**44:03:01:08.02.  Equipment standards for medical diagnostic X ray systems.** A diagnostic X ray system must meet the specifications in 21 C.F.R. §§ 1020.30 and 1020.31, in effect on April 1, 2022. In addition, a diagnostic X ray must meet the following standards:

(1)  Any deviation of a measured technique factor from an indicated value of kilovoltage peak (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;

(2)  The tube housing assembly supports must 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; and

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

**Source:** 26 SDR 96, effective January 23, 2000; 50 SDR 41, effective October 11, 2023.

**General Authority:** SDCL 34-21-4.1, 34-21-15.

**Law Implemented:** SDCL 34-21-4.1, 34-21-15.