Kansas Administrative Regulations

Department of Health and Environment

Article 35.—Radiation

28-35-242b. General requirements for all diagnostic X-ray systems.

In addition to meeting the other requirements of this part, each diagnostic X-ray system shall meet the following requirements:

(a)Warning label. The control panel containing the main power switch shall bear this or an equivalent warning statement, which shall be legible and accessible to view: "WARNING: This X-ray unit could be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

(b) Battery charge indicator. On each battery-powered X-ray generator, a visual means shall be provided on the control panel to indicate whether the battery is in a state of charge for proper operation.

(c) Leakage radiation from the diagnostic source assembly. The leakage radiation from the diagnostic source assembly measured at a distance of one meter in any direction from the source shall not exceed 25.8 μC/kg (100 milliroentgens) in one hour when the X-ray tube is operated at the leakage technique factors specified by the manfacturer. Compliance shall be determined by measuring the leakage radiation averaged over an area of 100 square centimeters, with no linear dimension greater than 20 centimeters.

(d) Radiation from components other than the diagnostic source assembly. The radiation emitted by a component other than the diagnostic source assembly shall not exceed 0.5 μC/kg (2 milliroentgens) in one hour at five centimeters from an accessible surface of the component in an assembled X-ray system operated under any design conditions. Compliance shall be determined by measuring the radiation averaged over an area of 100 square centimeters, with no linear dimension greater than 20 centimeters.

(e) Beam quality.

(1) Half-value layer.

(A) The half-value layer of a given X-ray tube potential shall not be less than the values shown in table I in this paragraph. Linear interpolation and extrapolation may be used if necessary to determine the half-value layer at an X-ray tube potential that is not listed in table I.

Table I

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 through 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

(B) For capacitor energy storage equipment, compliance shall be determined with the system fully charged and set at 10 mAs for each exposure.

(C) The required minimal half-value layer of the useful beam shall include the filtration contributed by all materials that are permanently located between the source and the patient.

(2) Filtration controls. For each X-ray system that has variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter or filters and shall prevent an exposure, unless the minimum amount of filtration necessary to produce the required HVL is in the useful beam for the given kVp that has been selected.

(f) Multiple tubes. If two or more radiographic tubes are controlled by one exposure switch, each tube that has been selected shall be clearly indicated before initiation of the exposure. This indication shall be both on the X-ray control panel and at or near the tube housing assembly that has been selected.

(g) Mechanical support of the tube head. The tube housing assembly supports shall be adjusted so that the tube housing assembly remains stable during each exposure, unless tube housing movement is a designed function of the X-ray system.

(h) Technique indicators.

(1) The technique factors to be used during each exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors that are set before the exposure shall be indicated.

(2) The requirements of paragraph (h)(1) may be met by permanent marking on equipment that has fixed technique factors. The indication of technique factors shall be visible from the operator's position, except in the case of spot films made by the fluoroscopist.

(i) Maintaining compliance. All diagnostic X-ray systems and their associated components used on humans and certified pursuant to the federal X-ray equipment performance standard in 21 CFR part 1020 shall be maintained in compliance with the applicable requirements of that standard.

(j) Locks. All position-locking, holding, and centering devices that are on X-ray system components and systems shall function as intended and shall be maintained according to each manufacturer's recommendations.

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