641—40.5(136C) General requirements for all diagnostic X-ray systems. In addition to the applicable requirements of this chapter, all diagnostic X-ray systems shall meet the requirements for manufacture as specified in 21 CFR 1020.30 and 1020.31.

40.5(1) *Warning label.* Diagnostic registrants shall comply with the warning label requirements of 21 CFR 1020.30(j).

40.5(2) *Leakage radiation from the diagnostic source assembly.* Diagnostic registrants shall comply with the leakage radiation from the diagnostic source assembly requirements of 21 CFR 1020.30(k).

40.5(3) *Radiation from components other than the diagnostic source assembly.* Diagnostic registrants shall comply with the radiation from components other than the diagnostic source assembly requirements of 21 CFR 1020.30(l).

40.5(4) *Beam quality.* Diagnostic registrants shall comply with the beam quality requirements of 21 CFR 1020.30(m).

40.5(5) *Battery charge indicator.* Diagnostic registrants shall comply with battery charge indicator requirements of 21 CFR 1020.30(o).

40.5(6) *Multiple tubes.* Diagnostic registrants shall comply with multiple tube requirements of 21 CFR 1020.31(k).

40.5(7) *Technique indicators.* Diagnostic registrants shall comply with technique indicator requirements of 21 CFR 1020.31(a).

40.5(8) *Beam-on indicators.* Diagnostic registrants shall comply with beam-on indicator requirements of 21 CFR 1020.31(j).

40.5(9) *Maintaining compliance.* Diagnostic registrants shall comply with the performance standards for ionizing radiation emitting product requirements of 21 CFR 1020.

40.5(10) *Systems designed for mammography.* All systems designed for mammography shall comply with the Mammography Quality Standards Act of 1998 as amended to August 1, 2025, and the provisions of 641—Chapter 41.

40.5(11) *Invasive breast localization X-ray machines.* All systems designed for invasive breast localization X-ray machines shall comply with the provisions of 641—Chapter 41.

40.5(12) *Medical cabinet X-ray machine for nonhuman use.* All systems designed for tissue specimen imaging shall comply with provisions of rules 641—37.8(136C) and 641—37.9(136C).

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