WAC 246-225-040 General requirements for diagnostic x-ray systems. In addition to other requirements of this chapter, diagnostic X-ray systems shall meet the following requirements:

(1) *Warning label.* The control panel containing the main power switch shall bear the warning 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."

(2) *Battery charge indicator.* On battery-powered generators, visual means shall be provided on the control panel to indicate the battery is in a state of charge adequate for proper operation.

(3) *Leakage radiation from the diagnostic source assembly.* The leakage radiation from the diagnostic source assembly, measured at a distance of 1 meter in any direction from the source, shall not exceed 2.58×10^{-5} coulombs per kilogram (100 milliroentgens) in one hour when the X-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of one hundred square centimeters with no linear dimension greater than twenty centimeters.

(4) *Radiation from components other than the diagnostic source assembly.* The radiation emitted by a component other than the diagnostic source assembly shall not exceed 5.16×10^{-7} coulombs per kilogram (2 milliroentgens) in one hour at 5 centimeters from an accessible surface of the component when 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 20 centimeters.

(5) *Beam quality.*

(a) 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 this section, Table I. If it is necessary to determine such half-value layer at an X-ray tube potential which is not listed in Table I, linear interpolation or extrapolation shall be made.

WAC 246-225-040 TABLE 1

Design operating range (kilovolts peak)	Measured potential (kilovolts peak)	Half-value layer (millimeters of aluminum equivalent)	Half-value layer (millimeter of aluminum equivalent for dental units)
Below 51—	30	0.3	N/A
	40	0.4	N/A
	50	0.5	1.5
51 to 70—	51	1.2	1.5
	60	1.3	1.5
	70	1.5	1.5
Above 70—	71	2.1	2.1
	80	2.3	2.3
	90	2.5	2.5
	100	2.7	2.7
	110	3.0	3.0
	120	3.2	3.2
	130	3.5	3.5
	140	3.8	3.8
	150	4.1	4.1

(b) For capacitor energy storage equipment, compliance shall be determined with the system fully charged and a setting of at least 10 mAs for each exposure.

(c) The required minimal half-value layer shall include the filtration contributed by materials permanently in position between the focal spot of the tube and the patient. (For example, a table top when the tube is mounted "under the table" and inherent filtration of the tube.)

(d) Filtration control. For X-ray systems with variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filters and shall prevent an exposure unless the minimum amount of filtration required by subdivision (a) of this subsection is in the useful beam for the selected kVp.

(6) *Multiple tubes.* Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes selected shall be clearly indicated prior to initiation of the exposure. Such indication shall be both on the X-ray control panel and near or on the selected tube housing assembly.

(7) *Mechanical support of tube head.* The tube housing assembly supports shall be adjusted such that the tube housing assembly remains stable during an exposure unless the tube housing movement during exposure is a designed function of the X-ray system.

(8) *Technique indicators.*

(a) The technique factors used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls are used, in which case the technique factors set prior to the exposure shall be indicated.

(b) On equipment having fixed technique factors, the requirement, under subdivision (a) of this subsection may be met by permanent markings. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

(9) Certified units. All diagnostic X-ray systems certified to comply with 21 C.F.R. 1020 shall meet the requirements of that certification.

(10) Linearity. The difference between the ratio of exposure to mAs at one mA or mAs setting and the ratio at another mA or mAs setting shall not exceed 0.10 times the sum of the ratios. This is written as:

$$X_1 - X_2 \leq 0.10\,(X_1 + X_2)$$

Where X_1 and X_2 are the ratios (mR/mAs) for each mA or mAs station.

The test shall be performed at any selections of mA or mAs without regard to focal spot size, provided neither focal spot size is less than 0.45 millimeter.

(11) kVp accuracy. The difference between the indicated and actual kVp of an X-ray machine shall not be greater than ten percent of the indicated kVp, or, alternatively, if available, the accuracy specifications of the control panel manufacturer must be met.

[Statutory Authority: RCW 70.98.050. WSR 94-01-073, § 246-225-040, filed 12/9/93, effective 1/9/94. Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 91-15-083 (Order 183), § 246-225-040, filed 7/23/91, effective 8/23/91. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-225-040, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.080. WSR 87-01-031

(Order 2450), § 402-28-035, filed 12/11/86; WSR 83-19-050 (Order 2026), § 402-28-035, filed 9/16/83. Statutory Authority: RCW 70.98.050. WSR 81-01-011 (Order 1570), § 402-28-035, filed 12/8/80; Order 1084, § 402-28-035, filed 1/14/76. Formerly WAC 402-28-030 (part).]