Kansas Administrative Regulations

Department of Health and Environment

Article 35.—Radiation

28-35-247a. Intraoral dental radiographic imaging systems.

In addition to K.A.R. 28-35-242a and 28-35-242b, this regulation shall apply to all X-ray equipment and the associated facilities used for dental radiography. The requirements for extraoral dental radiographic imaging systems shall be those requirements specified in K.A.R. 28-35-244a. Each registrant shall use only X-ray systems meeting the requirements of this regulation.

(a) Source-to-skin distance. X-ray systems designed for use with an intraoral image receptor shall be provided with a means to limit the SSD to not less than 18 centimeters.

(b) kVp limitations. Dental X-ray equipment with a nominal fixed kVp of less than 51 kVp shall not be used to make diagnostic dental radiographs of humans.

(c) Beam-limiting devices. Each radiographic imaging system designed for use with an intraoral image receptor shall be provided with a means to limit the useful beam so that the useful beam at the minimum SSD is containable in a circle with a diameter of no more than seven centimeters. An open-ended position indication device shall be used and shall provide the same degree of protection as the housing. Pointed PIDs shall not be used. The operator shall position the end of the PID as close as practicable to the skin of the patient. The useful beam shall be limited to the area of clinical interest.

(d) Radiation exposure control.

(1) Exposure initiation.

(A) 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 the operator’s deliberate action.

(B) When the timer is set to a “zero” or “off” position, if either position is provided, an exposure shall not be possible.

(2) Exposure indication. A means shall be provided for a 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) A means shall be provided to terminate each 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.

(B) An X-ray exposure control shall be incorporated into each X-ray system so that each exposure can be terminated by the operator at any time, except for exposures of one-half second or less.

(C) Each termination of an exposure shall cause the automatic resetting of the timer to its initial setting or to “zero.”

(4) Exposure duration or timer linearity. For each X-ray system that provides 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 time settings shall not differ by more than 0.10 times their sum. The linearity is calculated using the following equation:

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

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 when the exposure time selector provides continuous selection.

(5) Exposure control location and operator protection.

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

(B) Each X-ray system using mobile X-ray equipment or portable X-ray equipment used for one week or longer in the same location, including a room or suite, shall meet the requirements of this regulation.

(C) Each X-ray system using mobile X-ray equipment or portable X-ray equipment used for less than one week in the same location shall be provided either with a protective barrier that is at least two meters (6.5 feet) high for operator protection or with the means to allow the operator to be at least 2.0 meters (6.5 feet) from the tube housing assembly and outside the path of the useful beam while making exposures.

(e) Reproducibility. When the X-ray equipment is operated with an adequate power supply as specified by the manufacturer, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05 for any specific combination of selected technique factors.

(f) mA and mAs linearity. The requirements specified in this subsection 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 X-ray 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 ratio is calculated using the following equation:

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

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 when the mAs selector provides continuous selection.

(2) X-ray equipment having selection of X-ray tube current-exposure time product (mAs). For 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 ratio is calculated using the following equation:

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

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 two when 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 two settings. 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 regulation, “focal spot size” shall mean the nominal focal spot size specified by the X-ray tube manufacturer.

(g) Accuracy. The deviation of technique factors from the indicated values for kVp and exposure time, if time is independently selectable, shall not exceed the limits specified for that 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 time.

(h) Intraoral handheld X-ray equipment. In addition to the requirements of these regulations, the following requirements shall apply to handheld X-ray equipment:

(1)(A) No handheld X-ray equipment shall be sold or used in Kansas without approval by the U.S. food and drug administration and by the department.

(B) The handheld X-ray equipment shall be equipped with a backscatter shield of not less than 0.25 mm lead equivalent and 15.2 cm (6 inches) in diameter that is positioned as close as practicable to the distal end of the position indication device during use.

(2)(A) Each registrant shall adopt and follow protocols provided by the manufacturer and approved by the department regarding the safe operation of the handheld X-ray equipment. Each registrant shall secure the handheld X-ray equipment from unauthorized removal or use.

(B) Each registrant shall notify the department at least five days before use if the handheld X-ray equipment is to be used at locations other than those approved by the department.

(C) Each registrant shall maintain documentation that each operator has completed training as specified by the manufacturer and approved by the department.

(D) In addition to the records required by K.A.R. 28-35-242a(b), each registrant shall record the following:

(i) The manufacturer of each handheld X-ray system; and

(ii) the date of manufacture of each handheld X-ray system.

(E) Each registrant shall maintain for review a copy of all correspondence with the department, unit manufacturer, vendor, and registrant. The documents shall be in hard copy or electronic form. These documents shall be maintained until the handheld X-ray system is disposed of as specified in K.A.R. 28-35-165.

(3) Each operator shall wear an apron and thyroid shield of at least 0.25 mm lead equivalent, unless otherwise authorized by the department, when operating intraoral handheld X-ray equipment. Each operator shall use a stand to immobilize the handheld X-ray equipment if the operator has difficulty holding the handheld X-ray equipment stationary during the exposure.

(i) Administrative controls.

(1) Patient-holding and film-holding devices shall be used when the techniques permit.

(2) Except for handheld X-ray equipment, the tube housing and the position indication device (PID) shall not be held in the operator’s hands during an exposure.

(3) Each X-ray system shall be operated so that the useful beam at the patient's skin does not exceed the requirements of this regulation.

(4) Dental fluoroscopy without image intensification shall not be used.

(5) Handheld X-ray equipment shall not be used on a patient at any of the following locations unless the registrant has obtained prior written approval from the department:

(A) Within six feet of any bystander, unless the bystander is protected by a barrier of at least one-inch gypsum equivalent;

(B) in hallways or waiting rooms; or

(C) outside of treatment areas.

(j) Training requirements.

(1) In addition to the training specified in K.A.R. 28-35-256, each operator shall complete the following training:

(A) If using film, how to maintain a light-tight darkroom and use proper safe lighting and safeguards;

(B) if using film, how to perform evaluations of darkroom integrity and daylight loading systems for film fog on a semiannual basis or after a change that could impact film fog; and

(C) if using a filmless system, how to maintain and operate photostimulable phosphor (PSP) and direct digital radiography (DDR) systems according to manufacturer specifications.

(2) Each registrant shall provide initial training and annual evaluations of X-ray operators that includes the following:

(A) Positioning of the X-ray tube;

(B) image processing;

(C) operator location during X-ray exposure;

(D) source-to-skin distance;

(E) radiation protection;

(F) appropriate radiographic protocols; and

(G) applicable regulatory requirements.

(3) Each registrant shall maintain records of training and annual evaluations specified in paragraph (j)(2) for inspection by the department.

(Authorized by and implementing K.S.A. 48-1607; effective Dec. 30, 2005; amended Oct. 23, 2026.)

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