

the tube, as measured in accordance with this section.

(ii) The divergence of the exit beam from tubes designed primarily to demonstrate the effects of x radiation, with the beam blocking device in the open position, shall not exceed (Pi) steradians.

(2) *Measurements.* (i) Compliance with the exposure rate limit defined in paragraph (c)(1)(i) of this section shall be determined by measurements averaged over an area of one hundred (100) square centimeters with no linear dimension greater than twenty (20) centimeters.

(ii) Measurements of exposure rates from tubes in enclosures from which the tubes cannot be removed without destroying the function of the tube may be made at a distance of thirty (30) centimeters from any point on the external surface of the enclosure, provided:

(a) In the case of enclosures containing tubes designed primarily to demonstrate the production of x radiation, measurements shall be made with any beam blocking device in the beam blocking position, or

(b) In the case of enclosures containing tubes designed primarily to demonstrate the effects of a flow of electrons, measurements shall be made with all movable or removable parts of such enclosure in the position which would maximize external exposure levels.

(3) *Test conditions.* (i) Measurements shall be made under the conditions of use specified in instructions provided by the manufacturer.

(ii) Measurements shall be made with the tube operated under forward and reverse polarity.

(4) *Instructions, labels, and warnings.*

(i) Manufacturers shall provide, or cause to be provided, with each tube to which this section is applicable, appropriate safety instructions, together with instructions for the use of such tube, including the specification of a power source for use with the tube.

(ii) Each enclosure or tube shall have inscribed on or permanently affixed to it, tags or labels, which identify the intended polarity of the terminals and:

(a) In the case of tubes designed primarily to demonstrate the heat effect,

fluorescence effect, or magnetic effect, a warning that application of power in excess of that specified may result in the production of x-rays in excess of allowable limits; and (b) in the case of tubes designed primarily to demonstrate the production of x-radiation, a warning that this device produces x-rays when energized.

(iii) The tag or label required by this paragraph shall be located on the tube or enclosure so as to be readily visible and legible when the product is fully assembled for use.

§ 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, or after June 10, 2006.

(C) Spot-film devices and image intensifiers manufactured after April 26, 1977.

(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 that are electrically powered or connected with the x-ray system manufactured on or after June 10, 2006.

(G) Fluoroscopic air kerma display devices manufactured on or after June 10, 2006.

(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.

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(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 §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.

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

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

Aluminum equivalent means the thickness of 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 (cm) or larger by 20 cm or larger by 3.8 cm, that is large enough to intercept the entire x-ray beam.

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

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

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.

C-arm fluoroscope means a fluoroscopic x-ray system in which the image receptor and the x-ray tube

¹The 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.

housing assembly are connected or coordinated to maintain a spatial relationship. Such a system allows a change in the direction of the beam axis with respect to the patient without moving the patient.

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

Cassette holder means a device, other than a spot-film device, that supports

and/or fixes the position of an x-ray film 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.

\bar{X} = Mean value of observations in sample.

X_i = *i*th 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.

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

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 to matter of mass dm; thus D=de/dm, in units of J/kg, where the special name for the unit of absorbed dose is gray (Gy).

Equipment means x-ray equipment.

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

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

Fluoroscopic air kerma display device means a device, subsystem, or component that provides the display of AKR and cumulative air kerma required by §1020.32(k). It includes radiation detectors, if any, electronic and computer components, associated software, and data displays.

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

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

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

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 AKR 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.

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, x-ray image intensifier tube, solid-state detector, or gaseous detec-

tor, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations. In those cases where means are provided to preselect a portion of the image receptor, the term “image receptor” shall mean the preselected portion of the device.

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

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

Kerma means the quantity 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 particles liberated by uncharged particles in a mass dm of material; thus $K=dE_{tr}/dm$, in units of J/kg, where the special name for the unit of kerma is gray (Gy). When the material is air, the quantity is referred to as “air kerma.”

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

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

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 peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

Light field means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the 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 = $100(V_n - V_l)/V_l$

where:

V_n = No-load line potential and
 V_l = 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 means, for fluoroscopic systems, a distinct method of fluoroscopy or radiography provided by the manufacturer and selected with a set of several technique factors or other control settings uniquely associated with the mode. The set of distinct technique factors and control settings for the mode may be selected by the operation of a single control. Ex-

amples of distinct modes of operation include normal fluoroscopy (analog or digital), high-level control fluoroscopy, cineradiography (analog or digital), digital subtraction angiography, electronic radiography using the fluoroscopic image receptor, and photospot recording. In a specific mode of operation, certain system variables affecting air kerma, AKR, or image quality, such as image magnification, x-ray field size, pulse rate, pulse duration, number of pulses, source-image receptor distance (SID), or optical aperture, may be adjustable or may vary; their variation per se does not comprise a mode of operation different from the one that has been selected.

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

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

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 retrievable form of an image resulting from x-ray photons.

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

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

Solid state x-ray imaging device means an assembly, typically in a rectangular panel configuration, that intercepts x-ray photons and converts the photon energy into a modulated electronic signal representative of the x-ray intensity over the area of the imaging device. The electronic signal is then used to create an image for display and/or storage.

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

Source-image receptor distance (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 the fluoroscopic image receptor for the purpose of producing 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 milliampere-seconds (mAs);

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

(3) For CT 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 AKR is one-fourth of the maximum in the intersection.

X-ray high-voltage generator means a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament

transformers for the x-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.

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

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

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

X-ray tube means any electron tube which is designed for the conversion of electrical energy into x-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 Communication, Education, and Radiation Programs of the Center for Devices and Radiological Health. Manufacturers shall not be held responsible for non-compliance of their products if that non-compliance 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.

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(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 the Director, CDRH. 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 CDRH 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)(A) 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

(B) 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 under 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 under 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 gener-

ator. 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 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 (mm) 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 June 10, 2006, 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. The description of the mode shall identify those technique factors and system controls that are fixed or automatically adjusted by selection of the mode of operation, including the manner in which the automatic adjustment is controlled. 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 descriptive example(s) of any specific clinical procedure(s) or imaging task(s) for which the mode is recommended or designed and how each mode should be used. Such recommendations do not preclude other clinical uses.

(6) *Displays of values of AKR and cumulative air kerma.* For fluoroscopic x-ray systems manufactured on or after

June 10, 2006, the following shall be provided:

(i) A schedule of maintenance for any system instrumentation associated with the display of air kerma information necessary to maintain the displays of AKR and cumulative air kerma within the limits of allowed uncertainty specified by §1020.32(k)(6) and, if the capability for user calibration of the display is provided, adequate instructions for such calibration;

(ii) Identification of the distances along the beam axis:

(A) From the focal spot to the isocenter, and

(B) From the focal spot to the reference location to which displayed values of AKR and cumulative air kerma refer according to §1020.32(k)(4);

(iii) 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)(4)(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, operating instructions and maintenance schedules 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 0.88 milligray (mGy) air kerma (vice 100 milliroentgen (mR) exposure) 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 cm with no linear dimension greater than 20 cm.

(1) *Radiation from components other than the diagnostic source assembly.* The radiation emitted by a component other than the diagnostic source assembly shall not exceed an air kerma of 18 microGy (vice 2 mR exposure) in 1 hour at 5 cm from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm.

(m) *Beam quality—(1) Half-value layer (HVL).* The HVL of the useful beam for a given x-ray tube potential shall not be less than the appropriate value shown in table 1 in paragraph (m)(1) of this section under the heading “Specified Dental Systems,” for any dental x-ray system designed for use with intraoral image receptors and manufactured after December 1, 1980; under the heading “I—Other X-Ray Systems,” for any dental x-ray system designed for use with intraoral image receptors and manufactured before December 1, 1980, and all other x-ray systems subject to this section and manufactured before June 10, 2006; and under the heading “II—Other X-Ray Systems,” for all x-ray systems, except dental x-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after June 10, 2006. If it is necessary to determine such HVL at an x-ray tube potential which is not listed in table 1 in paragraph (m)(1) of this section, linear interpolation or extrapolation may be made. Positive means² shall be provided to ensure that at least the minimum filtration needed to achieve the above beam quality requirements is in the useful beam during each exposure. Table 1 follows:

²In the case of a system, which is to be operated with more than one thickness of filtration, this requirement can be met by a filter interlocked with the kilovoltage selector which will prevent x-ray emissions if the minimum required filtration is not in place.

TABLE 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 ³
Below 51		30	1.5	0.3	0.3
		40	1.5	0.4	0.4
		50	1.5	0.5	0.5
51 to 70		51	1.5	1.2	1.3
		60	1.5	1.3	1.5
		70	1.5	1.5	1.8
Above 70		71	2.1	2.1	2.5
		80	2.3	2.3	2.9
		90	2.5	2.5	3.2
		100	2.7	2.7	3.6
		110	3.0	3.0	3.9
		120	3.2	3.2	4.3
		130	3.5	3.5	4.7
		140	3.8	3.8	5.0
		150	4.1	4.1	5.4

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

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

³ All x-ray systems, except dental x-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after June 10, 2006.

(2) *Optional filtration.* Fluoroscopic systems manufactured on or after June 10, 2006, incorporating an x-ray tube(s) with a continuous output of 1 kilowatt or more and an anode heat storage capacity of 1 million heat units or more shall provide the option of adding x-ray filtration to the diagnostic source assembly in addition to the amount needed to meet the HVL provisions of §1020.30(m)(1). The selection of this additional x-ray filtration shall be either at the option of the user or automatic as part of the selected mode of operation. A means of indicating which combination of additional filtration is in the x-ray beam shall be provided.

(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 2 in paragraph (n) of this section, which are used between the patient and image receptor, may not exceed the indicated limits. Compliance shall be determined by x-ray measurements made at a potential of 100 kilovolts peak and with an x-ray beam that has an HVL specified in table 1 in paragraph (m)(1) of this section for the potential. This requirement applies to front panel(s) of cassette holders and film changers provided by the manufacturer for patient support or for prevention of foreign object intrusions. It does not apply to screens and their associated mechanical support panels or grids. Table 2 follows:

TABLE 2

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

(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 section 534(a)(5) or 538(b) of the Federal Food, Drug, and Cosmetic 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 modi-

fication 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 in the system records and maintains this information, and provided the modification of the x-ray system does not result in a failure to comply with §1020.31, 1020.32, or 1020.33.

[71 FR 34028, June 10, 2006, as amended at 72 FR 17401, Apr. 9, 2007]

§ 1020.31 Radiographic equipment.

The provisions of this section apply to equipment for radiography, except equipment for fluoroscopic imaging or for recording images from the