

902 KAR 100:115. Diagnostic x-ray.

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 requirements for the possession, use, and operation of diagnostic x-ray systems in relation to the healing arts.

Section 1. Applicability. This administrative regulation shall apply to diagnostic x-ray systems in relation to the healing arts, to persons, equipment and materials used in connection with the possession, use or operation of the systems.

Section 2. Warning Label. The control panel containing the main power switch shall bear the following warning statement or an equivalent statement, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

Section 3. Battery Charge Indicator. On battery-powered x-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

Section 4. Leakage Radiation from the Diagnostic Source Assembly. The leakage radiation from the diagnostic source assembly measured at distances of one (1) meter from the source shall not exceed 100 milliroentgens in one (1) hour if the x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than twenty (20) centimeters.

Section 5. Radiation from Components other than the Diagnostic Source Assembly. The radiation emitted by a component other than the diagnostic source assembly shall not exceed two (2) milliroentgens in one (1) hour at five (5) centimeters from accessible surfaces of the component if it is operated in an assembled x-ray system under conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than twenty (20) centimeters.

Section 6. Beam Quality. (1) The half-value layer (HVL) of the useful beam for a given x-ray tube potential shall not be less than the values shown in the following table:

TABLE OF ACCEPTABLE HALF-VALUE LAYER (HVL)		
Design operating range (Kilovolts peak)	Measured potential (Kilovolts peak)	Half-value Layer (Millimeters of aluminum)
Below 50	30	0.3
	40	0.4
	49	0.5

50 to 70	50	1.2
	60	1.3
	70	1.5
Above 70	71	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1

(2) If it is necessary to determine the half-value layer at an exposure tube potential which is not listed in the table above, linear interpolation or extrapolation may be made;

(3) The above HVL criteria is considered to have been met if it can be demonstrated that the aluminum equivalent of the total filtration in the primary beam is not less than that shown in the following table:

TABLE OF FILTRATION REQUIRED VS. OPERATING VOLTAGE	
Operating Voltage (kVp)	Total Filtration (inherent plus added) (millimeters aluminum equivalent)
Below 50	0.5
50 - 70	1.5
Above 70	2.5

(4) X-ray tubes with beryllium windows shall have a minimum of five-tenths (0.5) mm aluminum equivalent filtration permanently mounted in the useful beam;

(5) For capacitor energy storage equipment, compliance shall be determined with the maximum quantity of charge per exposure; and

(6) The required minimal aluminum equivalent filtration shall include the filtration contributed by materials which are always present between the focal spot of the tube and the patient (e.g., a tabletop if the tube is mounted "under the table" and inherent filtration of the tube).

Section 7. Filtration Controls. For x-ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) which prevents an exposure unless the minimum required amount of filtration is in the useful beam for the given kVp which has been selected.

Section 8. Mechanical Support of the Tube Head. The tube housing assembly supports shall be adjusted so that the tube housing assembly remains stable during an exposure unless the tube housing movement is a designed function of the x-ray system.

Section 9. Technique and Production Indicators. (1) The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated.

(2) The requirement of technique indicators may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

(3) A means shall be provided which gives positive indication of the production of x-rays if the x-ray tube is energized.

(4) On machines certified under the federal performance standard; and

(a) A visual indication of the production of x-rays and an audible signal indicating the exposure is terminated shall be provided; and

(b) Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer.

Section 10. Timers. Timers shall meet the following requirements:

(1) A means shall be provided to automatically terminate the exposure at a preset time interval, preset product of current and time, preset number of pulses, or a preset radiation exposure of the image receptor;

(2) Automatic termination of the exposure shall cause automatic resetting of the timer to its initial setting or to zero, except for dental panoramic systems. The timer shall not be capable of making an exposure if the timer is set to a zero or off position if either is provided;

(3) If four (4) timer tests are performed at identical timer settings, the average time period (T_{ave}) shall be greater than five (5) times the maximum period (T_{max}) minus the minimum period (T_{min}), (T_{ave}) greater than five (5) (T_{max} minus T_{min}).

Section 11. Exposure Switch. The exposure switch shall be of the dead man type.

Section 12. Exposure Reproducibility. The exposure produced shall be reproducible so that if technique factors are held constant, the coefficient of variation shall not exceed one-tenth (0.1). This requirement shall be deemed to have been met if, four (4) exposures at identical technique factors are made, the value of the average exposure (E_{ave}) is greater than five (5) times the maximum exposure (E_{max}) minus the minimum exposure (E_{min}), (E_{ave}) greater than five (5) (E_{max} minus E_{min}). If the diagnostic x-ray system is certified, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05 for specific combination of selected technique factors.

Section 13. Technique Chart. In the vicinity of each x-ray system's control panel a chart shall be provided which specifies for examinations which are performed by that system a list of information for each projection within that examination. The chart shall include but not be limited to the following:

(1) The patient's anatomical size versus technique factors to be utilized;

(2) The type and size of the film or film-screen combination to be used;

(3) The type and focal distance of the grid to be used, if used;

(4) The source to image receptor distance to be used; and

(5) The type and location of gonadal shielding to be used, if used.

Section 14. Personnel in X-ray Room. Except for patients who cannot be moved out of the room, only staff and ancillary personnel required for the medical procedure or training shall be in the room during the radiographic exposure. The patients and personnel shall be protected as follows:

(1) Other than the patient being examined, individuals in the x-ray room shall be positioned so that no part of the body not protected by five-tenths (0.5) mm lead equivalent, is struck by the useful beam.

(2) Staff and ancillary personnel shall be protected from direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 mm lead equivalent;

(3) Patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of not less than 0.25 mm lead equivalent or shall be so positioned that the nearest portion of the body is at least two (2) meters from both the tube head and the nearest edge of the image receptor; and

(4) If a portion of the body of staff or ancillary personnel is potentially subjected to stray radiation which results in that individual receiving one-quarter (1/4) of the maximum permissible dose as defined in these administrative regulations, additional protective devices may be required by the cabinet.

Section 15. Examination Information. Each facility shall maintain written records of each examination. The records shall include but not be limited to the following:

- (1) Appropriate patient identification data, including name, Social Security number, age and sex;
- (2) Date of examination;
- (3) A description of the examination or treatment given by routine or local title as denoted on the technique chart;
- (4) Deviation from standard procedure or technique, including repeat exposures, as denoted in the technique chart;
- (5) The x-ray system used, if there is more than one (1) system per facility;
- (6) the name of the person who performed the exam;
- (7) the name of the individual who ordered the exam; and
- (8) The name of the human holder.

Section 16. Image Interpretation. Each image (film, film set, etc.) shall be interpreted by a licensed practitioner, and a permanent record shall be made of the interpretation of the total examination.

Section 17. Gonadal Shielding. Gonadal shielding of not less than 0.25 millimeter lead equivalent shall be used for patients who have not passed the reproductive age during radiographic procedures in which the gonads are in the beam except for cases in which this would interfere with the diagnostic procedure.

Section 18. Procedures and Ancillary Equipment. Procedures and ancillary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized. The procedures and equipment shall include but not be limited to the following:

- (1) The speed of the film or film and screen combination shall be the fastest consistent with the diagnostic objective of the examination;
- (2) Portable and mobile equipment shall be used only for examinations if it is impractical to transfer the patient to a stationary radiographic installation; and
- (3) Radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.

Section 19. Multiple Tubes. If two (2) or more radiographic tubes are controlled by one (1) exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the x-ray control panel and at or near the tube housing assembly which has been selected. (1 Ky.R. 412; eff. 2-5-75; Am. 3 Ky.R. 553; eff. 3-2-77; 12 Ky.R. 1392; eff. 3-4-86; Am. 18 Ky.R. 1546; eff.1-10-92.)