**Section 360.50 Fluoroscopic Systems**

In addition to the provisions of Sections 360.10, 360.30, 360.40 and 360.41 of this Part, the requirements of this Section apply to x-ray equipment and associated facilities used for fluoroscopy.

a) Beam Limitation. The x-ray field shall be limited by stepless adjustable shutters. In addition:

1) The minimum field size at the greatest SID shall be no greater than 5 centimeters by 5 centimeters.

2) The mechanisms (manual/automatic mode selectors) provided for activating and positioning the beam-limiting shutters shall function properly. This requirement applies to shutters used in fluoroscopic procedures or spot filming procedures or both fluoroscopic and spot filming procedures.

3) Neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than three percent of the SID. The sum of the excess length and the excess width shall be no greater than four percent of the SID. This requirement applies to field sizes for fluoroscopic procedures or spot filming procedures or both fluoroscopic and spot filming procedures.

4) For fluoroscopic equipment with only a manual mode of beam limitation, the x-ray field produced shall be limited to the area of the spot film cassette at 40.6 centimeters (16 inches) above the tabletop. Additionally, during fluoroscopy, the operator shall restrict the beam to the area of the input phosphor.

5) Spot film devices shall meet the following additional requirements:

A) Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the image receptor to the size which has been selected on the spot film selector. Such adjustment shall be accomplished automatically except when the x-ray field size in the plane of the image receptor is smaller than that selected;

B) The center of the x-ray field in the plane of the image receptor shall be aligned with the center of the selected portion of the film to within two percent of the SID; and

C) If the angle between the plane of the image receptor and beam axis is variable, a device shall be provided to visually indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

6) The beam limitation requirements of this subsection shall not apply to fluoroscopic systems specifically designed for examination of extremities only and meeting the requirement of subsection (l) of this Section.

b) Fluoroscopic Timer. A manual reset, cumulative timing device shall be used which will either indicate elapsed on-time by an audible signal or turn off the system when the total exposure time exceeds a predetermined limit not exceeding 5 minutes in one or a series of exposures.

c) Primary Barrier/Interlock. These devices shall be provided and shall function so that:

1) The entire cross section of the useful beam is intercepted by the primary protective barrier of the fluoroscopic image assembly at any SID; and

2) The fluoroscopic tube is interlocked to prevent the unit from producing x-rays unless the primary barrier is in position to intercept the useful beam, as specified in subsection (1) of this Section, at all times.

d) Source-Skin Distance. The SSD shall not be less than:

1) 38 centimeters (15 inches) on all stationary fluoroscopes;

2) 20 centimeters (8 inches) on all mobile fluoroscopes; and

3) 9 centimeters (3.5 inches) for fluoroscopes specifically designed for examination of extremities only and meeting the requirements of subsection (l) of this Section.

e) Indication of Potential and Current. During fluoroscopy and recording of fluoroscopic images, the kVp and the mA shall be continuously indicated at the control panel and/or the operator's position.

f) Activation of the Fluoroscopic Tube. X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the operator for the entire time of any exposure. When recording serial fluoroscopic images, the operator shall be able to terminate the x-ray exposures at any time, but means may be provided to permit completion of any single exposure of the series in process.

g) Entrance Exposure Requirements

1) Maximum Exposure Rate. Fluoroscopic systems shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 2.58 mC/kg (10 R) per minute at the point where the center of the useful beam enters the patient, except:

A) During recording of fluoroscopic images; or

B) When an optional high level control is activated (see subsection (g)(2)).

2) When a high level control is activated, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5.15 mC/kg (20 R) per minute at the point where the center of the useful beam enters the patient. In addition, the following requirements apply to high level controls:

A) Separate means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator.

B) A continuous signal audible to the operator shall indicate that the high level control is being employed.

3) Compliance with the requirements of subsections (g)(1) and (2) of this Section shall be determined using technique factors that produce the maximum exposure rate. For systems employing automatic exposure rate control, material having an equivalency of at least 3 millimeters of lead shall be placed in the primary beam between the image receptor and the radiation measuring device. The lead or equivalent material shall be positioned to ensure that the entire primary beam is blocked.

AGENCY NOTE: Many fluoroscopic systems do not yield their maximum exposure rate at the maximum tube potential or tube current. The exposure rate should be checked at various kVp and mA settings to establish the maximum exposure rate for the system.

4) Fluoroscopic systems shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 1.29 mC/kg (5 R) per minute at the point where the center of the useful beam enters the patient, when measured under the following conditions:

A) Movable grids and compression devices shall be removed from the useful beam during the measurement.

B) For systems without automatic exposure rate control, the measurement shall be performed using technique factors clinically used for a standard adult patient thickness of 23 centimeters.

AGENCY NOTE: An attenuation block or other suitable material should be placed in the beam to protect the imaging system.

C) For systems with automatic exposure rate control, the measurement shall be performed with a 2.5 millimeter thick sheet of copper in the beam between the radiation measuring device and the image receptor.

AGENCY NOTE: Use of a 2.5 millimeter thick sheet of copper approximates the attenuation of a standard adult patient thickness of 23 centimeters, and assures consistency in the measurement of fluoroscopic exposure rate.

AGENCY NOTE: The Agency recommends additional measurements be made of the entrance exposure rate for fluoroscopic systems capable of recording fluoroscopic images, and the entrance exposure for spot film techniques for fluoroscopic systems with that modality. In either case, measurements should be made under the conditions specified in subsection (g)(4)(B) of this Section.

D) The requirements of subsection (g)(4) of this Section shall not apply to fluoroscopes specifically designed for examination of extremities only and meeting the requirements of subsection (1) of this Section.

5) Measurements performed pursuant to the requirements of subsections (g)(1) through (4) of this Section shall meet the following additional requirements:

A) If the source is below the table, the exposure rate shall be determined for the center of the useful beam 1 centimeter above the tabletop or cradle, with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters (12 inches) above the tabletop.

B) If the source is above the table, the exposure rate shall be determined at 30 centimeters (12 inches) above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

C) For a fixed SID C-arm type of fluoroscope, the exposure rate shall be determined 30 centimeters (12 inches) from the input surface of the fluoroscopic imaging assembly.

D) For a variable SID C-arm type of fluoroscope, the exposure rate shall be determined 30 centimeters (12 inches) from the input surface of the fluoroscopic imaging assembly with the end of the beam-limiting device or spacer positioned as close as possible to the point of measurement.

E) For a lateral type fluoroscope, the exposure rate shall be determined on the central axis of the primary beam at a point 15 centimeters (6 inches) from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than 15 centimeters to the centerline of the x-ray table.

AGENCY NOTE: A lateral type fluoroscope is a fluoroscope that cannot be rotated so that the source or the fluoroscopic imaging assembly can be positioned below the fluoroscopic table or cradle.

F) For a fluoroscopic system specifically designed for examination of extremities only, the exposure rate shall be determined for the minimum source-skin distance.

6) The measurements required by this subsection (g) shall be performed when the system is inspected as specified in 32 Ill. Adm. Code 410 as well as after any maintenance of the system which might affect the exposure rate.

7) The results of the measurements required by subsections (g)(1), (2) and (4) of this Section shall be posted or available at the control panel. The measurement results shall be stated in millicoulombs per kilogram (roentgens) per minute or microcoulombs per kilogram (milliroentgens) per second and shall include the technique factors used in determining such results. The name of the individual performing the measurements and the date the measurements were performed shall be included in the results.

AGENCY NOTE: The resolution and efficiency of the fluoroscopic imaging system should be evaluated periodically, whenever deterioration in the imaging system is suspected and when the measured exposure rate exceeds the standards of this Section.

h) Barrier Transmitted Radiation Rate Limits

1) The exposure rate due to transmission through the primary protective barrier shall not exceed 0.516 microC/kg (2mR) per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor per 258 microC/kg (1R) per minute of entrance exposure rate.

2) Measuring Compliance of Barrier Transmission

A) The exposure rate due to transmission through the primary protective barrier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

B) If the source is below the tabletop, the exposure rate shall be determined with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.

C) If the source is above the tabletop and the SID is variable, the exposure rate shall be determined with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters.

D) Movable grids and compression devices shall be removed from the useful beam during the measurement.

E) An attenuation block shall be positioned in the useful beam 10 centimeters from the point of measurement of entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly.

i) Staff and Ancillary Personnel Protection. The operator, assistants and observers allowed in the examining room shall be protected from scatter radiation by protective aprons of not less than 0.25 millimeter lead equivalent or whole body protective barriers or shall be positioned at a sufficient distance to ensure that the individual does not receive a radiation dose in excess of the limits specified in 32 Ill. Adm. Code 340.310.

j) Control of Scattered Radiation

1) For fluoroscopic systems utilizing an x-ray tube that is mounted below the table, the table shall be provided with shielding (bucky slot cover) equivalent to 0.25 millimeter lead equivalent to attenuate scattered radiation emanating from below the table.

2) A shield of at least 0.25 millimeter lead equivalent, such as overlapping protective drapes or hinged or sliding panels, shall be provided and used to intercept scatter radiation which would otherwise reach the operator and others near the machine. This shielding shall not be a substitute for the wearing of a protective apron (0.25 millimeter lead equivalent) for protection against scattered radiation.

3) Where sterile fields or special procedures prohibit the use of protective barriers or drapes, subsection (j)(2) of this Section shall not apply.

k) Additional Requirements for Stationary Fluoroscopic Systems Used for Cardiac Catheterization Procedures

1) Protective barriers shall be available for use by individuals whose presence is required in the room during activation of the x-ray tubes. If a protective barrier includes or consists of a transparent viewing panel, the viewing panel shall afford protection of not less than 0.5 millimeter of lead equivalent.

2) Protective aprons of not less than 0.25 millimeter of lead equivalent shall be worn in the fluoroscopy room by all individuals (except the patient).

AGENCY NOTE: Because modern equipment allows great flexibility in the direction of the beam, individuals in the room should step back from the x-ray system and behind protective barriers during activation of the x-ray tubes.

l) Additional Requirements for Fluoroscopic Systems Specifically Designed for Examination of Extremities Only

1) The radiation safety procedures required pursuant to Section 360.30(j) of this Part shall include the following:

A) A warning concerning the potential for, and the hazards of, increased patient radiation dose associated with x-ray systems employing short source-skin distances;

B) Procedures for obtaining imaging magnification with minimum patient dose, including imaging systems or screen-film combinations;

C) Technique factors for specific examinations for which the system is designed;

D) Radiation exposure data, including skin entrance exposure for each set of technique factors used.

2) The x-ray system shall be clearly labeled as follows: "For Examination of Extremities Only."

3) Fluoroscopic systems specifically designed for examination of extremities only shall be used solely for examination of extremities.

m) Radiation Therapy Simulation Systems. Radiation therapy simulation systems shall be exempt from the requirements of subsections (a), (b), (c), (g) and (h) of this Section provided that:

1) Such systems are designed and used in such a manner 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

2) Such systems that do not meet the requirements of subsection (b) of this Section 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.

n) Operator Restrictions. No person shall intentionally administer radiation to a human being with a fluoroscopic radiation machine unless such person is licensed to practice a treatment of human ailments under the Medical Practice Act of 1987, the Illinois Dental Practice Act or the Podiatric Medical Practice Act of 1987, except:

1) An accredited medical radiographer may operate a fluoroscope for static functions when diagnostic interpretation of the fluoroscopic image is not required by the radiographer and only under the supervision of a licensed practitioner; or

2) An accredited medical radiographer may operate a fluoroscope as directed by, and under the direct supervision of, a licensed practitioner who is physically present and participating in the procedure; or

3) An accredited medical radiographer or radiation therapist may operate a fluoroscope for radiation therapy simulation procedures under the supervision of a licensed practitioner; or

4) An accredited radiologist assistant may operate a fluoroscope under the supervision of a licensed practitioner certified by the American Board of Radiology or the American Osteopathic Board of Radiology.

(Source: Amended at 32 Ill. Reg. 3693, effective February 29, 2008)