Subpart C—Exportation of Electronic Products

§ 1010.20 Electronic products intended for export.

The performance standards prescribed in this subchapter shall not apply to any electronic product which is intended solely for export if:

(a) Such product and the outside of any shipping container used in the export of such product are labeled or tagged to show that such product is intended for export, and

(b) Such product meets all the applicable requirements of the country to which such product is intended for export.

[40 FR 32257, July 31, 1975]

PART 1020—PERFORMANCE STANDARDS FOR IONIZING RADIATION EMITTING PRODUCTS

Sec.

AUTHORITY: 21 U.S.C. 351, 352, 360e–360j, 360gg–360ss, 371, 381.

SOURCE: 38 FR 28632, Oct. 15, 1973, unless otherwise noted.

§ 1020.10 Television receivers.

(a) *Applicability.* The provisions of this section are applicable to television receivers manufactured subsequent to January 15, 1970.

(b) *Definitions.* (1) *External surface* means the cabinet or enclosure provided by the manufacturer as part of the receiver. If a cabinet or enclosure is not provided as part of the receiver, the external surface shall be considered to be a hypothetical cabinet, the plane surfaces of which are located at those minimum distances from the chassis sufficient to enclose all components of the receiver except that portion of the neck and socket of the cathode-ray tube which normally extends beyond the plane surfaces of the enclosure.

(2) *Maximum test voltage* means 130 root mean square volts if the receiver is designed to operate from nominal 110 to 120 root mean square volt power sources. If the receiver is designed to operate from a power source having some voltage other than from nominal 110 to 120 root mean square volts, maximum test voltage means 110 percent of the nominal root mean square voltage specified by the manufacturer for the power source.

(3) *Service controls* means all of those controls on a television receiver provided by the manufacturer for purposes of adjustment which, under normal usage, are not accessible to the user.

(4) *Television receiver* means an electronic product designed to receive and display a television picture through broadcast, cable, or closed circuit television.

(5) *Usable picture* means a picture in synchronization and transmitting viewable intelligence.

(6) *User controls* means all of those controls on a television receiver, provided by the manufacturer for purposes of adjustment, which on a fully assembled receiver under normal usage, are accessible to the user.

(c) *Requirements*—(1) *Exposure rate limit.* Radiation exposure rates produced by a television receiver shall not exceed 0.5 milliroentgens per hour at a distance of five (5) centimeters from any point on the external surface of the receiver, as measured in accordance with this section.

(2) *Measurements.* Compliance with the exposure rate limit defined in paragraph (c)(1) of this section shall be determined by measurements made with an instrument, the radiation sensitive volume of which shall have a cross section parallel to the external surface of the receiver with an area of ten (10) square centimeters and no dimension larger than five (5) centimeters. Measurements made with instruments having other areas must be corrected for spatial nonuniformity of the radiation field to obtain the exposure rate average over a ten (10) square centimeter area.

(3) *Test conditions.* All measurements shall be made with the receiver displaying a usable picture and with the power source operated at supply

voltages up to the maximum test voltage of the receiver and, as applicable, under the following specific conditions:

(i) On television receivers manufactured subsequent to January 15, 1970, measurements shall be made with all user controls adjusted so as to produce maximum x-radiation emissions from the receiver.

(ii) On television receivers manufactured subsequent to June 1, 1970, measurements shall be made with all user controls and all service controls adjusted to combinations which result in the production of maximum x-radiation emissions.

(iii) On television receivers manufactured subsequent to June 1, 1971, measurements shall be made under the conditions described in paragraph (c)(3) (ii) of this section, together with conditions identical to those which result from that component or circuit failure which maximizes x-radiation emissions.

(4) *Critical component warning.* The manufacturer shall permanently affix or inscribe a warning label, clearly legible under conditions of service, on all television receivers which could produce radiation exposure rates in excess of the requirements of this section as a result of failure or improper adjustment or improper replacement of a circuit or shield component. The warning label shall include the specification of operating high voltage and an instruction for adjusting the high voltage to the specified value.

§ 1020.20 Cold-cathode gas discharge tubes.

(a) *Applicability.* The provisions of this section are applicable to cold-cathode gas discharge tubes designed to demonstrate the effects of a flow of electrons or the production of x-radiation as specified herein.

(b) *Definitions. Beam blocking device* means a movable or removable portion of any enclosure around a cold-cathode gas discharge tube, which may be opened or closed to permit or prevent the emergence of an exit beam.

Cold-cathode gas discharge tube means an electronic device in which electron flow is produced and sustained by ionization of contained gas atoms and ion bombardment of the cathode.

Exit beam means that portion of the radiation which passes through the aperture resulting from the opening of the beam blocking device.

Exposure means the sum of the electrical charges on all of the ions of one sign produced in air when all electrons liberated by photons in a volume element of air are completely stopped in air divided by the mass of the air in the volume element. The special unit of exposure is the roentgen. One (1) roentgen equals 2.58×10^{-4} coulombs/kilogram.

(c) *Requirements*—(1) *Exposure rate limit.* (i) Radiation exposure rates produced by cold-cathode gas discharge tubes shall not exceed 10 mR./hr. at a distance of thirty (30) centimeters from any point on the external surface of 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.

(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.

(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 § 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.

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.

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.

$\bar{X}$ = 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;

[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.

(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, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

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 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.

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 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.

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

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

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.

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.

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.

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 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.

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.

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 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, 9200 Corporate Blvd., Rockville, MD 20850. 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 shall provide necessary information 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.

(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 2.58×10^{-5} coulombs per kilogram (C/kg) (100 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 5.16×10^{-7} C/kg (2 mR) 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 ''Other x-ray systems,'' for all other x-ray systems subject to this section. 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.

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

(2) *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

[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.

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 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 a HVL of 2.7 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.

[58 FR 26396, May 3, 1993, as amended at 59 FR 26403, May 19, 1994; 64 FR 35927, July 2, 1999; 65 FR 17138, Mar. 31, 2000]

§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 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. Except during panoramic dental radiography, termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero. It shall not be possible to make an exposure

when the timer is set to a zero or off position if either position is provided.

(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 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 to the indicated milliampere-seconds product (C/kg/mAs (or mR/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) 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 to the indicated milliampere-seconds product (C/kg/mAs (or mR/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) 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 mammography.* (i) Mammographic beam-limiting devices manufactured after September 30, 1999, shall be provided with means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor by more than 2 percent of the SID. This requirement can be met with a system that performs as prescribed in paragraphs (f)(4)(i), (f)(4)(ii), and (f)(4)(iii) of this section. For systems that allow changes in the SID, 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.

(ii) Each image receptor support device intended for installation on a system designed for mammography shall have clear and permanent markings to indicate the maximum image receptor size for which it is designed.

(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) 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) 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 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) *Primary protective barrier for mammography x-ray systems.* For mammography x-ray systems manufactured after September 30, 1999:

(1) At any SID where exposures can be made, the image receptor support device shall provide a primary protective barrier that intercepts the cross

section of the useful beam along every direction except at the chest wall edge.

(2) The x-ray tube shall not permit exposure unless the appropriate barrier is in place to intercept the useful beam as required in paragraph (m)(1) of this section.

(3) The transmission of the useful beam through the primary protective barrier shall be limited such that the exposure 5 centimeters from any accessible surface beyond the plane of the primary protective barrier does not exceed $2.58X10^{-8}$ C/kg (0.1 mR) for each activation of the tube.

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

[58 FR 26401, May 3, 1993; 58 FR 31067, May 28, 1993, as amended at 64 FR 35927, July 2, 1999]

§ 1020.32 Fluoroscopic equipment.

The provisions of this section apply to equipment for fluoroscopy and for the recording of images through an image intensifier 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 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 3.34×10^{-3} percent of the entrance exposure 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 rate shall be measured in accordance with paragraph (d) of this section. The exposure rate due to transmission through the primary barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters. 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 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.* (i) For image-intensified fluoroscopic equipment other than radiation therapy simulation systems, 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) 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) 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) 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.

(3) 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 rates.* For fluoroscopic equipment manufactured before May 19, 1995, the following requirements apply:

(1) *Equipment with automatic exposure rate control (AERC).* Fluoroscopic equipment that is provided with AERC shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 2.58×10^{-3} coulomb per kilogram (C/kg) per minute (10 roentgens per minute (10 R/min)) at the point where the center of the useful beam enters the patient, 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 rate in excess of 1.29×10^{-3} C/kg per minute (5 R/min) at the point where the center of the useful beam enters the patient, unless the high-level control is activated. Special means of activation of high-level controls shall be required. The high-level control shall

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 that is not provided with AERC shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of $1.29x10^{-3}$ C/kg per minute (5 R/min) at the point where the center of the useful beam enters the patient, 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 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 rate in excess of $2.58x10^{-3}$ C/kg per minute (10 R/min) in either mode at the point where the center of the useful beam enters the patient 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 rate in excess of $1.29x10^{-3}$ C/kg per minute (5 R/min) at the point where the center of the useful beam enters the patient, unless the high-level control is activated. Special means of activation of high-level controls shall be required. The high-level control shall 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.

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

(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 rate greater than $1.29x10^{-3}$ C/kg per minute (5 R/min) at the point where the center of the useful beam enters the patient shall be equipped with AERC. Provision for manual selection of technique factors may be provided.

(2) Fluoroscopic equipment shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of $2.58x10^{-3}$ C/kg per minute (10 R/min) at

the point where the center of the useful beam enters the patient 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 rate in excess of 5.16×10^{-3} C/kg per minute (20 R/min) at the point where the center of the useful beam enters the patient. 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) *Measuring compliance.* Compliance with paragraph (e) 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 fluoroscopic 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 (e) of this section.

(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.* 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).

(h) *Fluoroscopic timer.* Means shall be provided 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.

(i) *Mobile and portable fluoroscopes.* In addition to the foregoing requirements of this section, mobile and portable

fluoroscopes shall provide intensified imaging.

[58 FR 26404, May 3, 1993, as amended at 59 FR 26404, May 19, 1994]

§ 1020.33 Computed tomography (CT) equipment.

(a) *Applicability*. (1) The provisions of this section, except for paragraphs (b), (c)(1), and (c)(2) are applicable as specified herein to CT x-ray systems manufactured or remanufactured on or after September 3, 1985.

(2) The provisions of paragraphs (b), (c)(1), and (c)(2) are applicable to CT x-ray systems manufactured or remanufactured on or after November 29, 1984.

(b) *Definitions*. As used in this section, the following definitions apply:

(1) *Computed tomography dose index (CTDI)* means the integral of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan; that is:

$$\mathrm{CTDI} = 1/\mathrm{nT}\int_{-7\mathrm{T}}^{+7\mathrm{T}} \mathrm{D(z)dz}$$

where:

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

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

(2) *Contrast scale* means the change in linear attenuation coefficient per CT number relative to water; that is:

$$\text{Contrast scale} = \frac{\mu_x - \mu_w}{(\mathrm{CT})_x - (\mathrm{CT})_w}$$

where:

μ_w=Linear attenuation coefficient of water.
μ_x=Linear attenuation coefficient of material of interest.
$(CT)_w$=CT number of water.
$(CT)_x$=CT number of material of interest.

(3) *CT conditions of operation* means all selectable parameters governing the operation of a CT x-ray system including nominal tomographic section thickness, filtration, and the technique factors as defined in §1020.30(b)(36).

(4) *CT number* means the number used to represent the x-ray attenuation associated with each elemental area of the CT image.

(5) [Reserved]

(6) *CT dosimetry phantom* means the phantom used for determination of the dose delivered by a CT x-ray system. The phantom shall be a right circular cylinder of polymethl-methacrylate of density 1.19±0.01 grams per cubic centimeter. The phantom shall be at least 14 centimeters in length and shall have diameters of 32.0 centimeters for testing any CT system designed to image any section of the body (whole body scanners) and 16.0 centimeters for any system designed to image the head (head scanners) or for any whole body scanner operated in the head scanning mode. The phantom shall provide means for the placement of a dosimeter(s) along its axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. Means for the placement of a dosimeter(s) or alignment device at other locations may be provided for convenience. The means used for placement of a dosimeter(s) (i.e., hole size) and the type of dosimeter(s) used is at the discretion of the manufacturer. Any effect on the doses measured due to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom.

(7) *Dose profile* means the dose as a function of position along a line.

(8) *Modulation transfer function* means the modulus of the Fourier transform of the impulse response of the system.

(9) *Multiple tomogram system* means a CT x-ray system which obtains x-ray transmission data simultaneously during a single scan to produce more than one tomogram.

(10) *Noise* means the standard deviation of the fluctuations in CT number expressed as a percent of the attenuation coefficient of water. Its estimate

(S_n) is calculated using the following expression:

$$S_n \frac{100 \times CS \times s}{\mu_w}$$

where:

CS=Contrast scale.

μ_w=Linear attenuation coefficient of water.

s=Estimated standard deviation of the CT numbers of picture elements in a specified area of the CT image.

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

(12) *Picture element* means an elemental area of a tomogram.

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

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

(15) *Scan sequence* means a preselected set of two or more scans performed consecutively under preselected CT conditions of operations.

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

(17) *Single tomogram system* means a CT x-ray system which obtains x-ray transmission data during a scan to produce a single tomogram.

(18) *Tomographic plane* means that geometric plane which the manufacturer identifies as corresponding to the output tomogram.

(19) *Tomographic section* means the volume of an object whose x-ray attenuation properties are imaged in a tomogram.

(c) *Information to be provided for users.* Each manufacturer of a CT x-ray system shall provide the following technical and safety information, in addition to that required under §1020.30(h), to purchasers and, upon request, to others at a cost not to exceed the cost of publication and distribution of such information. This information shall be identified and provided in a separate section of the user's instruction manual or in a separate manual devoted only to this information.

(1) *Conditions of operation.* A statement of the CT conditions of operation used to provide the information required by paragraph (c) (2) and (3) of this section.

(2) *Dose information.* The following dose information obtained by using the CT dosimetry phantom. For any CT x-ray system designed to image both the head and body, separate dose information shall be provided for each application. All dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuating materials present.

(i) The CTDI at the following locations in the dosimetry phantom:

(*a*) Along the axis of rotation of the phantom.

(*b*) Along a line parallel to the axis of rotation and 1.0 centimeter interior to the surface of the phantom with the phantom positioned so that CTDI is the maximum obtainable at this depth.

(*c*) Along lines parallel to the axis of rotation and 1.0 centimeter interior to the surface of the phantom at positions 90, 180, and 270 degrees from the position in paragraph (c)(2)(i)(*b*) of this section. The CT conditions of operation shall be the typical values suggested by the manufacturer for CT of the head or body. The location of the position where the CTDI is maximum as specified in paragraph (c)(2)(i)(*b*) of this section shall be given by the manufacturer with respect to the housing of the scanning mechanism or other readily identifiable feature of the CT x-ray system in such a manner as to permit placement of the dosimetry phantom in this orientation.

(ii) The CTDI in the center location of the dosimetry phantom for each selectable CT condition of operation that

varies either the rate or duration of x-ray exposure. This CTDI shall be presented as a value that is normalized to the CTDI in the center location of the dosimetry phantom from paragraph (c)(2)(i) of this section, with the CTDI of paragraph (c)(2)(i) of this section having a value of one. As each individual CT condition of operation is changed, all other independent CT conditions of operation shall be maintained at the typical values described in paragraph (c)(2)(i) of this section. These data shall encompass the range of each CT condition of operation stated by the manufacturer as appropriate for CT of the head or body. When more than three selections of a CT condition of operation are available, the normalized CTDI shall be provided, at least, for the minimum, maximum, and midrange value of the CT condition of operation.

(iii) The CTDI at the location coincident with the maximum CTDI at 1 centimeter interior to the surface of the dosimetry phantom for each selectable peak tube potential. When more than three selections of peak tube potential are available, the normalized CTDI shall be provided, at least, for the minimum, maximum, and a typical value of peak tube potential. The CTDI shall be presented as a value that is normalized to the maximum CTDI located at 1 centimeter interior to the surface of the dosimetry phantom from paragraph (c)(2)(i) of this section, with the CTDI of paragraph (c)(2)(i) of this section having a value of one.

(iv) The dose profile in the center location of the dosimetry phantom for each selectable nominal tomographic section thickness. When more than three selections of nominal tomographic section thicknesses are available, the information shall be provided, at least, for the minimum, maximum, and midrange value of nominal tomographic section thickness. The dose profile shall be presented on the same graph and to the same scale as the corresponding sensitivity profile required by paragraph (c)(3)(iv) of this section.

(v) A statement of the maximum deviation from the values given in the information provided according to paragraph (c)(2) (i), (ii), (iii), and (iv) of this section. Deviation of actual values may not exceed these limits.

(3) *Imaging performance information.* The following performance data shall be provided for the CT conditions of operation used to provide the information required by paragraph (c)(2)(i) of this section. All other aspects of data collection, including the x-ray attenuation properties of the material in the tomographic section, shall be similar to those used to provide the dose information required by paragraph (c)(2)(i) of this section. For any CT x-ray system designed to image both the head and body, separate imaging performance information shall be provided for each application.

(i) A statement of the noise.

(ii) A graphical presentation of the modulation transfer function for the same image processing and display mode as that used in the statement of the noise.

(iii) A statement of the nominal tomographic section thickness(es).

(iv) A graphical presentation of the sensitivity profile, at the location corresponding to the center location of the dosimetry phantom, for each selectable nominal tomographic section thickness for which the dose profile is given according to paragraph (c)(2)(iv) of this section.

(v) A description of the phantom or device and test protocol or procedure used to determine the specifications and a statement of the maximum deviation from the specifications provided in accordance with paragraphs (c)(3)(i), (ii), (iii), and (iv) of this section. Deviation of actual values may not exceed these limits.

(d) *Quality assurance.* The manufacturer of any CT x-ray system shall provide the following with each system. All information required by this subsection shall be provided in a separate section of the user's instructional manual.

(1) A phantom(s) capable of providing an indication of contrast scale, noise, nominal tomographic section thickness, the spatial resolution capability of the system for low and high contrast objects, and measuring the mean CT number of water or a reference material.

(2) Instructions on the use of the phantom(s) including a schedule of testing appropriate for the system, allowable variations for the indicated parameters, and a method to store as records, quality assurance data.

(3) Representative images obtained with the phantom(s) using the same processing mode and CT conditions of operation as in paragraph (c)(3) of this section for a properly functioning system of the same model. The representative images shall be of two forms as follows:

(i) Photographic copies of the images obtained from the image display device.

(ii) Images stored in digital form on a storage medium compatible with the CT x-ray system. The CT x-ray system shall be provided with the means to display these images on the image display device.

(e) [Reserved]

(f) *Control and indication of conditions of operation*—(1) *Visual indication.* The CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of the CT conditions of operation shall be visible from any position from which scan initiation is possible.

(2) *Timers.* (i) Means shall be provided to terminate the x-ray exposure automatically by either deenergizing the x-ray source or shuttering the x-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110 percent of its preset value through the use of either a backup timer or devices which monitor equipment function. A visible signal shall indicate when the x-ray exposure has been terminated through these means and manual resetting of the CT conditions of operation shall be required prior to the initiation of another scan.

(ii) Means shall be provided so that the operator can terminate the x-ray exposure at any time during a scan, or series of scans under x-ray system control, of greater than one-half second duration. Termination of the x-ray exposure shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.

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

(2) For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. The relationship of the reference plane to the planes of the tomograms shall be provided to the user in addition to other information provided according to §1020.30(h). This reference plane can be offset from the location of the tomographic planes.

(3) The distance between the indicated location of the tomographic plane or reference plane and its actual location may not exceed 5 millimeters.

(4) For any offset alignment system, the manufacturer shall provide specific instructions with respect to the use of this system for patient positioning, in addition to other information provided according to §1020.30(h).

(5) If a mechanism using a light source is used to satisfy the requirements of paragraphs (g) (1) and (2) of this section, the light source shall allow visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.

(h) *Beam-on and shutter status indicators.* (1) Means shall be provided on the control and on or near the housing of the scanning mechanism to provide visual indication when and only when x rays are produced and, if applicable, whether the shutter is open or closed. If the x-ray production period is less than one-half second, the indication of x-ray production shall be actuated for one-half second. Indicators at or near the housing of the scanning mechanism shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.

(2) For systems that allow high voltage to be applied to the x-ray tube continuously and that control the emission of x rays with a shutter, the radiation emitted may not exceed 100 milliroentgens (2.58×10^{-5} coulomb/kilogram) in 1 hour at any point 5 centimeters outside the external surface of the housing of the scanning mechanism when the shutter is closed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimensions greater than 20 centimeters.

(i) *Scan increment accuracy.* The deviation of indicated scan increment from actual scan increment may not exceed 1 millimeter. Compliance shall be measured as follows: The determination of the deviation of indicated versus actual scan increment shall be based on measurements taken with a mass 100 kilograms or less, on the patient support device. The patient support device shall be incremented from a typical starting position to the maximum incrementation distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel.

(j) *CT number mean and standard deviation.* (1) A method shall be provided to calculate the mean and standard deviation of CT numbers for an array of picture elements about any location in the image. The number of elements in this array shall be under user control.

(2) The manufacturer shall provide specific instructions concerning the use of the method provided for calculation of CT number mean and standard deviation in addition to other information provided according to § 1020.30(h).

[49 FR 34712, Aug. 31, 1984; 49 37381, Sept. 24, 1984, as amended at 49 FR 47388, Dec. 4, 1984; 56 FR 36098, Aug. 1, 1991; 67 FR 9587, Mar. 4, 2002]

§ 1020.40 Cabinet x-ray systems.

(a) *Applicability.* The provisions of this section are applicable to cabinet x-ray systems manufactured or assembled on or after April 10, 1975, except that the provisions as applied to x-ray systems designed primarily for the inspection of carry-on baggage are applicable to such systems manufactured or assembled on or after April 25, 1974. The provisions of this section are not applicable to systems which are designed exclusively for microscopic examination of material, e.g., x-ray diffraction, spectroscopic, and electron microscope equipment or to systems for intentional exposure of humans to x-rays.

(b) *Definitions.* As used in this section the following definitions apply:

(1) *Access panel* means any barrier or panel which is designed to be removed or opened for maintenance or service purposes, requires tools to open, and permits access to the interior of the cabinet.

(2) *Aperture* means any opening in the outside surface of the cabinet, other than a port, which remains open during generation of x radiation.

(3) *Cabinet x-ray system* means an x-ray system with the x-ray tube installed in an enclosure (hereinafter termed *cabinet*) which, independently of existing architectural structures except the floor on which it may be placed, is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of x radiation. Included are all x-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and in similar facilities. An x-ray tube used within a shielded part of a building, or x-ray equipment which may temporarily or occasionally incorporate portable shielding is not considered a cabinet x-ray system.

(4) *Door* means any barrier which is designed to be movable or opened for routine operation purposes, does not generally require tools to open, and permits access to the interior of the cabinet. For the purposes of paragraph (c)(4)(i) of this section, inflexible hardware rigidly affixed to the door shall be considered part of the door.

(5) *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.

(6) *External surface* means the outside surface of the cabinet x-ray system, including the high-voltage generator, doors, access panels, latches, control knobs, and other permanently mounted hardware and including the plane across any aperture or port.

(7) *Floor* means the underside external surface of the cabinet.

(8) *Ground fault* means an accidental electrical grounding of an electrical conductor.

(9) *Port* means any opening in the outside surface of the cabinet which is designed to remain open, during generation of x-rays, for the purpose of conveying material to be irradiated into and out of the cabinet, or for partial insertion for irradiation of an object whose dimensions do not permit complete insertion into the cabinet.

(10) *Primary beam* means the x radiation emitted directly from the from the target and passing through the window of the x-ray tube.

(11) *Safety interlock* means a device which is intended to prevent the generation of x radiation when access by any part of the human body to the interior of the cabinet x-ray system through a door or access panel is possible.

(12) *X-ray system* means an assemblage of components for the controlled generation of x-rays.

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

(c) *Requirements*—(1) *Emission limit.* (i) Radiation emitted from the cabinet x-ray system shall not exceed an exposure of 0.5 milliroentgen in one hour at any point five centimeters outside the external surface.

(ii) Compliance with the exposure limit in paragraph (c)(1)(i) of this section shall be determined by measurements averaged over a cross-sectional area of ten square centimeters with no linear dimension greater than 5 centimeters, with the cabinet x-ray system operated at those combinations of x-ray tube potential, current, beam orientation, and conditions of scatter radiation which produce the maximum x-ray exposure at the external surface, and with the door(s) and access panel(s) fully closed as well as fixed at any other position(s) which will allow the generation of x radiation.

(2) *Floors.* A cabinet x-ray system shall have a permanent floor. Any support surface to which a cabinet x-ray system is permanently affixed may be deemed the floor of the system.

(3) *Ports and apertures.* (i) The insertion of any part of the human body through any port into the primary beam shall not be possible.

(ii) The insertion of any part of the human body through any aperture shall not be possible.

(4) *Safety interlocks.* (i) Each door of a cabinet x-ray system shall have a minimum of two safety interlocks. One, but not both of the required interlocks shall be such that door opening results in physical disconnection of the energy supply circuit to the high-voltage generator, and such disconnection shall not be dependent upon any moving part other than the door.

(ii) Each access panel shall have at least one safety interlock.

(iii) Following interruption of x-ray generation by the functioning of any safety interlock, use of a control provided in accordance with paragraph (c)(6)(ii) of this section shall be necessary for resumption of x-ray generation.

(iv) Failure of any single component of the cabinet x-ray system shall not cause failure of more than one required safety interlock.

(5) *Ground fault.* A ground fault shall not result in the generation of x-rays.

(6) *Controls and indicators for all cabinet x-ray systems.* For all systems to which this section is applicable there shall be provided:

(i) A key-actuated control to insure that x-ray generation is not possible with the key removed.

(ii) A control or controls to initiate and terminate the generation of x-rays other than by functioning of a safety interlock or the main power control.

(iii) Two independent means which indicate when and only when x-rays are being generated, unless the x-ray generation period is less than one-half second, in which case the indicators shall be activated for one-half second, and which are discernible from any point at which initiation of x-ray generation is possible. Failure of a single component

of the cabinet x-ray system shall not cause failure of both indicators to perform their intended function. One, but not both, of the indicators required by this subdivision may be a milliammeter labeled to indicate x-ray tube current. All other indicators shall be legibly labeled ''X-RAY ON''.

(iv) Additional means other than milliammeters which indicate when and only when x-rays are being generated, unless the x-ray generation period is less than one-half second in which case the indicators shall be activated for one-half second, as needed to insure that at least one indicator is visible from each door, access panel, and port, and is legibly labeled ''X-RAY ON''.

(7) *Additional controls and indicators for cabinet x-ray systems designed to admit humans.* For cabinet x-ray systems designed to admit humans there shall also be provided:

(i) A control within the cabinet for preventing and terminating x-ray generation, which cannot be reset, overridden or bypassed from the outside of the cabinet.

(ii) No means by which x-ray generation can be initiated from within the cabinet.

(iii) Audible and visible warning signals within the cabinet which are actuated for at least 10 seconds immediately prior to the first initiation of x-ray generation after closing any door designed to admit humans. Failure of any single component of the cabinet x-ray system shall not cause failure of both the audible and visible warning signals.

(iv) A visible warning signal within the cabinet which remains actuated when and only when x-rays are being generated, unless the x-ray generation period is less than one-half second in which case the indicators shall be activated for one-half second.

(v) Signs indicating the meaning of the warning signals provided pursuant to paragraphs (c)(7) (iii) and (iv) of this section and containing instructions for the use of the control provided pursuant to paragraph (c)(7)(i) of this section. These signs shall be legible, accessible to view, and illuminated when the main power control is in the ''on'' position.

(8) *Warning labels.* (i) There shall be permanently affixed or inscribed on the cabinet x-ray system at the location of any controls which can be used to initiate x-ray generation, a clearly legible and visible label bearing the statement:

CAUTION: X-RAYS PRODUCED WHEN ENERGIZED

(ii) There shall be permanently affixed or inscribed on the cabinet x-ray system adjacent to each port a clearly legible and visible label bearing the statement:

CAUTION: DO NOT INSERT ANY PART OF THE BODY WHEN SYSTEM IS ENERGIZED—X-RAY HAZARD

(9) *Instructions.* (i) Manufacturers of cabinet x-ray systems shall provide for purchasers, and to others upon request at a cost not to exceed the cost of preparation and distribution, manuals and instructions which shall include at least the following technical and safety information: Potential, current, and duty cycle ratings of the x-ray generation equipment; adequate instructions concerning any radiological safety procedures and precautions which may be necessary because of unique features of the system; and a schedule of maintenance necessary to keep the system in compliance with this section.

(ii) Manufacturers of cabinet x-ray systems which are intended to be assembled or installed by the purchaser shall provide instructions for assembly, installation, adjustment and testing of the cabinet x-ray system adequate to assure that the system is in compliance with applicable provisions of this section when assembled, installed, adjusted and tested as directed.

(10) *Additional requirements for x-ray baggage inspection systems.* X-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and at similar facilities, shall be provided with means, pursuant to paragraphs (c)(10) (i) and (ii) of this section, to insure operator presence at the control area in a position which permits surveillance of the ports and doors during generation of x-radiation.

(i) During an exposure or preset succession of exposures of one-half second

or greater duration, the means provided shall enable the operator to terminate the exposure or preset succession of exposures at any time.

(ii) During an exposure or preset succession of exposures of less than one-half second duration, the means provided may allow completion of the exposure in progress but shall enable the operator to prevent additional exposures.

(d) *Modification of a certified system.* The modification of a cabinet x-ray system, previously certified pursuant to §1010.2 by any person engaged in the business of manufacturing, assembling or modifying cabinet x-ray systems shall be construed as manufacturing under the act if the modification affects any aspect of the system's performance for which this section has an applicable requirement. The manufacturer who performs such modification shall recertify and reidentify the system in accordance with the provisions of §§1010.2 and 1010.3 of this chapter.

[39 FR 12986, Apr. 10, 1974]

PART 1030—PERFORMANCE STANDARDS FOR MICROWAVE AND RADIO FREQUENCY EMITTING PRODUCTS

AUTHORITY: 21 U.S.C. 351, 352, 360, 360e–360j, 371, 381; 42 U.S.C. 263b–263n.

§1030.10 Microwave ovens.

(a) *Applicability.* The provisions of this standard are applicable to microwave ovens manufactured after October 6, 1971.

(b) *Definitions.* (1) *Microwave oven* means a device designed to heat, cook, or dry food through the application of electromagnetic energy at frequencies assigned by the Federal Communications Commission in the normal ISM heating bands ranging from 890 megahertz to 6,000 megahertz. As defined in this standard, ''microwave ovens'' are limited to those manufactured for use in homes, restaurants, food vending, or service establishments, on interstate carriers, and in similar facilities.

(2) *Cavity* means that portion of the microwave oven in which food may be heated, cooked, or dried.

(3) *Door* means the movable barrier which prevents access to the cavity during operation and whose function is to prevent emission of microwave energy from the passage or opening which provides access to the cavity.

(4) *Safety interlock* means a device or system of devices which is intended to prevent generation of microwave energy when access to the cavity is possible.

(5) *Service adjustments or service procedures* means those servicing methods prescribed by the manufacturer for a specific product model.

(6) *Stirrer* means that feature of a microwave oven which is intended to provide uniform heating of the load by constantly changing the standing wave pattern within the cavity or moving the load.

(7) *External surface* means the outside surface of the cabinet or enclosure provided by the manufacturer as part of the microwave oven, including doors, door handles, latches, and control knobs.

(8) *Equivalent plane-wave power density* means the square of the root-mean-square (rms) electric field strength divided by the impedance of free space (377 ohms).

(c) *Requirements*—(1) *Power density limit.* The equivalent plane-wave power density existing in the proximity of the external oven surface shall not exceed 1 milliwatt per square centimeter at any point 5 centimeters or more from the external surface of the oven, measured prior to acquisition by a purchaser, and, thereafter, 5 milliwatts per square centimeter at any such point.

(2) *Safety interlocks.* (i) Microwave ovens shall have a minimum of two operative safety interlocks. At least one operative safety interlock on a fully assembled microwave oven shall not be operable by any part of the human body, or any object with a straight insertable length of 10 centimeters. Such interlock must also be concealed, unless its actuation is prevented when access to the interlock is possible. Any visible actuator or device to prevent actuation of this safety interlock must not be removable without disassembly of the oven or its door. A magnetically operated interlock is considered to be