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Title: Section 16.58 - Fluoroscopic installations excluding veterinary installations

16.58 Fluoroscopic installations excluding veterinary installations.

(a) Equipment.

(1) The protective tube housing shall be of the diagnostic type.

(2) Equipment shall be constructed so that the entire cross section of the useful beam is always intercepted by the primary protective barrier irrespective of the position.

(i) Collimators and adjustable diaphragms or shutters used to restrict the size of the useful beam shall provide the same degree of protection as is required of the tube housing.

(ii) The exposure shall automatically terminate when the barrier is removed from the useful beam.

(3) The aluminum equivalent of the total filtration in the useful beam shall not be less than that shown below:

(i) for equipment manufactured prior to August 1, 1974:

Operating kVp	Minimum total filtration (Inherent plus added)
Below 50 kVp	0.5 mm aluminum
50-70 kVp	1.5 mm aluminum
Above 70 kVp	2.5 mm aluminum

(ii) for equipment manufactured after August 1, 1974.

Designed Operating Range (kVp)	Measured Operating Potential (kVp)	Minimum HVL mm of Al
Below 51	30	0.3
	40	0.4
	50	0.5
51 to 70	51	1.2
	60	1.3
	70	1.5
	71	2.1
Above 70	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1

(4) Fluoroscopic exposure switch shall be of the dead-man type.

(5) The source-tabletop distance shall not be less than 12 inches (30 cm) and should not be less than 15 inches (38 cm).

(6) Fluoroscopy equipment shall not be operated for human use unless a cumulative timing device, activated by the fluoroscope exposure switch, is functioning. It shall indicate the passage of a period of irradiation, not exceeding five minutes, either by a signal audible to the operator or by temporary interruption of the irradiation.

(7) (i) The fluoroscopic exposure rate when measured under the following conditions shall not exceed 5 Roentgens per minute:

(a) the controls are set to the dose rate mode used for the fluoroscopic procedure most commonly performed on that fluoroscopic unit;

(b) the image intensifier is set to the largest field of view;

(c) the image intensifier is at 12 inches (30 cm) above the tabletop or the overtable fluoro tube is at a source to image distance normally used for an average patient;

(d) a patient phantom composed of 1 and ½ inch (3.8 cm) thickness of Type 1100 aluminum and 0.02 inch (0.5 mm) thickness of copper or an equivalent device is completely intercepting the useful beam; and

(e) the measurement is made at the measurement location specified in 21 CFR Section 1020.32(d)(3) (see section 16.200 of this part).

(ii) If the exposure rate cannot be measured, the exposure integrated for one minute under the same conditions as subsection (7)(i) shall not exceed 5 Roentgens.

(8) Using the measurement locations specified in 21 CFR Section 1020.32(d)(3) (see section 16.200 of this part), the maximum exposure rate measured in air shall not exceed 10 roentgens per minute except as follows:

(i) Equipment manufactured before May 19, 1995 and certified in accordance with 21 CFR Part 1020 (see section 16.200 of this Part) and having an optional high level control is limited to a maximum output of 5 Roentgens per minute unless the high level control is activated and an audible signal to that effect is provided. When the high level is activated, the maximum exposure rate measured in air at a point where the center of the useful beam enters the patient shall not exceed 20 Roentgens per minute.

(ii) Certified equipment manufactured after May 19, 1995 with automatic exposure rate and having an optional high level control is limited to a maximum output of 10 Roentgens per minute unless the high level control is activated and an audible signal to that effect is provided. When the high level control is activated, the maximum exposure rate measured in air at a point where the center of the useful beam enters the patient shall not exceed 20 Roentgens per minute.

(iii) Certified equipment manufactured after May 19, 1995 without automatic exposure rate is limited to 5 Roentgens per minute unless the high level control is activated and an audible signal to that effect is provided. When the high level control is activated, the maximum exposure rate measured in air at a point where the center of the useful beam enters the patient shall not exceed 20 Roentgens per minute.

(9) With the system configured for the most frequently performed procedure, the fluoroscopic and fluorographic, if the system is equipped for image acquisition, exposure rates shall be measured with each of the following attenuators in the beam:

0.75 inches (19 mm) of aluminum (pediatric patient -- 25 kg.),

1.50 inches (38 mm) of aluminum (small adult patient -- 50 kg.),

1.50 inches (38 mm) of aluminum and 0.02 inches (0.5 mm) of copper (average adult patient -- 75 kg.),

1.50 inches (38 mm) of aluminum and 0.08 inches (2.0 mm) of copper (large adult patient -- 100 kg.),

1.50 inches (38 mm) of aluminum and 0.08 inches (2.0 mm) of copper and 0.12 inches (3.0 mm) of lead (for maximum fluoroscopic exposure rate only).

The fluoroscopic exposure rates for the most frequently performed procedure shall be posted so that they are conspicuous to the operator.

(10) Primary protective barriers shall provide the following protection:

(i) for uncertified equipment, with the image intensifier 14 inches (36 cm) from the tabletop, the exposure rate two inches (5 cm) beyond the image intensifier shall not exceed 30 mR/hr for each roentgen per minute at the tabletop with the intensifier in the useful beam without a patient and with the fluoroscope operating at the highest potential available for use.

(ii) for certified equipment, the exposure rate due to transmission through the barrier with the attenuation block in the useful beam combined with radiation from the image intensifier, if provided, shall not exceed two milliroentgens per hour at four inches (10 cm) from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute or entrance exposure rate.

(11) In the absence of a tabletop, a cone or spacer frame shall limit the source-to-skin distance to not less than 12 inches (30 cm) for all mobile fluoroscopic equipment. Units intended for specific surgical application may be used at shorter source skin distances but in no case less than 8 inches (20 cm).

(12) The spatial resolution of the fluoroscopic system shall be measured using a test tool composed of a line pair (lp) plate with discreet line pair groups and a maximum lead foil thickness of 0.1 mm or an equivalent device. The test tool shall be placed on a 0.75 inch (19 mm) thickness of type 1100 aluminum, large enough to completely intercept the useful beam, with the test tool 12 inches (30 cm) from the entrance surface of the image receptor assembly. If the system has variable source-to-image distance (SID), the measurement SID shall not exceed 40 inches (100 cm). The image receptor of the fluoroscopic system shall be operated in the largest available field of view (FOV) that does not exceed six inches (15 cm). If all the fluoroscopic system's FOVs exceed six inches (15 cm), the system shall be operated in the smallest FOV. The minimum spatial resolution at center of the beam for all FOVs shall be determined by the following equation:

$2 \text{ lp/mm} \times (6 \text{ inches (15cm)}/\text{size of FOV used}) = \text{minimum number of lp/mm.}$

(13) The low contrast performance of the fluoroscopic system shall be capable of resolving a minimum hole size of 3 mm using a test tool composed of a 1.0 mm aluminum sheet with two sets of four holes of dimension 1.0, 3.0, 5.0 and 7.0 mm and a phantom composed of a 1 and ½ inch (3.8 cm) thickness of Type 1100 aluminum large enough to completely intercept the useful beam or an equivalent device. The test tool shall be 12 inches (30 cm) from the entrance surface of the image receptor assembly. The image receptor of the fluoroscopic system shall be operated in the largest available field of view (FOV) that does not exceed six inches (15 cm). If all the fluoroscopic system's FOVs exceed six inches (15 cm), the system shall be operated in the smallest FOV.

(14) Radiation therapy simulation systems shall be exempt from the requirements of paragraphs (2), (6), (7) and (8) of this subdivision provided that:

(i) the systems are designed and used in a manner such that no individual other than the patient is in the x-ray room during periods of time when the system is producing x-rays; and

(ii) systems which do not meet the requirements of paragraph (6) of this subdivision are provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. Procedures shall require in such cases that the timer be reset between examinations.

(b) Conditions for operation of equipment.

(1) The operator of the installation shall make and record the exposure and exposure rate measurements made pursuant to paragraph (a)(7) and (8) of this section, where the center of the useful beam enters the patient during routine fluoroscopy and cinefluoroscopy, at annual intervals or more frequently if outputs are found to exceed the limits defined in this section.

(2) Unless measurements indicate that they are not needed protective garments of at least 0.25 mm lead equivalent each shall be worn by all persons within the fluoroscopic room except for the patient.

(3) Only persons needed in the fluoroscopic room shall be present during irradiation.

(4) The cumulative fluoroscopic time must be reset for each new patient.

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