4732.0825 FLUOROSCOPIC X-RAY SYSTEMS EXCEPT RADIATION THERAPY SIMULATORS.

Subpart 1. **Applicability.** All fluoroscopic systems must meet the requirements in this chapter and the applicable performance standards of nationally recognized standards, such as:

A. Code of Federal Regulations, title 21, section 1020.32;

B. the manufacturer's specifications; or

C. part 4732.1100.

Subp. 2. **Fluoroscopic training requirements.** Except licensed practitioners of the healing arts, any individual activating the fluoroscopic system must be trained in the aspects of fluoroscopic equipment use listed in items A to J. The topics to be covered and documented are:

A. x-ray generation and control;

B. x-ray dosimetry;

C. image formation;

D. image acquisition;

E. image processing and management;

F. radiation effects;

G. patient dose-management fundamentals;

H. staff radiation safety;

I. professional standards and regulatory requirements; and

J. other miscellaneous items appropriate to site-specific use.

Subp. 3. **Registrant requirements.** The registrant must ensure that:

A. the written safety procedures provide precautionary measures to be adhered to when image intensified fluoroscopes are used for specific surgical applications;

B. portable fluoroscopic equipment must have spacer cones and the spacer cones must remain with the portable fluoroscopic equipment at all times. Appropriate spacer cones must be placed on the portable fluoroscopic equipment that is used outside of the surgical setting;

C. any individual who is in the room during a fluoroscopic procedure must wear a protective garment of not less than 0.5 millimeter lead equivalence; and

D. all fluoroscopic x-ray equipment must be provided with a bucky-slot cover panel, if applicable, and either lead drapes attached to the intensifying tower or self-supporting shields of not less than 0.5 millimeter lead equivalent material.

Subp. 4. **Limitation of useful beam x-ray field.**

A. All fluoroscopic systems must be provided with image intensification equipment to view the fluoroscopic images.

B. Spot-film devices must meet the field limitation and alignment requirements in Code of Federal Regulations, title 21, section 1020.31.

Subp. 5. **Entrance exposure rate allowable limits.** Fluoroscopic systems must meet requirements in Code of Federal Regulations, title 21, section 1020.32.

A. Fluoroscopic equipment with automatic exposure rate control (AERC) must not be operable at any combination of tube potential and current that results in an air kerma rate in excess of ten roentgens per minute or 2.58×10^{-3} C/kg per minute at the point where the center of the useful beam enters the patient, except:

(1) during recording of fluoroscopic images when using photographic film; or

(2) when an optional high-level control is provided. When so provided, the equipment must not be operable at any combination of tube potential and current that results in an air kerma rate in excess of five R/min (1.29×10^{-3} C/kg per minute) at the point where the center of the useful beam enters the patient, unless the high-level control is activated. Special means of activation of high-level controls is required. The high-level control must be operable only when the operator provides continuous manual activation. A continuous signal audible to the fluoroscopist must indicate that the high-level control is being employed.

B. Fluoroscopic equipment without AERC (manual mode) must not be operable at any combination of tube potential and current that results in an air kerma rate in excess of five R/min (1.29×10^{-3} C/kg per minute) at the point where the center of the useful beam enters the patient:

(1) during the recording of fluoroscopic images; or

(2) when an optional high-level control is activated. Special means of activation of high-level controls is required. The high-level control must be operable only when the operator provides continuous manual activation. A continuous signal audible to the fluoroscopist must indicate that the high-level control is being employed.

C. Fluoroscopic equipment with both an AERC mode and a manual mode must not be operable at any combination of tube potential and current that results in an air kerma

rate in excess of ten R/min (2.58 x 10^{-3} C/kg per minute) in either mode at the point where the center of the useful beam enters the patient, except:

(1) during the recording of fluoroscopic images when using photographic film; or

(2) when the mode or modes have an optional high-level control, in which case that mode or modes must not be operable at any combination of tube potential and current that results in an air kerma rate in excess of five R/min (1.29 x 10^{-3} C/kg per minute) at the point where the center of the useful beam enters the patient, unless the high-level control is activated. Special means of activation of high-level controls is required. The high-level control must be operable only when the operator provides continuous manual activation.

D. The registrant with fluoroscopic systems manufactured after May 19, 1995, must ensure that the entrance exposure rate allowable limits in this subpart are met.

(1) Fluoroscopic equipment operable at any combination of tube potential and current that results in an air kerma rate greater than five R/min (1.29 x 10^{-3} C/kg per minute) at the point where the center of the useful beam enters the patient must be equipped with automatic exposure rate control. Provision for manual selection of technique factors may be provided.

(2) Fluoroscopic equipment must not be operable at any combination of tube potential and current that results in an exposure rate in excess of ten R/min (2.58 x 10^{-3} C/kg per minute) at the point where the center of the useful beam enters the patient, except:

(a) during the recording of images from an x-ray image-intensifier tube using photographic film; or

(b) when an optional high-level control is activated, the equipment must not be operable at any combination of tube potential and current that results in an air kerma rate in excess of 20 R/min (5.16 x 10^{-3} C/kg per minute) at the point where the center of the useful beam enters the patient. Special means of activation of high-level control is required. The high-level control must only be operable when the operator provides continuous manual activation. A continuous signal audible to the fluoroscopist must indicate that the high-level control is being employed.

Subp. 6. **Indication of kilovoltage and milliamperage.** For fluoroscopic x-ray systems, kilovoltage and the milliamperage must be continuously indicated.

Subp. 7. **Source-to-skin distance.** The source-to-skin distance must not be less than:

A. 15 inches (38 centimeters) on stationary fluoroscopes;

B. 14 inches (35.5 centimeters) on stationary fluoroscopes manufactured prior to August 1, 1974;

C. 11.8 inches (30 centimeters) on all portable fluoroscopes; and

D. 7.9 inches (20 centimeters) for image intensified fluoroscopes used for specific surgical applications.

Subp. 8. **Control of scattered radiation.** The procedures in this subpart must be used to control scattered radiation from all fluoroscopes.

A. When a fluoroscopic table with an under table x-ray tube is used, the bucky opening must be shielded to attenuate the scattered radiation by at least 70 percent. Lead drapes must be attached to the intensifier tower to attenuate scattered radiation by at least 70 percent.

B. For other under table configurations, provisions must be made through equipment design or radiation protection measures to ensure that individuals do not receive a dose in excess of the allowable dose limits listed in parts 4732.0410 to 4732.0430.

C. For single-tube above table combination radiographic and fluoroscopic x-ray systems used in the fluoroscopic mode, protective aprons of not less than 0.5 millimeter lead equivalence must be used to ensure that any individual who is in the room during a fluoroscopic procedure does not receive a dose greater than the allowable dose limits in part 4732.0410. In addition, portable lead shields, barriers, or aprons of not less than 0.5 millimeter lead equivalence must be used.

D. For portable C-arm fluoroscopes, provisions must be made through the use of protective aprons of not less than 0.5 millimeter lead equivalence to ensure that any individual other than the patient who may be exposed during a fluoroscopic procedure does not receive a dose in excess of the allowable dose limits in part 4732.0410.

Subp. 9. **Radiation therapy simulation systems.** A radiation therapy simulation system is exempt from the requirements of subpart 3, provided:

A. the system is designed and used so that no individual other than the patient is in the simulation room when the system is producing x-rays; and

B. the system has a means to indicate the cumulative time that an individual patient has been exposed to x-rays. Procedures must require in such cases that the timer be reset between examinations.

Subp. 10. **Real-time cabinet fluoroscopic systems.** A real-time cabinet fluoroscopic system used for research must meet the requirements in part 4732.1040.

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