44:03:01:08.02. Equipment standards for medical diagnostic X ray machines. The standards for any medical diagnostic X ray machine are as follows:

(1) 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) If the machine contains a battery-powered X ray generator, a visual means shall be provided on the control panel to indicate if the battery is in a state of charge adequate for proper operation;

(3) Any leakage radiation from the diagnostic source assembly measured at a distance of one meter in any direction from the source may not exceed 100 milliroentgens in one hour;

(4) The filtration or beam quality is considered adequate if the total filtration in the beam is not less than the following table:

Operating Voltage vs. Total Filtration Required	
	(Total filtration = inherent plus added)
Operating Voltage	
(Peak kilovolt) (kVp)	(Millimeters aluminum equivalent)
Below 50	0.5 millimeters
50 -- 70	1.5 millimeters
Above 70	2.5 millimeters

(5) A variable, positive beam limitation with rectangular area and a light-defining device shall be provided for all fixed X ray machines. The X ray beam dimensions may not exceed the size of film used by greater than two percent of SID on any side. The machine shall include a means to align the center of the X ray field with respect to the center of the image receptor to within two percent of the SID. If a light localizer is used to define the X ray field, it shall provide an average illumination of not less than 160 lux (15.0 foot-candles) at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field. Exempt is any X ray machine that is designed with all parameters fixed, including alignment, source-to-distance, and technique factors;

(6) The machine shall include a device to terminate the exposure after a preset time. The accuracy of such a device shall be within five percent of the time set for machines manufactured on or after August 1, 1974, and within ten percent of the time set for machines manufactured before August 1, 1974;

(7) Any deviation of a measured technique factor from an indicated value of kVp may not exceed any limit specified for that system by its manufacturer or, in the absence

of any manufacturer's specifications, the deviation may not exceed ten percent of the indicated value for kVp;

(8) The coefficient of variation may not exceed 0.10 when all technique factors are held constant. This requirement is met if, when four exposures are made at identical technique factors, the value of the average exposure (E) is greater than or equal to five times the maximum exposure (E max) minus the minimum exposure (E min), i.e., E > 5(E max - E min);

(9) MA/mAs linearity requirements apply if the equipment is being operated on a power supply as specified by the manufacturer for any fixed X ray tube potential within the range of 40 percent to 100 percent of the maximum rated:

(a) For equipment having independent selection of X ray tube current (mA), the average ratios (X_1) exposure to the indicated milliampere-seconds product, in units of coulombs per kilograms per milliampere second (or milliroentgen per milliampere-seconds), obtained at any two consecutive tube current settings may not differ by more than ten hundredths times their sum:

$$X_1 - X_2 < 0.10 (X_1 + Z_2)$$

where X_1 and X_2 are the average values obtained by two mAs selector settings, or at two settings differing by no more than a factor of two where the mAs selector provides continuous selection;

(b) For equipment having a combined X ray tube current-exposure time product (mAs) selector, but not a separate tube current (mA) selector, the average ratios (X_1) of exposure to the indicated milliampere-seconds product, in units of coulombs per kilogram per milliampere second (or mR/mAs), obtained at any two consecutive mAs selector settings may not differ by more than ten hundredths times their sum:

$$X_1 - X_2 < 0.10 (X_1 + Z_2)$$

where X_1 and X_2 are the average values obtained by two mAs selector settings, or at two settings differing by no more than a factor of two where the mAs selector provides continuous selection;

(10) If two or more radiographic tubes are controlled by one exposure switch, the tube that has been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be on the X ray control panel and also at or near the tube housing assembly which has been selected;

(11) The tube housing assembly supports shall be adjusted so that the tube housing assembly remains stable during an exposure unless tube housing movement is a designed function of the X ray system;

(12) Any diagnostic X ray system and its associated components used on humans and certified pursuant to the Federal X Ray Equipment Performance Standard (21 C.F.R. Part 1020) as of January 1, 1998, shall be maintained in compliance with applicable requirements of that standard; and

(13) All position locking, holding, and centering devices on the machine shall function as intended by the manufacturer.

Source: 26 SDR 96, effective January 23, 2000.
General Authority: SDCL 34-21-4.1, 34-21-15.
Law Implemented: SDCL 34-21-4.1, 34-21-15.