

641—40.6(136C) General requirements for all fluoroscopy and interventional X-ray systems. In addition to the applicable requirements of this chapter, all fluoroscopic and interventional X-ray systems shall meet the requirements for manufacture as specified in 21 CFR 1020.32 to include all of the following minimum requirements.

40.6(1) Fluoroscopic equipment. Only image-intensified or direct-digital receptor fluoroscopic equipment shall be used for fluoroscopy. Non-image intensified fluoroscopic equipment cannot be used.

40.6(2) Primary protective barrier. Fluoroscopic and interventional X-ray registrants shall comply with primary protective barrier requirements of 21 CFR 1020.32(a).

40.6(3) Field limitation. Fluoroscopic and interventional X-ray registrants shall comply with field limitation requirements of 21 CFR 1020.32(b).

40.6(4) Activation of tube. Fluoroscopic and interventional X-ray registrants shall comply with activation of tube requirements of 21 CFR 1020.32(c).

40.6(5) Air kerma rates. Fluoroscopic and interventional X-ray registrants shall comply with air kerma rate requirements of 21 CFR 1020.32(d).

40.6(6) Measuring compliance of equipment parameters. Compliance with fluoroscopy equipment parameters required in this chapter shall be conducted by a qualified expert and according to manufacturer or nationally recognized standards at intervals not to exceed 12 months.

40.6(7) Indication of potential and current. Fluoroscopic and interventional X-ray registrants shall comply with indication of potential and current requirements of 21 CFR 1020.32(f).

40.6(8) Source-skin distance. Fluoroscopic and interventional X-ray registrants shall comply with source-skin distance requirements of 21 CFR 1020.32(g).

40.6(9) Fluoroscopic irradiation time, display, and signal. Fluoroscopic and interventional X-ray registrants shall comply with fluoroscopic irradiation time, display, and signal requirements of 21 CFR 1020.32(h).

40.6(10) Display of last-image-hold (LIH). Fluoroscopic and interventional X-ray registrants shall comply with display of LIH requirements of 21 CFR 1020.32(j).

40.6(11) Displays of values of AKR and cumulative air kerma. Fluoroscopic and interventional X-ray registrants shall comply with displays of values of AKR and cumulative air kerma requirements of 21 CFR 1020.32(k).

40.6(12) Protection from scatter radiation.

a. For stationary fluoroscopic systems, ancillary shielding, such as drapes, self-supporting curtains, or viewing shields, shall be available and used as supplemental protection for all individuals other than the patient in the room during a fluoroscopy procedure.

b. Where sterile fields or special procedures prohibit the use of normal protective barriers or drapes, all of the following conditions shall be met:

(1) Shielding required under paragraph 40.6(12)“*a*” shall be maintained to the degree possible under the clinical conditions;

(2) All persons, except the patient, in the room where fluoroscopy is performed shall wear protective aprons that provide a lead equivalent shielding of at least 0.25 mm;

(3) The fluoroscopic field size shall be reduced to the minimum required for the procedure being performed (area of clinical interest);

(4) Operating and safety procedures shall reflect the above conditions, and operators shall exhibit awareness of situations requiring the use and nonuse of the protective drapes.

40.6(13) Equipment operation. All imaging formed by the use of fluoroscopic X-ray systems shall be directly viewed and interpreted by a licensed practitioner of the healing arts.

a. Overhead fluoroscopy cannot be used as a positioning tool for general purpose radiographic examinations.

b. Facilities that use fluoroscopic X-ray systems shall maintain a record of cumulative fluoroscopic exposure time used and the number of spot films for each examination. This record shall include all of the following:

(1) Patient identification;

(2) Type of examination;

- (3) Date of examination;
- (4) Operator's name.
- c. The operation of a fluoroscopy X-ray system for clinical purposes is limited to those individuals permitted to operate radiation machines as specified in 641—Chapter 38 and persons who have received additional training provided by a qualified expert specific to:
 - (1) Radiation protection methods for patients and staff;
 - (2) Units of measurement and dose, including DAP (dose-area product) values and air kerma;
 - (3) Factors affecting fluoroscopic outputs;
 - (4) High level control options;
 - (5) Dose management, including dose reduction techniques, monitoring, and recording;
 - (6) Principles and operation of the specific fluoroscopic X-ray system(s) to be used;
 - (7) Fluoroscopic and fluorographic outputs of each mode of operation on the system(s) to be used clinically;
 - (8) Applicable requirements of these regulations.
- d. Operators shall be competent in the standard operating procedures of the unit in use, including the use of available dose-saving features, and the relative radiation output rates of the various modes of operation.
- e. Procedure planning for fluoroscopic procedures on pregnant female patients shall include feasible modifications to minimize the dose to the conceptus.
- f. Procedure planning for fluoroscopic procedures on pediatric patients shall include feasible modifications to minimize dose.
- g. The registrant monitor dose during a fluoroscopic procedure.
- h. The facility shall establish a written policy regarding patient dose management in fluoroscopically guided procedures in conformance with the ACR-AAPM Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures (ACR Resolution 44 – 2013), NCRP Report 168, or equivalent.

40.6(14) *Additional requirements for stationary fluoroscopic systems used for fluoroscopically guided interventional or special procedures.* Protective barriers shall be available for use by individuals whose presence is required in the room during activation of the X-ray tube(s).

- a. If a protective barrier includes or consists of a transparent viewing panel, the viewing panel shall afford protection of not less than 0.5 mm of lead equivalent.
- b. Protective aprons of not less than 0.25 mm of lead equivalent shall be worn in the fluoroscopy room by all individuals (except the patient).
- c. Any individual required to be in the room for short periods of time may not be required to wear a protective apron if exposure levels below minimum as seen on film badge reports can be verified.
- d. Individuals not using protective aprons should follow ALARA by using time and distance to reduce exposure. Any declared pregnant woman must meet the requirements of 641—subrule 37.11(14).

40.6(15) *Supervision of fluoroscopy.* The use of fluoroscopy by radiologic technologists and radiologic students shall be performed under the direct supervision of a licensed practitioner, a radiologist assistant or an ARNP, pursuant to 481—subrule 621.4(5), for the purpose of localization or to obtain images for diagnostic or therapeutic purposes.

40.6(16) *Dose-area-product monitor requirements.* All fluoroscopic equipment used for interventional or special procedures shall be equipped with a dose-area-product monitor capable of recording the total radiation dose received by a patient when the fluoroscopic tube is used.

- a. Each facility using fluoroscopic equipment for special procedures shall include in the patient's chart and in a log for department review the patient radiation exposure received per procedure.
- b. The registrant shall maintain the records required by this subrule and shall make them available to the department upon request.

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