

902 KAR 100:120. General diagnostic radiography.

RELATES TO: KRS 211.842-211.852, 211.990(4)

STATUTORY AUTHORITY: KRS 194.050, 211.090, 211.844

NECESSITY, FUNCTION, AND CONFORMITY: The Cabinet for Human Resources is authorized by KRS 211.844 to provide by administrative regulation for the registration and licensing of the possession or use of sources of ionizing or electronic product radiation and the handling and disposal of radioactive waste. The purpose of this administrative regulation is to provide special requirements for the possession, use, and operation of radiographic x-ray systems used in relation to the healing arts, except systems used for dental intra-oral or veterinary radiography.

Section 1. Applicability. This administrative regulation shall apply to radiographic x-ray systems used in relation to the healing arts, except dental intra-oral, fluoroscopic, veterinary radiographic, or computed tomography and to persons, equipment and materials used in connection with the possession, use or operation of the systems.

Section 2. Permanent Structural Shielding. Permanent structural shielding and protective barriers shall be used as necessary to insure that no person other than the patient receives a dose equivalent in excess of the limits specified in these regulations.

Section 3. Beam Limitation. The useful beam shall be limited to the area of clinical interest as follows:

(1) General purpose stationary and mobile x-ray systems.

(a) A means shall be provided for stepless adjustment of the size of the x-ray field. The minimum field size at an SID of 100 centimeters shall be equal to or less than five (5) by five (5) centimeters;

(b) No dimension of the x-ray field, measured in the plane of the image receptor, shall exceed the corresponding dimension of the image receptor by more than two (2) percent of the source to image receptor distance (SID) measured if the plane of the image receptor is perpendicular to the primary ray of the x-ray field; and

(c) A method shall be 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 (2) percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

(d) The cabinet may grant an exemption as provided by 902 KAR 100:015 Section 7(1) on non-certified x-ray to the requirements of paragraphs (a) and (c) of this subsection for equipment registered prior to the effective date of this administrative regulation.

(2) In addition to the requirements of subsection (1) of this section, stationary general purpose x-ray systems, both certified and noncertified, shall meet the following requirements:

(a) A method shall be provided to indicate if the axis of the x-ray 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 (2) percent of the SID and to indicate the SID to within two (2) percent.

(b) The beam limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted; and

(c) Indication of field size dimensions and SID's shall be specified in inches or centimeters, so that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam limiting device to within two (2) percent of the SID if the beam axis is indicated to be perpendicular to the plane of the image receptor.

(3) Radiographic equipment designed for only one (1) image receptor size at a fixed SID shall be

provided with 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 (2) percent of the SID, or shall be provided with means to both size 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) Radiographic systems designed only for mammography and general purpose radiographic systems, if special attachments for mammography are in service, shall be provided with means to limit the useful beam so that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated SID except the edge of the image receptor designed to be adjacent to the chest wall where the x-ray field may not extend beyond this edge by more than two (2) percent of the SID. This requirement can be met with a system which performs as prescribed in subsection (5)(c) of this section. If the beam-limiting device and image receptor support device are designed to be used to immobilize the breast during a mammographic procedure and the SID may vary, the SID indication specified in subsection (5)(c) of this section shall be the maximum SID for which the beam limiting device or aperture is designed. In addition, each image receptor support intended for installation on a system designed only for mammography shall have clear and permanent markings to indicate the maximum image receptor size for which it is designed.

(5) For x-ray systems other than those described in subsections (1), (2), (3), (4) and (5) of this section:

(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 (2) percent of the SID if the axis of the x-ray beam is perpendicular to the plane of the image receptor and align the center of the x-ray field with the center of the image receptor to within two (2) percent of the SID, or means shall be provided to both size 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; or

(b) Shall meet the requirements for a general purpose x-ray system as specified in subsection (1) of this section; or

(c) If alignment means are also provided, an assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed with each device having clear and permanent markings to indicate the image receptor size and SID for which it is designed or a beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit 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.

Section 4. Field Limitation and Alignment on General Purpose X-ray Systems. (1) For stationary, general purpose x-ray systems which contain a tube housing assembly, an x-ray control, and, for those systems so equipped, a table, certified in accordance with 21 CFR 1020.30(c), positive beam limitation shall be provided if the following conditions are met:

(a) The image receptor is inserted into a permanently mounted cassette holder;

(b) The image receptor length and width are each less than fifty (50) centimeters;

(c) The x-ray beam axis is within plus or minus three (3) degrees of vertical and the SID is ninety (90) centimeters to 130 centimeters inclusive or the x-ray beam axis is within plus or minus three (3) degrees of horizontal and the SID is ninety (90) centimeters to 205 centimeters inclusive;

(d) The x-ray beam axis is perpendicular to the plane of the image receptor to within plus or minus three (3) degrees;

(e) Neither tomographic nor stereoscopic radiography is being performed; and

(f) The positive beam limitation (PBL) system has not been intentionally overridden in accordance

with subsection (3) of this section.

(2) PBL shall prevent the production of x-rays if;

(a) Either the length or width of the x-ray field in the plane of the image receptor differs, except as permitted by subsection (5) of this section, from the corresponding image receptor dimensions by more than three (3) percent of the SID; or

(b) The sum of the length and width differences as stated in paragraph (a) of this subsection without regard to sign exceeds four (4) percent of the SID.

(3) If a means of overriding the PBL system exists, that means:

(a) Shall be designed for use only in the event of PBL system failure or if the system is being serviced;

(b) Shall require that a key be utilized to defeat the PBL, that the key or key remain in place during the entire time the PBL system is overridden and that the key switch be clearly and durably labeled "For X-ray Field Limitation System Failure" if the means of overriding the PBL system is in a position that the operator would consider it part of the operational controls or if it is referenced in the operator's manual or in other materials intended for the operator; and

(c) Shall be used only for that period of time necessary for the repair or service of the system.

(4) Compliance with subsection (2) of this section shall be determined if the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of subsection (1) of this section are met. Compliance shall be determined no sooner than five (5) seconds after insertion of the image receptor.

(5) The positive beam limitation system shall be capable of operation, at the discretion of the operator, so that the size of the field may 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 (5) by five (5) centimeters.

(6) 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 subsection (2) of this section, then any change of image receptor size or SID shall cause the automatic return.

Section 5. X-ray Control (Exposure Switch). (1) A control shall be incorporated into each x-ray system so such that an exposure can be terminated instantly except for exposures of one-half (1/2) second or less, or during serial radiography a means shall be provided to permit completion of a single exposure of the series in process.

(2) The location of x-ray exposure controls on stationary x-ray systems shall be regulated as follows:

(a) Stationary x-ray systems shall be required to have the x-ray control permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure; and

(b) The exposure controls shall be behind a window of lead equivalent glass equal to that required by the adjacent barrier or an appropriate viewing system shall be provided so that the operator can see the patient without having to leave the protected area during the exposure.

(3) Mobile and portable x-ray systems which are used for one (1) week or more in one (1) location (one (1) room or suite), shall be considered stationary for the purposes of this administrative regulation and these systems shall meet the requirements of subsection (2) of this section.

(4) Mobile and portable x-ray systems which are used for greater than one (1) hour and less than one (1) week in one (1) location (one (1) room or suite) shall meet the requirement of subsection (3) of this section or be provided with a protective barrier one and nine-tenths (1.9) meters in height having a window of lead equivalent glass equal to that required of the barrier and placed at least one and eight-tenths (1.8) meters from the tube housing assembly and at least one and eight-tenths (1.8) meters from the patient.

(5) Mobile and portable x-ray systems which are used for one (1) hour or less in one (1) location (one (1) room or suite) shall meet the requirement of subsection (3) or (4) of this Section or be provided with a method of x-ray control that permits the operator to be at least three and six-tenths (3.6) meters from the tube housing assembly during an exposure.

Section 6. Automatic Exposure Controls (Phototimers). If an automatic exposure control is utilized, the following requirements shall be met:

(1) An indicator shall be provided on the control panel to indicate if this mode of operation is selected;

(2) If the x-ray tube potential is equal to or greater than fifty (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 (2) pulses;

(3) The minimum exposure time for equipment other than that specified in subsection (2) of this section shall be equal to or less than one-sixtieth (1/60) second or a time interval required to deliver five (5) mAs, whichever is greater;

(4) The product of peak x-ray tube potential, current, and exposure time shall be limited to not more than sixty (60) kW per exposure or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except if the x-ray tube potential is less than fifty (50) kVp in which case the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and

(5) A visible signal shall indicate that an exposure has been terminated at the limits described in subsection (4) of this section, and manual resetting shall be required before further automatic time exposures can be made.

Section 7. Source to Skin or Image Receptor Distance. (1) All mobile or portable radiographic x-ray systems shall be provided with a durable, securely-fastened means to limit the source to skin distance to not less than thirty (30) centimeters.

(2) Radiographic x-ray systems shall be equipped with a device or reference, other than a collimator light localizer, which shall indicate reference, or measure the selected source to receptor distance to within two and five-tenths (2.5) centimeters.

Section 8. Standby Radiation from Capacitor Energy Storage Equipment. Radiation emitted from the x-ray tube if the exposure switch or timer is not activated shall not exceed a rate of two (2) milliroentgens per hour at five (5) centimeters from an accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

Section 9. Personnel Monitoring. Personnel monitoring shall be required for individuals operating portable or mobile x-ray systems.

Section 10. Linearity. On x-ray systems certified under the federal performance standard, if the equipment allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer in accordance with the requirements of applicable federal standards, for a fixed x-ray tube potential within the range of forty (40) to 100 percent of the maximum rating, the average ratios of exposure to the indicated milliampere-seconds product obtained at two (2) consecutive tube current settings shall not differ by more than one-tenth (0.1) times their sum $X_1 - X_2 < 0.10 (X_1 + X_2)$. (1 Ky.R. 412; eff. 2-5-75; Am. 3 Ky.R. 555; eff. 3-2-77; 12 Ky.R. 1395; eff. 3-4-86; Am. 18 Ky.R. 1550; eff. 1-10-92.)