Kansas Administrative Regulations

Department of Health and Environment

Article 35.—Radiation

28-35-248a. Computed tomography (CT) X-ray systems.

(a) Definitions. In addition to the definitions in part 1 of these regulations, the following definitions shall be applicable to this regulation:

(1) "Computed tomography dose index" and "CTDI" mean the integral from -7T to +7T of the dose profile along a line perpendicular to the tomographic plane divided by the product of the normal tomographic section thickness and the number of tomograms produced in a single scan, as follows:

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

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" and "CS" mean the change in the linear attenuation coefficient per CTN relative to water, as follows:

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

where:

μ_x	=	Linear attenuation coefficient of the material of interest;

μ_w = linear attenuation coefficient of water;

CTN_x = average CTN of the material of interest;

CTN_w = average CTN of water.

(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 technique factors.

(4) "CT gantry" means the tube housing assemblies, beam-limiting devices, and detectors and the supporting structures and frames that hold these components.

(5) "CT number" and "CTN" mean the number used to represent the X-ray attenuation associated with each elemental area of the CT image, as follows:

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

where:

k = A constant, which is normally 1,000 when the Houndsfield scale of CTN is used;

μ_x = linear attenuation coefficient of the material of interest; and

μ_w = linear attenuation coefficient of water.

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

(7) "Elemental area" means the smallest area within a tomogram for which the X-ray attenuation properties of a body are depicted.

(8) "Multiple tomogram system" means a computed tomography X-ray system that obtains X-ray transmission data simultaneously during a single scan to produce more than one tomogram.

(9) "Noise" means the standard deviation of the fluctuations in CTN expressed as a percentage of the attenuation coefficient of water. Noise is estimated using the following equation:

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

where:

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

(10) "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 the X-ray transmission data are collected.

(11) "Picture element" means an elemental area of a tomogram.

(12) "Reference plane" means a plane that is displaced from and parallel to the tomographic plane.

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

(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 the displacement.

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

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

(17) "Single tomogram system" means a CT X-ray system that obtains X-ray transmission data during a scan to produce a single tomogram.

(18) "Tomographic plane"means the geometric plane that is identified 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.

(b) Requirements for equipment.

(1) Termination of exposure.

(A) A means shall be provided to terminate the X-ray exposure automatically by either de-energizing the X-ray source or shuttering the X-ray beam if equipment failure affecting data collection occurs. This 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 that monitor equipment function.

(B) A visible signal shall indicate when the X-ray exposure has been terminated as specified in paragraph (b)(1)(A).

(C) Each operator shall be able to terminate the X-ray exposure at any time during a scan, or series of scans under CT X-ray systems control, of greater duration than one-half second.

(2) Tomographic plane indication and alignment.

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

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

(C) If a device using a light source is used, the light source shall provide illumination levels sufficient to permit the visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.

(3) Beam-on and shutter-status indicators and control switches.

(A) The CT X-ray control and gantry shall provide a visual indication whenever X-rays are produced and, if applicable, whether the shutter is open or closed.

(B) Each emergency button or switch shall be clearly labeled as to its function.

(4) Indication of CT conditions of operation. The CT X-ray system shall be designed so that the CT conditions of operation to be used during a scan or a scan sequence shall be indicated before the initiation of a scan or a scan sequence. This requirement may

be met by permanent markings on equipment that has all or some of these conditions of operation at fixed values. An indication of the CT conditions of operation shall be visible from any position from which scan initiation is possible.

(5) Extraneous radiation. When data are not being collected for image production, the radiation adjacent to the tube port shall not exceed the levels permitted in these regulations.

(6) Maximum surface CTDI identification. The angular position where the maximum surface CTDI occurs shall be identified to allow for the reproducible positioning of a CT dosimetry phantom.

(7) Additional requirements applicable to CT X-ray systems containing a gantry manufactured after September 3, 1985.

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

(B) If the X-ray production period is less than one-half second, the indication of X-ray production shall be actuated for at least one-half second. Indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.

(C) The deviation of the indicated scan increment versus the actual increment shall not exceed plus or minus one millimeter for any mass weighing from 0 to 100 kilograms and resting on the support device. The patient-support device shall be adjusted in increments from a typical starting position to the maximum 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 range of positions.

(D) Premature termination of the X-ray exposure by the operator shall necessitate the resetting of the CT conditions of operation before the initiation of another scan.

(c) Facility design requirements.

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

(2) Viewing systems.

(A) Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be located so that the operator can observe the patient from the control panel.
(B) If the primary viewing system is an electronic means, an alternate viewing system, which may be electronic, shall be available for use if the primary viewing system fails.
(d) Surveys, calibrations, spot checks, and operating procedures.
(1) Surveys.
(A) All CT X-ray systems installed after the effective date of this regulation and those systems not previously surveyed shall have a survey performed by, or under the direction of, a qualified expert. In addition, the surveys shall be performed after each change in the facility or equipment that might cause a significant increase in radiation hazard.
(B) Each registrant shall obtain a written report of the survey from the qualified expert. The registrant shall make a copy of the report available to the department upon request.
(2) Radiation calibrations.
(A) The calibration of the radiation output of the CT X-ray system shall be performed by, or under the direction of, a qualified expert who is physically present at the facility during the calibration.
(B) The calibration of each CT X-ray system shall be performed at the intervals specified by a qualified expert and after any change or replacement of components that, in the opinion of the qualified expert, could cause any change in the radiation output.
(C) The calibration of the radiation output of each CT X-ray system shall be performed with a calibrated dosimetry system. The calibration of the system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding two years.
(D) One or more CT dosimetry phantoms shall be used in determining the radiation output of a CT X-ray system. Each phantom shall meet all of the following requirements and conditions of use:
(i) Each CT dosimetry phantom shall consist of right-circular cylinders of polymethyl methacrylate with a density of 1.19 plus or minus 0.01 grams per cubic centimeter. Each phantom shall be at least 14 centimeters in length and shall have a diameter of

32.0 centimeters for testing CT X-ray systems designed to image any section of the body and 16.0 centimeters for systems designed to image the head or for whole-body scanners operated in the head-scanning mode.

(ii) Each CT dosimetry phantom shall provide a means for the placement of one or more dosimeters along the axis of rotation and along a line parallel to the axis of rotation at 1.0 centimeter from the outer surface and within the phantom. A means for the placement of dosimeters or alignment devices at other locations may be provided.

(iii) The 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 by inclusion in the statement of maximum deviation for the value obtained using the phantom.

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

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

(F) Calibration shall meet all of the following requirements:

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

(ii) The CTDI along the two axes shall be measured. The CT dosimetry phantom shall be oriented so that the measurement point at 1.0 centimeter from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface CTDI identified. The CT conditions of operation shall correspond to typical values used by the registrant.

(iii) The required spot checks shall be made.

(G) The calibration procedures shall be in writing. Records of all calibrations performed shall be maintained for inspection by the department.

(3) Spot checks.

(A) The spot check procedures shall be in writing and shall have been developed by a qualified expert.
(B) The spot check procedures shall incorporate the use of a CT dosimetry phantom that has a capability of providing an indication of contrast scale, noise, nominal tomographic section thickness, and the resolution capability of the system for low-contrast and high-contrast objects, and of measuring the mean CTN for water or other reference material.
(C) All spot checks shall be included in the calibration and shall be made at time intervals and under system conditions specified by a qualified expert.
(D) The spot checks shall include acquisition of images obtained with the CT dosimetry phantom or phantoms using the same processing mode and CT conditions of operation that are used to perform calibrations. The images shall be retained in two forms as follows, until a new calibration is performed:
(i) Photographic copies of the images obtained from the image display device; and
(ii) images stored in digital form on a storage medium compatible with the CT X-ray system.
(E) Written records of the spot checks performed shall be maintained for inspection by the department.
(4) Operating procedures.
(A) The CT X-ray system shall not be operated except by an individual who has been specifically trained in its operation.
(B) Information shall be available at the control panel regarding the operation and calibration of the system. This information shall include the following:
(i) The dates of the latest calibration and spot checks and the location within the facility where the results of those tests can be obtained;
(ii) instructions on the use of the CT dosimetry phantom or phantoms, including the schedule of spot checks appropriate for the system, the allowable variations for the indicated parameters, and the results of at least the most recent spot checks conducted on the system;
(iii) the distance in millimeters between the tomographic plane and the reference plane, if a reference plane is utilized; and

(iv) a current technique chart available at the control panel that specifies, for each routine examination, the CT conditions of operation and the number of scans per examination.

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