shall be in units of cGy; shall include all contributions generated from fluoroscopic and radiographic radiation; shall represent the total air kerma accrued from the commencement of an examination or procedure and shall be updated during the examination or procedure each time that fluoroscopic or radiographic x-ray production is deactivated.

(3) During fluoroscopy and while recording during fluoroscopy, the value of the air kerma rate shall be displayed. Following fluoroscopy or radiography, the value of the cumulative air kerma shall be displayed.

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

(5) Values displayed for the air kerma rate and cumulative air kerma shall be determined for conditions of free-in-air irradiation at one of the following reference locations specified according to the type of fluoroscope. The reference location shall be identified and described specifically in information provided to users according to §1020.30(h)(6)(iii):

(i) For fluoroscopes with x-ray source below the table, x-ray source above the table, and of lateral type, the reference locations shall be the respective locations specified in §1020.32(d)(7)(i), (ii), and (v) for measuring compliance with air-kerma rate limits.

(ii) For C-arm type fluoroscopes, the reference location shall be 15 centimeters from the isocenter toward the x-ray source along the beam axis. Alternatively, the reference location shall be along the beam axis at point(s) deemed by the manufacturer to represent the intersection of the x-ray beam entrance surface and the patient skin.

(6) The displays of the values of air kerma rate and cumulative air kerma shall be able to be reset to zero prior to the commencement of a new examination or procedure.