Kansas Administrative Regulations

Department of Health and Environment

Article 35.—Radiation—Part 5. Use of X-Rays in the Healing Arts.

28-35-243a. Fluoroscopic X-ray systems.

Each fluoroscopic X-ray system used shall be image-intensified and shall meet the following requirements:

(a) Limitation of useful beam.

(1) Primary barrier.

(A) The fluoroscopic imaging assembly shall be provided with a primary protective barrier that intercepts the entire cross section of the useful beam at any SID.

(B) The X-ray tube used for fluoroscopy shall not produce X-rays unless the barrier is in position to intercept the entire useful beam.

(2) Fluoroscopic beam limitation.

(A) For certified fluoroscopic systems with or without a spot film device, 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 three percent of the SID. The sum of the excess length and the excess width shall be no greater than four percent of the SID.

(B) For uncertified fluoroscopic systems with a spot film device, the X-ray beam with the shutters fully opened during fluoroscopy or spot filming shall be no larger than the largest spot-film size for which the device is designed. Measurements shall be made at the minimum SID available but at a distance of not less than 20 centimeters from the tabletop to the film plane.

(C) For uncertified fluoroscopic systems without a spot film device, the requirements of this regulation shall apply.

(D) Other requirements for fluoroscopic beam limitation shall include the following:

(i) A 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 or a visible area of greater than 300 square centimeters, or both, shall be provided with a means for stepless adjustment of the X-ray field.

(ii) All equipment with a fixed SID and a visible area of 300 square centimeters or less shall be provided either with 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.

(iii) If provided, stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum attainable to a field size of five centimeters by five centimeters or less.

(iv) For equipment manufactured after February 25, 1978, if the angle between the image receptor and beam axis is variable, a means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor.

(v) For noncircular 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 that pass through the center of the visible area of the image receptor.

(3) Spot-film beam limitation. Each spot-film device shall meet the following requirements:

(A) A means shall be provided between the source and the patient for adjustment of the X-ray field size in the plane of the film, to the size of that portion of the film that has been selected on the spot film selector. This adjustment shall be automatically accomplished except when the X-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot-film devices manufactured after June 21, 1979, if the X-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option.

(B) 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 three percent of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum of the length and width differences, without regard to sign, shall not exceed four percent of the SID.

(C) It shall be possible to adjust the X-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to or less than five centimeters by five centimeters.

(D) The center of the X-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within two percent of the SID.

(E) For spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, a 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.

(4) Override. Each method used to override any of the automatic X-ray field size adjustments required in paragraphs (a)(2) and (3) shall meet the following requirements:

(A) Be designed for use only if system failure occurs;

(B) incorporate a signal visible at the fluoroscopist's position that indicates whenever the automatic field size adjustment is overridden; and

(C) be clearly and durably labeled with the following, or equivalent wording:

FOR X-RAY FIELD
LIMITATION SYSTEM FAILURE

(b) Activation of the fluoroscopic tube. All X-ray production in the fluoroscopic mode shall be controlled by a device that requires continuous manual activation by the fluoroscopist during the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the X-ray exposure or exposures at any time, but a means may be provided to permit completion of any single exposure of the series in process.

(c) Exposure rate limits.

(1) Allowable limits for the entrance exposure rate.

(A) Fluoroscopic equipment that is provided with an automatic exposure rate control shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 2.6 mC/kg (10 roentgens) per minute at the point where

the center of the useful beam enters the patient, except under either of the following conditions:

(i) When fluoroscopic images are being recorded; or

(ii) when an optional high-level control is provided. When provided, the X-ray system shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 1.3 mC/kg (5 roentgens) per minute at the point where the center of the useful beam enters the patient, unless the high-level control is activated. A 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.

(B) Fluoroscopic equipment that is not provided with an automatic exposure rate control shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 1.3 mC/kg (5 roentgens) per minute at the point where the center of the useful beam enters the patient, except during either of the following:

(i) When fluoroscopic images are being recorded; or

(ii) when an optional high-level control is activated. A special means of activation of the high-level control 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.

(C) Fluoroscopic equipment that is provided with both an automatic exposure rate control 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 2.6 mC/kg (10 roentgens) per minute in either mode at the point where the center of the useful beam enters the patient, except under either of the following conditions:

(i) When fluoroscopic images are being recorded; or

(ii) when the mode or modes have an optional high-level control. The 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 1.3 mC/kg (5 roentgens) per minute at the point where the center of the useful beam enters the patient, unless the high-level control is

activated. A special means of activating of the high-level control 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.

(D) Fluoroscopic equipment manufactured after May 19, 1995 that can exceed 1.3 mC/kg (5 roentgens) per minute shall be equipped with an automatic exposure rate control. All entrance exposure rate limits shall be 2.6 mC/kg (10 roentgens) per minute with an upper limit of 5.2 mC/kg (20 roentgens) per minute when the high-level control is activated.

(E) Compliance with the requirements of this subsection shall be determined as follows:

(i) If the source is below the X-ray table, the exposure rate shall be measured at one 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) For any fluoroscopy system capable of changing the X-ray beam orientation, which is also known as a C-arm system, the exposure rate shall be measured at 30 centimeters from the input surface of the fluoroscopic imaging assembly. The source may be positioned at any available SID, if 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) For a lateral-type fluoroscope, the exposure rate shall be measured at a point that is 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. A moveable tabletop 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.

(2) Periodic measurements of the entrance exposure rate shall be taken by a qualified expert for both the typical and the maximum values according to all of the following requirements:

(A) The measurements shall be taken annually and after any maintenance of the system that might affect the exposure rate.

(B) The results of these measurements shall be posted at a location where any fluoroscopist has ready access to the results while using the fluoroscope and in the record required by this regulation. The measurement results shall be stated in coulombs per kilogram (roentgens) per minute and shall include the technique factors used in determining the results. The name of the individual performing the measurements and the date on which the measurements were performed shall be included in the results.

(C) The conditions under which periodic measurements of the entrance exposure rate are taken shall meet the following requirements:

(i) Each measurement shall be made under the conditions that meet the requirements of this regulation.

(ii) The kVp, mA, and other selectable parameters shall be adjusted to those settings typical in clinical use for a patient with an abdomen that is 23 cm thick.

(iii) Each X-ray system that incorporates any automatic exposure rate controls shall have sufficient attentuative material placed in the useful beam to produce milliamperage and kilovoltage that meet the requirements of this regulation.

(D) The conditions under which periodic measurements of the maximum entrance exposure are taken shall meet the following requirements:

(i) The measurement shall be made under the conditions that meet the requirements of this regulation.

(ii) The kVp, mA, and other selectable parameters shall be adjusted to those settings that produce the maximum entrance exposure rate.

(iii) Each X-ray system that incorporates automatic exposure rate controls shall have sufficient attentuative material placed in the useful beam to produce the maximum entrance exposure rate of the system.

(d) Barrier-transmitted radiation rate limits.

(1) The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed 0.5 μC/kg (2 milliroentgens) per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond

the plane of the image receptor for each mC/kg (4 roentgens) per minute of entrance exposure rate.

(2) Measuring compliance of barrier transmission.

(A) The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measuring the radiation averaged over an area of 100 square centimeters, with no linear dimension greater than 20 centimeters.

(B) If the source is below the tabletop, the measurement shall be taken with the input surface of the fluoroscopic imaging assembly positioned at 30 centimeters above the tabletop.

(C) If the source is above the tabletop and the SID is variable, the measurement shall be taken with the end of the beam-limiting device or spacer placed as close to the tabletop as possible, but not closer than 30 centimeters.

(D) All movable grids and compression devices shall be removed from the useful beam during the measurement.

(e) Indication of potential and current. During fluoroscopy and cinefluorography, the kV and the mA shall be continuously indicated.

(f) Source-to-skin distance (SSD). Unless otherwise approved by the food and drug administration, the SSD shall not be less than the following:

(1) 38 centimeters on stationary fluoroscopic systems manufactured on or after August 1, 1974;

(2) 35.5 centimeters on stationary fluoroscopic systems manufactured before August 1, 1974;

(3) 30 centimeters on all mobile fluoroscopes; and

(4) 20 centimeters for all mobile fluoroscopes when used for specific surgical applications.

(g) Fluoroscopic timer.

(1) A method shall be provided to preset the cumulative amount of time during which the fluoroscopic X-ray tube is on. The maximum cumulative amount of time during which the fluoroscopic X-ray tube is on shall not exceed five minutes without resetting the timing device.

(2) A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative time. The signal shall continue to sound while X-rays are produced until the timing device is reset.

(h) Control of scattered radiation.

(1) Each fluoroscopic table, when combined with the medical procedures performed, shall be such that no unprotected part of the body of any staff member or ancillary individual shall be exposed to unattenuated scattered radiation that originates from under the table. The attenuation required shall be not less than 0.25 millimeter lead-equivalent.

(2) The equipment configuration and operating procedures used shall prevent any portion of the body of any staff member or ancillary individual, except the extremities, from being exposed to the unattenuated scattered radiation emanating from above the tabletop, unless either of the following conditions is met:

(A) The individual is at least 120 centimeters from the center of the useful beam.

(B) The radiation has passed through not less than 0.25 millimeter of lead-equivalent material including drapes, a bucky-slot cover panel, and self-supporting curtains, in addition to any lead equivalency provided by any protective apron.

(3) Exemptions to paragraph (h)(2) may be granted by the secretary if a sterile field does not permit the use of the normal protective barriers. If the use of prefitted sterilized covers for the barriers is practical, an exemption shall not be granted. Exceptions shall be automatically granted for the following fluoroscopic procedures only if a sterile field does not permit the use of the normal protective barriers:

(A) Angiograms;

(B) arthrograms;

(C) biliary drainage procedures;

(D) fluoroscopic biopsy procedures;

(E) myelograms;

(F) percutaneous cholangiograms;

(G) percutaneous nephrostomies;

(H) sinograms or fistulograms; and

(I) T-tube cholangiograms.

(i) Spot-film exposure reproducibility. Each fluoroscopic system equipped with a spot-film mode shall meet the exposure reproducibility requirements of K.A.R. 28-35-244a when operating in the spot-film mode.

(j) Radiation therapy simulation systems. Each radiation therapy simulation system shall be exempt from the requirements of subsection (c) of this regulation. In addition, this type of system shall be exempt from the following:

(1) The requirements of subsections (a) and (d) of this regulation, if the system is designed and used so that no individual other than the patient is in the X-ray room when the system is producing X-rays; and

(2) the requirements of subsection (g) of this regulation, if the system is provided with a means of indicating the cumulative time that an individual patient has been exposed to X-rays. Procedures shall be established to require that the cumulative time be reset between examinations.

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