WAC 246-225-050 Fluoroscopic X-ray systems. Fluoroscopic X-ray systems shall meet the following requirements:

(1) Limitation of useful beam.

(a) The fluoroscopic tube shall not produce X-rays unless the primary barrier is in position to intercept the entire useful beam at all times.

(b) The entire cross section of the useful beam shall be intercepted by the primary protective barrier of the fluoroscopic image assembly at any source-to-image-distance (SID).

(c) Nonimage-intensified fluoroscopic equipment shall not be used.

(d) For fluoroscopic equipment without a spot film device, neither the length nor the width of the fluoroscopic 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. Measurements shall be made at the minimum SID available but at no less than 20 centimeters (8 inches) table top to image receptor distance.

(e) For uncertified fluoroscopic equipment with a spot film device, the fluoroscopic X-ray beam with the shutters wide open (during either fluoroscopy itself or spot films) shall be no larger than the dimensions of the largest spot film size for which the device is designed. Measurements shall be made at the minimum SID available, but at no less than 20 centimeters (8 inches) table top to the film plane distance.

(f) For certified (21 C.F.R. 1020) fluoroscopic equipment with a spot film device, neither the length nor the width of the fluoroscopic 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 width shall be no greater than four percent of the SID. Measurements shall be made at the minimum SID available, but at no less than 20 centimeters (8 inches) table top to film plane distance.

(g) Fluoroscopic equipment beam limitation:

(i) Means shall be provided to reduce the beam size at the plane of the image receptor to 125 square centimeters or less; and

(ii) The minimum field size at the greatest SID shall be equal to or less than 5 centimeters by 5 centimeters.

(2) *Activation of the fluoroscopic tube.* X-ray production in the fluoroscopic mode shall be controlled by a deadman switch.

(3) *Entrance <u>exposure</u> rate allowable limits.*

(a) For equipment with or without automatic brightness control, the <u>exposure</u> rate measured at the point where the center of the useful beam enters the patient shall not exceed 2.58×10^{-3} coulombs per kilogram per minute (ten roentgens per minute), except during film recording of fluoroscopic images or when an optional high level control (HLC) is activated.

(b) For equipment provided with HLC, the equipment shall not be operable at a combination of tube potential and current which will result in an <u>exposure</u> rate in excess of 1.29×10^{-3} coulombs per kilogram per minute (5 roentgens per minute) at the point where the center of the useful beam enters the patient, unless the HLC is activated.

(i) Special means of activation of high level controls, such as additional pressure applied continuously by the operator, shall be required to avoid accidental use.

(ii) A continuous signal audible to the fluoroscopist shall indicate the high level control is employed.

(c) Measuring compliance of entrance exposure rate limits. Compliance with subsection (3) of this section shall be determined as follows:

(i) Movable grids and compression devices shall be removed from the useful beam during the measurement;

(ii) If the source is below the table, exposure rate shall be measured 1 centimeter above the table top or cradle;

(iii) If the source is above the table, the exposure rate shall be measured at 30 centimeters above the table top with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement;

(iv) In a C-arm type of fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided the end of the beam-limiting device or spacer is no closer than 30 centimeters from the input surface of fluoroscopic imaging assembly; and

(v) In a lateral-type fluoroscope, the exposure rate shall be measured at a point 15 centimeters from the center line of the X-ray table with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the table top is movable, the table top 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 center line of the X-ray table.

(d) Periodic measurement of entrance exposure rate limits.

(i) Periodic measurements of the exposure rate shall be made. An adequate period for such measurements shall be annually or after maintenance of the system affecting the exposure rate.

(ii) Results of exposure rate measurements shall be available where the fluoroscopist has ready access to the measurements while using that fluoroscope. Results of the measurements shall include:

(A) The maximum possible coulombs per kilogram per minute (R/minute), as well as the technique factors associated with it;

(B) The name of the person performing the measurements;

(C) The last date the measurements were performed; and

(D) The type of device used in making the measurements.

(iii) Conditions of measurement:

(A) The kVp shall be adjusted to that which will produce the maximum entrance exposure rate;

(B) The high level control, if present, shall not be activated;

(C) The X-ray systems that incorporate automatic exposure rate control (automatic brightness control) shall have sufficient material, for example, lead or lead equivalence, placed in the useful beam to produce the maximum output of the X-ray system; and

(D) X-ray systems not incorporating automatic exposure rate control shall utilize whatever combination of kVp, mA, and other selectable parameters that will generate the highest exposure rate of the X-ray system. Materials, for example, an attenuation block, may be placed in the useful beam to protect the imaging system, as long as the material does not affect the measurement of the exposure rate.

(4) *Barrier transmitted radiation rate limits.*

(a) The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall

not exceed 5.16 x 10^{-7} coulombs per kilogram per hour (2 milliroentgens per hour) for each 2.58 x 10^{-4} coulombs per kilogram per minute (roentgen per minute) of entrance exposure rate. The barrier transmission measurement shall be made at 10 centimeters from an accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor.

(b) Measuring compliance of barrier transmission.

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

(ii) If the source is below the table top, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the table top.

(iii) If the source is above the table top and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the table top as it can be placed, provided the beam-limiting device or spacer shall not be closer than 30 centimeters.

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

(5) *Indication of potential and current.* During fluoroscopy and cinefluorography, X-ray tube potential and current shall be continuously indicated.

(6) *Source-skin distance (SSD).* The source to skin distance shall not be less than:

(a) 38 centimeters on stationary fluoroscopes;

(b) 30 centimeters on mobile fluoroscopes; and

(c) 20 centimeters for image intensified fluoroscopes used for specific surgical application. The user must provide precautionary measures for the use of the fluoroscope due to its short SSD.

(7) *Fluoroscopic timer.*

(a) Means shall be provided to preset the cumulative on-time of the fluoroscopic tube. The maximum cumulative time of the timing device shall not exceed five minutes without resetting.

(b) A signal audible to the fluoroscopist shall indicate the completion of a preset cumulative on-time. Such signal shall continue to sound while X-rays are produced until the timing device is reset. Alternatively, the timing device may terminate exposures at the end of the preset time.

(c) Total fluoroscopic on-time for each patient shall be recorded, either in patient's chart or in a separate log.

(8) *Control of scattered radiation.*

(a) Fluoroscopic table designs when combined with normal operating procedures shall be such that no unprotected part of staff or ancillary person's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be not less than 0.25 mm lead equivalent.

(b) Equipment configuration when combined with procedures shall be such that no portion of staff or ancillary person's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the table top unless:

(i) The radiation has passed through not less than 0.25 mm lead equivalent material, for example, drapes, Bucky-slot cover-sliding or folding panel, or self-supporting curtains, in addition to lead equiv-

alency provided by the protective apron referred to under WAC 246-225-020 (2)(e); and

(ii) Exceptions to subdivision (b) of this subsection may be made in some special procedures where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the department shall not permit such exception.

(9) *Radiation therapy simulation systems.* Radiation therapy simulation systems shall be exempt from the requirements of subsection (3) of this section. In addition, these systems shall be exempt from:

(a) Subsections (1) and (4) of this section provided such systems are designed and used in such a manner that no individual other than the patient is in the X-ray room when the system is producing X-rays; and

(b) Subsection (7) of this section if such systems are provided with a means of indicating the cumulative time that an individual patient has been exposed to X-rays.

[Statutory Authority: RCW 70.98.050. WSR 94-01-073, § 246-225-050, filed 12/9/93, effective 1/9/94. Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 91-15-083 (Order 183), § 246-225-050, filed 7/23/91, effective 8/23/91. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-225-050, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.080. WSR 87-01-031 (Order 2450), § 402-28-040, filed 12/11/86; WSR 83-19-050 (Order 2026), § 402-28-040, filed 9/16/83. Statutory Authority: RCW 70.98.050. WSR 81-01-011 (Order 1570), § 402-28-040, filed 12/8/80; Order 1084, § 402-28-040, filed 1/14/76; Order 1, § 402-28-040, filed 1/8/69; Rules (part), filed 10/26/66.]