Kansas Administrative Regulations

Department of Health and Environment

Article 35.—Radiation

28-35-244a. Radiographic imaging systems other than fluoroscopic, dental intraoral, or computed tomography X-ray systems.

(a) Beam-limiting devices, except for mammographic systems. Each registrant shall ensure that the useful beam is collimated to the area of clinical interest. This requirement shall be deemed to have been met if a positive beam-limiting device meeting the manufacturer's specifications and the requirements of this regulation has been used or if evidence of collimation is shown on at least three sides or three corners of the film, including projections from the shutters of the collimator, cone cutting at the corners, and borders at the film's edge.

(1) General-purpose stationary and mobile X-ray systems including X-ray systems used for veterinary purposes, other than portable X-ray equipment, installed after the effective date of these regulations.

(A) Each registrant shall use only X-ray systems provided with the means for independent stepless adjustment of at least two dimensions of the X-ray field.

(B) Each registrant shall ensure that a method is provided for visually defining the perimeter of the X-ray field. 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 two percent of the distance from the source to the center of the visually defined field when the surface upon which the visually defined field appears is perpendicular to the axis of the useful beam.

(C) An exemption from paragraphs (a)(1)(A) and (B) may be granted by the secretary for noncertified X-ray systems if the registrant submits a written application for the exemption and that application meets the following conditions:

(i) Demonstrates that it is impractical to comply with paragraphs (a)(1)(A) and (B); and

(ii) demonstrates that the purpose of paragraphs (a)(1)(A) and (B) will be met by other methods.

(2) Additional requirements for stationary general purpose X-ray systems. In addition to the requirements of paragraph (a)(1), each registrant shall ensure that all stationary general-purpose X-ray systems, both certified and noncertified, meet all of the following requirements:

(A) A method shall be provided to indicate when the axis of the useful 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 two percent of the SID, and to indicate the SID to within two percent.

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

(C) The indication of the field size dimensions and SID shall be specified in inches or centimeters, or both, and shall be such that aperture adjustments result in X-ray field dimensions in the plane of the image receptor that correspond to X-ray field dimensions indicated by the beam-limiting device to within two percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

(3) X-ray systems designed for one size of image receptor. Radiographic equipment designed for only one size of image receptor at a fixed SID shall be provided with the 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 two percent of the SID, or shall be provided with the means to both adjust the size of and align the X-ray field so that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

(4) X-ray systems other than those described in this subsection and X-ray systems used for veterinary purposes installed before the effective date of this regulation and all portable X-ray equipment used for veterinary purposes.

(A) A means shall be provided to limit the X-ray field in the plane of the image receptor so that the field does not exceed each dimension of the image receptor by

more than two percent of the SID when the axis of the useful beam is perpendicular to the plane of the image receptor.

(B) A means shall be provided to align the center of the X-ray field with the center of the image receptor to within two percent of the SID, or the means shall be provided to both adjust the size of and align the X-ray field so that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. Compliance shall be determined with the axis of the useful beam perpendicular to the plane of the image receptor.

(C) The requirements of paragraphs (a)(4)(A) and (B) may be met with an X-ray system that meets the requirements for a general-purpose X-ray system as specified in paragraph (a)(1) or, when alignment means are also provided, may be met with either of the following:

(i) An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirements for each combination of image receptor size and SID for which the system is designed, with each device having clear and permanent markings to indicate the image receptor size and SID for which the system is designed; or

(ii) a beam-limiting device having multiple fixed apertures sufficient to meet the requirements for each combination of image receptor size and SID for which the system 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.

(b) Radiation exposure control.

(1) Exposure initiation. A means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, including the depression of a switch. Radiation exposure shall not be initiated without a deliberate action. In addition, it shall not be possible to initiate an exposure when the timer is set to a “zero” or “off” position if either position is provided.

(2) Exposure indication. A means shall be provided for visual indication observable at or from the operator's protected position whenever X-rays are produced.

In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(3) Exposure termination. A means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. Except for dental panoramic systems, termination of each exposure shall cause the automatic resetting of the timer to its initial setting or to “zero.”

(A) Manual exposure control. An X-ray control shall be incorporated into each X-ray system so that each exposure can be terminated by the operator at any time, except for either of the following:

(i) During any exposure of one-half second or less; or

(ii) during serial radiography, when a means shall be provided to permit the completion of any single exposure of the series in process.

(B) Automatic exposure controls. When an automatic exposure control is provided, all of the following requirements shall be met:

(i) The mode of operation selected shall be indicated on the control panel.

(ii) If the X-ray tube potential is equal to or greater than 50 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.

(iii) The minimum exposure time for all equipment shall be equal to or less than one-sixtieth of a second or the time interval required to deliver 5 mAs, whichever is greater.

(iv) Either the product of the peak X-ray tube potential, current, and exposure time shall be limited to not more than 60 kWs per exposure, or the product of the X-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure. However, when the X-ray tube potential is less than 50 kVp, the product of the X-ray tube current and exposure time shall be limited to not more than 2,000 mAs per exposure.

(v) A visible signal shall indicate when an exposure has been terminated and manual resetting shall be required before further automatically timed exposures can be made.

(4) Exposure duration or timer linearity. For systems that provide for the independent selection of exposure time settings, the average ratios (X_1) of exposure to the indicated timer setting, in units of C $kg^{-1}s^{-1}$ (mR/s), obtained at any two clinically used timer settings shall not differ by more than 0.10 times their sum. This calculation is written as follows:

$$|X_1 - X_2| \leq 0.10(X_1 + X_2)$$

where X_1 and X_2 are the average C $kg^{-1}s^{-1}$ (mR/s) values obtained at each of two consecutive exposure time selector settings or at two settings differing by no more than a factor of three where the exposure time selector provides continuous selection.

(5) Exposure control location. The X-ray exposure control shall be placed so that the operator can view the patient while making any exposure.

(6) Operator protection, except for X-ray systems used for veterinary purposes.

(A) Stationary systems. Each stationary X-ray system shall be required to have the X-ray control in a protected area so that the operator is required to remain in that protected area during the entire exposure.

(B) Mobile and portable X-ray systems. Each mobile and each portable X-ray system shall meet the following requirements:

(i) If used for one week or more at the same location, including a room or a suite, meet the requirements of paragraph (b)(6)(A); or

(ii) except for department-approved handheld X-ray equipment, if used for less than one week at the same location, be provided with either a protective barrier that is at least two meters or 6.5 feet high for operator protection during exposures or a means to allow the operator to be at least two meters or 6.5 feet from the tube housing assembly and outside the path of the useful beam during the exposure.

(7) Operator protection for X-ray systems used for veterinary purposes. Except for department-approved handheld X-ray equipment, all stationary, mobile, or portable X-ray systems used for veterinary purposes shall be provided with either a protective

barrier that is at least two meters or 6.5 feet high for operator protection during exposures or a means to allow the operator to be at least 2.0 meters or 6.5 feet from the tube housing assembly and outside the path of the useful beam during exposures.

(c) Source-to-skin distance. Each mobile or portable radiographic system shall be provided with the means to limit the source-to-skin distance to equal to or greater than 30 centimeters, except for X-ray systems used for veterinary purposes or X-ray systems specifically approved by the FDA.

(d) Exposure reproducibility. When all technique factors are held constant, including control panel selections associated with automatic exposure control systems, the coefficient of variation of exposure for both manual and automatic exposure control systems shall not exceed 0.05. This requirement shall apply to all clinically used techniques.

(e) Prohibitions on X-ray equipment utilizing capacitor energy storage. X-ray equipment utilizing capacitor energy storage shall not be used to image humans two years after the effective date of this regulation.

(f) Radiation from X-ray equipment utilizing capacitor energy storage in standby status. The radiation emitted from the X-ray tube when the X-ray system is fully charged and the exposure switch, timer, or any discharge mechanism is not activated shall not exceed a rate of 0.26 microgray (mR exposure) in one minute at five centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

(g) Radiation from X-ray equipment utilizing capacitor energy storage when discharging. The radiation emitted from the X-ray tube when the X-ray system is discharged through the X-ray tube either manually or automatically by use of a discharge switch or deactivation of the input power shall not exceed an air kerma of 0.88 milligray (100 milliroentgens exposure) in one hour at 100 cm from the X-ray source with a beam-limiting device fully open. Compliance shall be determined by measurements of the maximum air kerma per discharge multiplied by the total number of discharges in one hour. The measurements shall be averaged over an area of 100 square cm with no linear dimension greater than 20 cm.

(h) Accuracy. Deviation of the measured technique factors from the indicated values of kVp and exposure time shall not exceed the limits specified for each X-ray system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed 10 percent of the indicated value for kVp and 20 percent for exposure time.

(i) mA and mAs linearity. The following requirements shall apply when the X-ray equipment is operated with a power supply as specified by the manufacturer for any fixed X-ray tube potential within the range of 40 percent to 100 percent of the maximum rated mA or mAs.

(1) X-ray equipment having independent selection of F tube current (mA). The average ratios of air kerma to the indicated milliampere-seconds product (mGy/mAs) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum. This calculation is written as follows:

$$|X_1 - X_2| \leq 0.10(X_1 + X_2)$$

where X_1 and X_2 are the average mGy/mAs values obtained at each of two consecutive mAs selector settings or at two settings differing by no more than a factor of three if the mAs selector provides continuous selection.

(2) X-ray equipment having selection of X-ray tube current-exposure time product (mAs). For X-ray equipment manufactured after May 3, 1994, the average ratios of air kerma to the indicated milliampere-seconds product (mGy/mAs) obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum. This calculation is written as follows:

$$|X_1 - X_2| \leq 0.10(X_1 + X_2)$$

where X_1 and X_2 are the average mGy/mAs values obtained at each of two consecutive mAs selector settings or at two settings differing by no more than a factor of three where the mAs selector provides continuous selection.

(3) Measuring compliance. Determination of compliance shall be based on at least four exposures taken within one hour, at each of the two settings specified by this subsection. These two settings may include any two focal spot sizes, unless 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 shall mean the nominal focal spot size specified by the X-ray tube manufacturer.

(j) Additional requirements applicable to certified systems only. Diagnostic X-ray systems incorporating one or more certified components shall be required to meet the following additional requirements that relate to that certified component or those certified components.

(1) Beam-limiting devices for stationary and mobile general-purpose X-ray systems.

(A) A means of stepless adjustment of the size of the X-ray field shall be provided. The minimum field size at an SID of 100 centimeters shall be equal to or less than five centimeters by five centimeters.

(B) If a light localizer is used to define the X-ray field, the localizer shall provide an average illumination of not less than 160 lux or 15 foot-candles at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based on measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems manufactured on and after May 27, 1980 shall be exempt from this requirement.

(C) The edge of the light field at 100 centimeters or at the maximum SID, whichever is less, shall have a contrast ratio, when corrected for ambient lighting, of not less than four for beam-limiting devices designed for use on stationary equipment and a contrast ratio of not less than three for beam-limiting devices designed for use on mobile equipment. The contrast ratio shall be defined as I_1/I_2 where I_1 is the illumination at three millimeters from the edge of the light field toward the center of the field and I_2 is the illumination at three millimeters from the edge of the light field away from the center of the field. Compliance shall be determined by using a measuring instrument that has an aperture of one millimeter in diameter.

(D) Each beam-limiting device manufactured after the effective date of this regulation shall numerically indicate the field size in the plane of the image receptor to which the beam-limiting device is adjusted.

(E) Compliance measurements shall be made at discrete SIDs and image receptor dimensions in common clinical use 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) SIDs of 100, 150, and 200 cm or 36, 40, 48, and 72 inches and nominal image receptor dimensions of 13, 18, 24, 30, 35, 40, and 43 cm or 5, 7, 8, 9, 10, 11, 12, 14, and 17 inches shall be acceptable for the compliance measurements of paragraph (j)(1)(E).

(2) Beam-limiting devices and alignment on stationary general-purpose X-ray systems equipped with positive beam limitation. If PBL is being used, all of the following requirements shall be met:

(A) The PBL shall prevent the production of X-rays when any of the following occurs:

(i) The length or width of the X-ray field in the plane of the image receptor differs, except as permitted by paragraph (j)(2)(C), from the corresponding image receptor dimensions by more than three percent of the SID.

(ii) The sum of the length and width differences as stated in paragraph (j)(2)(A)(i), without regard to sign, exceeds four percent of the SID.

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

(B) Compliance with paragraph (j)(2)(A) shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor. Compliance shall be determined no sooner than five seconds after insertion of the image receptor.

(C) The PBL system shall be capable of operation, at the discretion of the operator, so that the size of the field can be made smaller than the size of the image receptor through stepless adjustment of the field size. The minimum field size at an SID of 100 centimeters shall be equal to or less than five centimeters by five centimeters.

(D) The PBL system shall be designed so that if a change in image receptor does not cause an automatic return to PBL function as described in paragraph (j)(2)(A), then

any change of image receptor size or SID shall cause the automatic return to PBL function.

(E) A key shall be required for any PBL override capability that is accessible to the operator. It shall not be possible to remove the key while PBL is overridden. This override capability may be for all SIDs and image receptor sizes. Each key switch or key shall be clearly and durably labeled “For X-ray Field Limitation System Failure.”

The override capability shall be considered accessible to the operator if the override capability is referenced in the operator’s manual or in other substance intended for the operator or if the override capability is in a location that the operator would consider the override capability part of the operational controls.

(F) If a facility permanently disables a PBL system, the standards for manual collimation shall apply.

(3) Beam-limiting devices for portable X-ray equipment. Beam-limiting devices for portable X-ray equipment shall meet the beam-limiting device requirements in paragraph (a)(1) or (j)(2).

(k) Tube stands for portable X-ray equipment. A tube stand or other mechanical support shall be used for portable X-ray equipment, so that the X-ray tube housing assembly is stationary and does not need to be held in the operator’s hands during exposures.

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***** Authenticated Kansas Administrative Regulation *****