reference locations shall be the respective locations specified in §1020.32(d)(3)(i), (d)(3)(ii), or (d)(3)(v) for measuring compliance with air-kerma rate limits.

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

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

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

[70 FR 34039, June 10, 2005]

§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-ray with a shutter, the radiation emitted may not exceed 0.88 milligray (vice 100 milliroentgen exposure) in 1 hour at any point 5 cm outside the external surface of the housing of the scanning mechanism when the shutter is closed. Compliance shall be determined by measurements average over an area of 100 square cm with no linear dimension greater than 20 cm.

(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).

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§ 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