

902 KAR 100:125. Fluoroscopic x-ray except for computed tomography x-ray systems.

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 fluoroscopic x-ray systems in the healing arts.

Section 1. Applicability. This regulation shall apply to fluoroscopic x-ray systems and to persons, equipment and materials used in connection with the possession and use or operation of these such systems.

Section 2. Equipment. Fluoroscopic x-ray systems shall meet the following requirements:

- (1) The tube housing assembly shall be of the diagnostic type;
- (2) Cones or shutters used to restrict the size of the useful beam shall provide the same degree of attenuation as required of the tube housing; and
- (3) Fluoroscopic imaging devices used for optical viewing which are not mechanically linked to the x-ray tube shall not be utilized.

Section 3. Protective Barrier and Field Size. (1) The fluoroscopic tube shall not be capable of producing x-rays unless the primary protective barrier is in position to intercept the entire useful beam.

(2) The entire cross-section of the useful beam shall be intercepted by the primary protective barrier of the fluoroscopic image assembly at every SID (e.g., source to image receptor distance).

Section 4. Limitation to the Imaging Surface. The x-ray field shall be restricted so that the following requirements are met:

(1) On nonimage-intensified fluoroscopic x-ray systems, the x-ray field shall not extend beyond the entire visible area of the image receptor. This requirement applies to field size during both fluoroscopic procedures and spot filming procedures. In addition:

- (a) Means shall be provided for stepless adjustment of the field size;
- (b) The minimum field size at the greatest SID shall be equal to or less than five (5) by five (5) centimeters;
- (c) Equipment manufactured after February 25, 1978, if the angle between the image receptor and the beam axis of the x-ray beam is variable, shall be provided with the means to indicate if the axis of the x-ray beam is perpendicular to the plane of the image receptor; and
- (d) Compliance with this subsection shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(2) On image-intensified fluoroscopic systems with manual shutter controls, the x-ray beam shall not exceed the area of the largest image receptor, if measured with the fluoroscopic image assembly positioned thirty-five and five-tenths (35.5) centimeters from the table top or panel surface, and with the manual shutter controls opened to the fullest extent. Collimators located between the image receptor and patients shall not be used to fulfill this requirement. Means shall be provided to reduce the x-ray field size to five (5) by five (5) centimeters or less at the maximum SID; or

(3) For image-intensified fluoroscopic equipment, neither the length nor 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 (3) percent of the SID. The sum of the excess length and width shall be no greater than four (4) percent of the SID.

(a) For rectangular 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 which pass through the center of the visible area of the image receptor.

(b) 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 shall be provided with means for stepless adjustment of the x-ray field. Equipment with a fixed SID and a visible area of 300 square centimeters or less shall be provided with stepless adjustment of the x-ray field or with means to further limit the x-ray field size at the plane of the image receptor to 125 square centimeters or less. Stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size of five (5) by five (5) centimeters or less.

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

(4) Spot film devices which are certified components shall meet the following additional requirements:

(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 the portion of the film which has been selected on the spot film selector. This adjustment shall be automatically accomplished except if 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) 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 (5) by five (5) centimeters;

(c) 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 (2) percent of the SID; and

(d) On spot film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate if 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.

(5) If a means exists to override the automatic x-ray field size adjustments required in this section, that means:

(a) Shall be designed for use only if the system fails:

(b) Shall incorporate a signal visible at the fluoroscopist's position which shall indicate if the automatic field size adjustment is overridden; and

(c) Shall be clearly and durably labeled as follows:

"FOR X-RAY FIELD LIMITATION SYSTEM FAILURE".

Section 5. Activation of the Fluoroscopic Tube. X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of an exposure. If recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposures, but means may be provided to permit completion of a single exposure of the series in process.

Section 6. Exposure Rate Limits. The entrance exposure rate allowable limits and requirements are as follows:

(1) The exposure rate at the point where the center of the useful beam enters the patient shall not exceed ten (10) roentgens per minute, except during recording of fluoroscopic images or if provided

with optional high level control;

(2) If provided with optional high level control, the equipment shall not be operable at a combination of tube potential and current which results in an exposure rate in excess of five (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 only be operable if continuous manual activation is provided by the operator.

(b) A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(3) Certified systems which do not incorporate an automatic exposure control shall not be operable at a combination of tube potential and current which results in an exposure rate in excess of five (5) roentgens per minute at the point where the center of beam enters the patient except during recording of fluoroscopic images or if provided with an optional high level control;

(4) Compliance with the entrance exposure rate limits shall be determined as follows:

(a) Movable grids and compression devices shall be removed from the useful beam during the measurement;

(b) If the source is below the table, exposure rate shall be measured one (1) centimeter above the tabletop or cradle;

(c) If the source is above the table, the exposure rate shall be measured at thirty (30) centimeters above the tabletop with the end of the beam limiting device or spacers positioned as closely as possible to the point of measurement;

(d) C-arm fluoroscopes, both stationary and mobile, shall meet the entrance exposure rate limits in subsections (1), (2) and (3) of this section thirty (30) centimeters from the input surface of the fluoroscope imaging assembly with the source positioned at an available SID if the end of the spacer assembly or beam-limiting device is not closer than thirty (3) centimeters from the input surface of the fluoroscopic imaging assembly.

(5) Periodic measurements of the exposure rate shall be made. An adequate period for these measurements shall be annually or after maintenance of the system which might affect the exposure rate;

(a) Results of these measurements shall be posted where a fluoroscopist has ready access to them while using that fluoroscopic x-ray system and in the records required by these administrative regulations. Results of the measurements shall include the exposure rate in roentgens per minute, as well as the physical factors used to determine the data, the name of the person who performed the measurements, and the date the measurements were performed;

(b) Conditions of periodic measurement of entrance exposure rate are as follows:

1. The kVp shall be the kVp typical of clinical use of the x-ray system;

2. The measurement shall be made under the conditions of subsection (4) of this section;

3. Fluoroscopic x-ray system(s) that incorporate automatic exposure control (e.g., automatic brightness control) shall have sufficient material placed in the useful beam to produce a milliamperage typical of the use of the fluoroscopic x-ray system; and

4. Fluoroscopic x-ray system(s) that do not incorporate automatic exposure control shall utilize a milliamperage typical of the clinical use of the fluoroscopic x-ray system. Materials (e.g., an attenuation block) shall be placed in the useful beam to protect the imaging system.

Section 7. Radiation Rate Limits Transmitted Through the Primary Barrier. 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 two (2) milliroentgens per hour at ten (10) centimeters from accessible surfaces of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.

The transmitted exposure rate shall be measured so that the following requirements are met:

- (1) The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than twenty (20) centimeters;
- (2) If the x-ray source is below the table top, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned thirty (30) centimeters above the table top;
- (3) If the x-ray source is above the table top and the SID is variable, the measurement shall be made with the end of the beam limiting device or spacer as close to the table top as it can be placed, except that it shall not be closer than thirty (30) centimeters;
- (4) Movable grids and compression devices shall be removed from the useful beam during the measurement; and
- (5) The attenuation block shall be positioned in the useful beam ten (10) centimeters from the point of measurement of the entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly.

Section 8. Indication of Tube Potential and Current. During fluoroscopy and cinefluorography, x-ray tube potential and current shall be continuously indicated on the control panel or within view of the fluoroscopist.

Section 9. Source to Skin Distance. The source to skin distance shall not be less than:

- (1) Thirty-eight (38) centimeters on stationary fluoroscopes certified under the federal performance standard;
- (2) Thirty-five and five-tenths (35.5) centimeters on stationary fluoroscopes which are not certified under the federal performance standard;
- (3) Thirty (30) centimeters on mobile fluoroscopic x-ray systems; or
- (4) Twenty (20) centimeters for image-intensified fluoroscopes used for specific surgical applications. The written safety procedures shall provide precautionary measures to be adhered to during the use of this device.

Section 10. Fluoroscopic Timer. A means shall be provided to preset the cumulative on-time of the fluoroscopic x-ray system. The fluoroscopic x-ray system shall not be able to be activated without this timer also being activated. The end of the predetermined period of irradiation shall be indicated by an audible signal. The audible signal shall continue until the timing device is reset. The maximum cumulative time of the timing device shall not exceed five (5) minutes without resetting.

Section 11. Mobile Fluoroscopes. Mobile fluoroscopic systems shall be provided with image intensification. It shall be impossible to operate mobile fluoroscopic systems unless the useful beam is intercepted by the image intensifier.

Section 12. Control of Scattered Radiation. (1) Fluoroscopic table designs combined with procedures utilized shall expose no unprotected part of staff or an ancillary person's body to unattenuated scattered radiation which originates from under the table. The attenuation required shall not be less than 0.25 mm lead equivalent; and

- (2) Equipment configuration design combined with procedures shall expose no portion of staff or an ancillary person's body, except the extremities, to the unattenuated scattered radiation emanating from above the tabletop unless that individual:
 - (a) Is at least 120 cm from the center of the useful beam, or
 - (b) The radiation has passed through not less than 0.25 mm lead equivalent material (e.g., leaded drapes, Bucky slot cover panel, or self supporting leaded curtains) in addition to lead equivalency

provided by protective aprons.

(3) Exceptions to subsection (2)(a) and (b) of this section may be made in some special procedures 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, the cabinet shall not permit an exception.

Section 13. Operating Procedures and Auxiliary Equipment. The following operating procedures and auxiliary equipment shall be utilized, if applicable, in the operation of a fluoroscopic x-ray system:

(1) Fluoroscopy performed by technologists shall be under the direction of a radiologist and be exclusively for localization purposes;

(2) Spot film images shall be obtained only by a licensed practitioner of the healing arts;

(3) Protective gloves of at least 0.25 mm lead equivalent shall be readily available to the fluoroscopist during every examination;

(4) The eyes of the fluoroscopist shall be adequately dark-adapted before using nonimage-intensified fluoroscopic x-ray systems;

(5) Extraneous light that interferes with the fluoroscopic examination shall be eliminated;

(6) Hand-held fluoroscopic screens shall not be used;

(7) Protective aprons of at least 0.25 mm lead equivalence shall be worn by the fluoroscopist and by persons in the fluoroscopic room except the patient during each examination;

(8) Fluoroscopic x-ray systems designed strictly for fluoroscopy shall not be used for spot filming or radiography; and

(9) Dental fluoroscopic x-ray systems without image intensification shall not be used.

Section 14. Radiation Therapy Simulation Systems. Radiation therapy simulation systems shall be exempt from the requirements of Sections 4, 6, and 10 of this administrative regulation if:

(1) Systems are designed and used in a manner that no individual other than the patient is in the x-ray room if the system is producing x-rays; and

(2) Systems which do not meet the requirements of Section 10 of this administrative regulation are provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. Procedures shall require in these cases that the timer be reset between examinations. 1 Ky.R. 413; eff. 2-5-75; Am. 3 Ky.R. 557; eff. 3-2-77; 12 Ky.R. 1397; eff. 3-4-86; 18 Ky.R. 1554; eff. 1-10-92.)