DEPARTMENT OF HEALTH

Minnesota Rules, Chapter 4732 X-ray Revision

DRAFT FLUOROSCOPIC X-RAY SYSTEMS, 1.0

4732.#### FLUOROSCOPIC X-RAY SYSTEMS

Subpart 1. **Applicability**. A registrant's stationary, mobile, or portable fluoroscopic x-ray system must:

A. comply with the requirements of this part and Code of Federal Regulations, title 21, section 1020.30 to 1020.40 or successor requirements; and

B. be used to view fluoroscopic images with only image-intensified or direct receptor fluoroscopic x-ray systems.

Subp.2. **Limitation of the useful beam.**

A. The fluoroscopic imaging assembly must be provided with a primary protective barrier that intercepts the entire cross section of the useful beam at any source-image-distance.

B. The x-ray tube used for fluoroscopy must not produce x-rays unless the primary protective barrier is in position to intercept the useful beam and the imaging device is in place and operable.

C. The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam combined with radiation from the fluoroscopic imaging receptor must not exceed 3.34 x 10-3 percent of the entrance exposure rate, at a distance of 10 cm from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor. (21CFR 1020.32(a)(1))

Commented [JC(1]: Advisory Committee: Discuss use of unauthorized hand-held fluoroscopic x-ray systems for human use. At this time, FDA does not have approved hand-held fluoroscopic systems.

Commented [JC(2]: 4732.0825, subpart 4, item A

Commented [JC(3]: Subp. 84**. Useful beam.** "Useful beam" means the radiation which passes through the tube housing port and the aperture of the beam limiting device when the exposure switch or timer is activated.

Commented [JC(4]: Similar: NJ, TX, NE, VA, OH, FL, MI, PA, WA, IA, AK, NC, IL

Commented [JC(5]: Subp. 57. Protective barrier or barrier. "Protective barrier" or "barrier" means a structural barrier of radiation-absorbing materials used to reduce radiation exposure and includes:
1. "Primary protective barrier" means the material, excluding filters, placed in the useful beam.
2. "Secondary protective barrier" means a barrier sufficient to absorb the stray radiation to the required degree.

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Subp. 3. **Measuring compliance; primary protective barrier.** For all measurements under this subpart, the attenuation block must be positioned in the useful beam 10 cm from the point of measurement of entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly. Movable grids and compression devices must be removed from the useful beam.

A. The exposure rate due to transmission through the primary protective barrier, combined with radiation from the fluoroscopic image receptor, must be determined by measurements averaged over an area of 100 cm^2 with no linear dimension greater than 20 cm.

B. If the source is below the tabletop, then the measurement must be made with the input surface of the fluoroscopic imaging assembly positioned 30 cm above the tabletop.

C. If the source is above the tabletop and the SID is variable, then the measurement must be made with the end of the beam-limiting device or spacer cone as close to the tabletop as it can be placed, provided that it must not be closer than 30 cm.

D. The exposure rate must be measured according to subpart 9. (21CFR 1020.32(a)(2))

Subp. 4. **Field limitation; x-ray systems manufactured on or after February 25, 1978.** The following requirements apply to fluoroscopic x-ray systems manufactured on or after February 25, 1978:

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Commented [JC(8]: MDH intends to add fluoroscopic imaging assembly to Definitions part.
Fluoroscopic imaging assembly *means a subsystem in which x-ray photons produce a set of fluoroscopic or radiographic recorded images from the fluoroscopic image receptor. Fluoroscopic imaging assembly includes image receptors such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.*

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Commented [JC(10]: Advisory Committee: This refers to certified equipment according to 21 CFR 1020.32. Should we no longer allow uncertified equipment?

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A. When the angle between the image receptor and the beam axis of the x-ray beam is variable, means must be provided for a fluoroscopic x-ray system to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor. Compliance with items J and L must be determined with the beam axis indicated to be perpendicular to the plane of the image receptor. (21 CFR 1020.32(b)(1))

B. Means must be provided to permit further limitation of the x-ray field to sizes smaller than the limits of the circular image receptors under item J and limits of the rectangular image receptors under item L.

C. Beam-limiting devices manufactured after May 22, 1979, and incorporated in fluoroscopic x-ray systems with a variable SID or capability of a visible area of greater than 300 cm^2, must be provided with means for stepless adjustment of the x-ray field.

D. Fluoroscopic x-ray systems with a fixed SID and the capability of a visible area of no greater than 300 cm^2 must be provided with:

(1) stepless adjustment of the x-ray field; or

(2) a means to further limit the x-ray field size at the plane of the image receptor to 125 cm^2 or less.

E. At the greatest SID, stepless adjustment must provide continuous field sizes from the maximum obtainable to a field size containable in a square of 5 cm by 5 cm. (21CFR 1020.32(b)(2))

F. Spot-film devices must meet the following requirements:

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(1) Means must 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 of that portion of the image receptor which has been selected on the spot-film selector. Such adjustment must be accomplished automatically when the x-ray field size in the plane of the image receptor is greater than the selected portion of the image receptor. (21CFR1020.31(h))

(2) If the x-ray field size is less than the size of the selected portion of the image receptor, then the field size must not open automatically to the size of the selected portion of the image receptor unless the operator has selected that mode of operation. (21CFR1020.31(h)(1))

(3) Neither the length nor the width of the x-ray field in the plane of the image receptor must differ from the corresponding dimensions of the selected portion of the image receptor by more than three percent of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum must not exceed four percent of the SID without regard to sign, of the length and width differences.

(4) For spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, then means must be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance must be determined with the beam axis indicated to be perpendicular to the plane of the image receptor. (21CFR1020.31(h)(2))

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Commented [BB(17]: Similar: IA, AK, VA, NC, NE, OH, MI, NJ, IL, FL

G. The center of the x-ray field in the plane of the image receptor must be aligned with the center of the selected portion of the image receptor to within two percent of the SID. (21CFR1020.31(h)(3))

H. Means must be provided to reduce the x-ray field size in the plane of the image receptor to a size smaller than the selected portion of the image receptor such that for spot film devices that are used on: (21CFR1020.31(h)(4))

(1) fixed-SID fluoroscopic x-ray systems which are not required to, and do not provide stepless adjustment of the x-ray field, the minimum field size, at the greatest SID, does not exceed 125 square cm; or (21CFR1020.31(h)(4)(i))

(2) fluoroscopic x-ray systems that have a variable SID and/or stepless adjustment of the field size, the minimum field size, at the greatest SID, must be containable in a square of five cm by five cm. (21CFR1020.31(h)(4)(ii))

I. If a means exists to override any of the required automatic x-ray field size adjustments, then the means must meet the following requirements:

(1) The means must be designed for use only in the event of systems failure.

(2) The means must incorporate a signal visible at the qualified operator's position that indicates whenever the automatic field size adjustment is overridden.

(3) A capability may be provided for overriding the automatic x-ray field size adjustment in case of system failure. If it is so provided, a signal visible at the qualified operator position must indicate whenever the automatic x-ray field size adjustment override is engaged. Each system failure override switch

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must be labeled as follows: X-ray Field Limitation System Failure. (21CFR1020.31(h)(5))

J. Fluoroscopic x-ray systems and radiography using the fluoroscopic imaging assembly with circular receptors manufactured before June 10, 2006 must comply with the following requirements: (21CFR 1020.32(b)(4)(i))

(1) Neither the length nor width of the x-ray field in the plane of the image receptor must 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 must be no greater than four percent of the SID; and (21CFR 1020.32(b)(4)(i)(A))

(2) For rectangular x-ray fields used with circular image receptors, the error in alignment must be determined along the length and width dimensions of the x-ray field that pass through the center of the visible area of the image receptor. (21CFR 1020.32(b)(4)(i)(B))

K. For fluoroscopic x-ray systems manufactured on or after June 10, 2006, the maximum area of the x-ray field in the plane of the image receptor must comply with one of the following requirements: (21CFR 1020.32(b)(4)(ii))

(1) when any linear dimension of the visible area of the image receptor measured through the center of the visible area is less than or equal to 34 cm in any direction, at least 80 percent of the area of the x-ray field overlaps the visible area of the image receptor; or (21CFR 1020.32(b)(4)(ii)(A))

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(2) when any linear dimension of the visible area of the image receptor measured through the center of the visible area is greater than 34 cm in any direction, the x-ray field measured along the direction of greatest misalignment with the visible area of the image receptor does not extend beyond the edge of the visible area of the image receptor by more than two cm. (21CFR 1020.32(b)(4)(ii)(B))

L. Fluoroscopic x-ray systems and radiography using fluoroscopic imaging assembly with rectangular image receptors manufactured on or after June 10, 2006 must comply with the following requirements: (21CFR1020.32(b)(5))

(1) Neither the length nor width of the x-ray field in the plane of the image receptor exceeds 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 must not be greater than 4 percent of the SID; and (21CFR1020.32(b)(5)(i))

(2) The error in alignment is determined along the length and width dimensions of the x-ray field that passes through the center of the visible area of the image receptor. (21CFR1020.32(b)(5)(ii))

M. If the fluoroscopic x-ray field size is adjusted automatically as the SID or image receptor size is changed, then a capability may be provided for overriding the automatic adjustment in case of system failure. If a capability is provided, then a signal visible at the qualified operator's position must indicate whenever the automatic field adjustment is overridden. Each system failure override switch must be labeled as follows: FOR X-RAY FIELD LIMITATION SYSTEM FAILURE.

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(21CFR 1020.32(b)(6))

Subp. 5. **Activation of tube**.

A. X-ray production in the fluoroscopic mode must be controlled by a device that requires continuous pressure by a qualified operator for the entire time of the exposure.

B. When recording fluoroscopic images in a series from the image receptor, a qualified operator must be able to terminate the x-ray exposure at any time, but means may be provided to permit completion of any single exposure of the series in process. (21CFR 1020.32(c))

Subp. 6. **Exposure rates; x-ray systems manufactured before May 19, 1995.**

Fluoroscopic x-ray systems manufactured before May 19, 1995 must meet the following exposure rates requirements:

A. Fluoroscopic x-ray systems provided with automatic exposure rate control must not be operable at any combination of tube potential and current that results in an exposure rate in excess of 88 mGy per minute (vice 10 R/min exposure rate) at the measurement point specified under subpart 9, except during recording of fluoroscopic images. (21CFR 1020.32(d)(1)(i))

B. Fluoroscopic x-ray systems provided without automatic exposure rate control must not be operable at any combination of tube potential and current that results in an exposure rate in excess of 44 mGy per minute (vice 5 R/min exposure rate) at the measurement point specified in subpart 9, except during recording of fluoroscopic images. (21CFR 1020.32(d)(1)(ii))

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Commented [JC(29]: 4732.0825, subpart 5, item A

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Automatic exposure rate control means a device that automatically controls one or more technique factors in order to obtain, at a preselected location, a required quantity of radiation per unit time.

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C. Fluoroscopic x-ray systems provided with both an automatic exposure rate control mode and a manual mode must not be operable at any combination of tube potential and current that results in an exposure rate in excess of 88 mGy per minute (vice 10 R/min exposure rate) in either mode at the measurement point where the center of the useful beam enters the patient except during recording of fluoroscopic images, excluding last image hold. (21CFR 1020.32(d)(1)(iii))

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Similar: NC

Commented [BB(33]: Advisory Committee: Texas added "excluding last image hold". Should we include this here, and elsewhere in Subpart 6?

Subp. 7. **Exposure rates; x-ray systems manufactured on or after May 19, 1995.**

Fluoroscopic x-ray systems manufactured on or after May 19, 1995 must meet the following exposure rates requirements:

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A. Fluoroscopic x-ray systems must be equipped with automatic exposure rate control if operable at any combination of tube potential and current that results in an exposure rate greater than 44 mGy per minute (vice 5 R/min exposure rate) at the measurement point specified in subpart 9. Provision for manual selection of technique factors may be provided. (21CFR 1020.32(d)(2)(i))

Commented [BB(35]: 4732.0825, subpart 5, item D(1)

B. Fluoroscopic x-ray systems must not be operable at any combination of tube potential and current that results in an exposure rate in excess of 88 mGy per minute (vice 10 R/min exposure rate) at the measurement point under subpart 9, except: (21CFR 1020.32(d)(2)(ii))

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(1) for fluoroscopic x-ray systems manufactured prior to June 10, 2006, during the recording of images from a fluoroscopic image receptor using

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photographic film or a video camera when the x-ray source is operated in a pulsed mode. (21CFR 1020.32(d)(2)(iii)(A))

(2) for fluoroscopic x-ray systems manufactured on or after June 10, 2006, for the purpose of providing the qualified operator with recorded images after termination of the exposure. Such recording does not include images resulting from a last-image-hold feature that are not recorded. (21CFR 1020.32(d)(2)(iii)(B))

Subp. 8. **Fluoroscopic x-ray systems with optional high-level control.**

A. When high-level control is selected and the control is activated, the fluoroscopic x-ray system must not be operable at any combination of tube potential and current that results in an exposure rate in excess of 176 mGy per minute (vice 20 R/min exposure rate) at the measurement point under subpart 9.

B. Means of activation of high-level controls must require that:

(1) the high-level control be operable only when continuous manual activation is provided by a qualified operator; and

(2) a continuous signal audible to the qualified operator indicates that the high-level control is activated.

Subp. 9. **Exposure rate; measuring compliance.** Measuring compliance with exposure rate for fluoroscopic x-ray systems must comply with the following:

A. If the source is below the x-ray table, then the exposure rate must be measured at one cm above the tabletop or cradle. (21CFR 1020.32(d)(3)(i))

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Very similar to 21CFR1020.32(d)(2)(iii)(c)

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Commented [JC(40]: Similar: NE, AK, VA, OH, MI, NJ

B. If the source is above the x-ray table, the exposure rate must be measured at 30 cm above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. (21CFR 1020.32(d)(3)(ii))

C. In a C-arm type of fluoroscopic x-ray system, including both stationary and mobile types, the exposure rate must be measured at 30 cm from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, so that the end of the beam-limiting device or spacer cone is no closer than 30 cm from the input surface of the fluoroscopic imaging assembly. (21CFR 1020.32(d)(3)(iii))

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D. In a C-arm type of fluoroscopic x-ray system having an SID less than 45 cm, the exposure rate must be measured at the minimum SSD. (21CFR 1020.32(d)(3)(iv))

E. In a lateral type of fluoroscopic x-ray system, the exposure rate must be measured at a point 15 cm 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 cone positioned as closely as possible to the point of measurement. If the tabletop is movable, then it must be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer cone no closer than 15 cm to the centerline of the x-ray table. (21CFR 1020.32(d)(3)(v))

Subp. 10. **Indication of potential and current.** During fluoroscopy and cinefluorography, x-ray tube potential and current must be indicated continuously at the control panel or qualified operator's position. Deviation of x-ray tube potential and current from the indicated

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value must not exceed the maximum deviation as specified by the manufacturer. (21CFR 1020.32(f))

Subp. 11. **Fluoroscopic time, display, and signal; x-ray systems manufactured before June 10, 2006.** Fluoroscopic x-ray systems manufactured before June 10, 2006 must meet the following time, display, and signal requirements:

A. Fluoroscopic x-ray systems must be provided with means to preset the cumulative on-time of the fluoroscopic x-ray tube. The maximum cumulative time of the timing device must not exceed five minutes without resetting.

B. A signal that is audible to the qualified operator must indicate the completion of any preset cumulative on-time. This signal must continue to sound while x-rays are produced until the timing device is reset.

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Subp. 12. **Fluoroscopic time, display, and signal; x-ray systems manufactured on or after June 10, 2006.** Fluoroscopic x-ray systems manufactured on or after June 10, 2006 must meet the following time, display, and signal requirements:

A. Fluoroscopic x-ray systems must display the fluoroscopic on-time at the qualified operator's working position. This display must function independently of the audible signal described in item E. (21CFR 1020.32(h)(2)(i))

B. When the fluoroscopic x-ray tube is activated, the fluoroscopic on-time in minutes and tenths of minutes must be displayed continuously and updated at least once every six seconds. (21CFR 1020.32(h)(2)(i)(A))

C. The fluoroscopic on-time must be displayed within six seconds of termination of an exposure and remain displayed until reset. (21CFR 1020.32(h)(2)(i)(B))

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D. Means must be provided to reset the display to zero before starting a new examination or procedure. (21CFR 1020.32(h)(2)(i)(C))

E. A signal that is audible to the qualified operator must sound for each passage of five minutes of fluoroscopic on-time during an examination. The signal must sound until manually reset or, if automatically reset, the signal must sound for at least two seconds. (21CFR 1020.32(h)(2)(ii))

Subp. 13. **Source-to-skin distance.**

A. Means must be provided to limit the source-to-skin distance to:

(1) not less than 38 cm on stationary fluoroscopic x-ray systems; and

(2) not less than 30 cm on mobile and portable fluoroscopic x-ray systems.

B. Provisions may be made for operation at a shorter source-to-skin distance that is not less than 20 cm when a fluoroscopic x-ray system is used for a specific surgical application in a sterile field.

C. Stationary, mobile, or portable C-arm fluoroscopic x-ray systems manufactured on or after June 10, 2006, having a maximum source-to-image receptor distance of less than 45 cm, must meet the following requirements:

(1) Means must be provided to limit the source-to-skin distance to not less than 19 cm;

(2) Stationary, mobile, or portable C-arm x-ray systems must be labeled for extremity use only; and

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Commented [JC(47]: Advisory Committee: Thoughts on adding a definition of "sterile field", or include in rule part? *A sterile field is an area created by placing sterile surgical drapes around the patient's surgical site and on the table that will hold sterile instruments and other supplies needed during an examination.* (http://team.uhsystem.com/raddept/pdf/sec15/Rad%20Proc%2015.7.pdf http://www.uhsystem.com/index.htm)

Commented [JC(48]: Advisory Committee: Discuss "for extremity use only". From SSRCR, Part F.5

(3) Provisions may be made for operation at a shorter source-to-skin distance under subitem (1) that is not less than 10 cm when a fluoroscopic x-ray system is used for a specific surgical application in a sterile field.

Subp. 14. **Display of last-image-hold.** Fluoroscopic x-ray systems manufactured on or after June 10, 2006 must meet the following display of last-image hold requirements: (21CFR 1020.32(j))

A. Fluoroscopic x-ray systems must be equipped with display last-image-hold, which is the image following termination of the fluoroscopic exposure.

B. Means must be provided to indicate to the qualified operator if a displayed image is the last-image-hold radiograph or fluoroscopy. Display of the last-image-hold radiographic image must be replaced by the fluoroscopic image concurrently with re-initiation of fluoroscopic exposure, unless separate displays are provided for the last-image-hold radiograph and fluoroscopic images. (21CFR 1020.32(j)(3))

Subp. 15. **Displays of values of exposure rate and cumulative exposure.** Fluoroscopic x-ray systems manufactured on or after June 10, 2006 must display the exposure rate and cumulative exposure at the qualified operator's working position and must meet the following requirements for each x-ray tube used during an examination or procedure: (21CFR 1020.32(k))

A. When the x-ray tube is activated and the number of images produced per unit time is greater than six images per second, the exposure rate in mGy/min must

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be displayed continuously and updated at least once every second. (21CFR 1020.32(k)(1))

B. The cumulative exposure in units of mGy must be displayed either within five seconds of termination of an exposure or displayed continuously and updated at least once every five seconds. (21CFR 1020.32(k)(2))

C. The display of the exposure rate must be distinguishable from the display of the cumulative exposure. (21CFR 1020.32(k)(3))

D. The exposure rate and cumulative exposure must represent the value for conditions of free-in-air irradiation at one of the following reference locations specified according to the type of fluoroscope: (21CFR 1020.32(k)(4))

   (1) In fluoroscopic x-ray systems with an x-ray source below the x-ray table, the x-ray source above the table, or of lateral type, the reference location must be the respective locations under subpart 9, items A, B or E for measuring compliance with exposure rate limits. (21CFR 1020.32(k)(4)(i))

   (2) In C-arm fluoroscopic x-ray systems, the reference location must be 15 cm from the isocenter toward the x-ray source along the beam axis. Alternatively, the reference location must be at a point specified by the manufacturer to represent the location of the intersection of the x-ray beam with the patient's skin. (21CFR 1020.32(k)(4)(ii))

E. Fluoroscopic x-ray systems must be able to reset to zero the display of cumulative exposure before the start of a new examination or procedure. (21CFR 1020.32(k)(5))

F. The displayed exposure rate and cumulative exposure must not deviate from the actual values by more than ±35 percent over the range of 6 mGy/min and 100 mGy to the maximum indication of exposure rate and cumulative exposure, respectively. Compliance must be determined with an on-time greater than three seconds. (21CFR 1020.32(k)(6))

Subp. 16. **Equipment performance evaluation; testing requirements; frequency.**

Commented [JC(52]: **Advisory Committee:** Thoughts on adding a requirement for equipment performance evaluation within 30 days after repair of a machine component that would affect the radiation output, including timer, tube, and power supply, etc…

A. A registrant using a fluoroscopic x-ray system is responsible for the equipment performance evaluation testing requirements under subparts 17 to 23.

B. A registrant must have equipment performance evaluation testing performed over all clinical ranges used by the registrant.

C. Initial equipment performance evaluation testing must be performed at installation before first patient use by a qualified medical physicist or a service technician who is under the general supervision of a qualified medical physicist.

D. Periodic equipment performance evaluation testing must be performed at intervals not to exceed 12 months (365 calendar days) from the date of the previous equipment performance evaluation. A registrant may have a grace period of 30 calendar days to comply with the periodic equipment performance evaluation testing interval requirement under this item.

E. Equipment performance evaluation testing must be performed by a qualified medical physicist or a service technician who is under the general supervision of a qualified medical physicist.

F. If a registrant's fluoroscopic x-ray system fails to meet any of the equipment performance evaluation testing under subparts 17 to 23, then a registrant must:

(1) not use the fluoroscopic x-ray system; and

(2) have a service provider calibrate the fluoroscopic x-ray system so that the operating parameter complies with subparts 17 to 23.

Subp. 17. **Equipment performance evaluation; exposure rates.** A measurement and verification of compliance of maximum exposure rate for fluoroscopy and high-level control, if available.

A. Measurements must be made according to subpart 9.

B. Maximum output at tabletop or equivalent minimum SSD exposure rates for x-ray systems manufactured before May 19, 1995 must be:

(1) < 5 R (44 mGy) per minute for systems without automatic exposure rate control;

(2) < 10 R (88 mGy) per minute for systems with automatic exposure rate control; or

(3) < 20 R (176 mGy) per minute for high-level control.

C. Maximum output at tabletop or equivalent minimum SSD exposure rates for x-ray systems manufactured on or after May 19, 1995 must be:

(1) < 5 R (44 mGy) per minute for systems without automatic exposure rate control;

(2) < 10 R (88 mGy) per minute for systems with automatic exposure rate control; or

(3) < 20 R (176 mGy) per minute for high-level control.

Subp. 18. **Equipment performance evaluation; display exposure rate.** Measurement of the displayed exposure rate and cumulative exposure must be performed according to subpart 15, item F.

Subp. 19. **Equipment performance evaluation; filtration (half-value layer) test.**

A. The half-value layer of the useful beam for a given kVp must not be less than the values shown in item B.

B. Values for half-value layer of useful beam for x-ray tube:

Design operating range (kVp)	Measured kVp	Half-value layer (millimeter of aluminum) Other x-ray Systems*
Below 50	30	0.3
	40	0.4
	50	0.5
51-70	51	1.2
	60	1.3
	70	1.5
Above 70	71	2.1 [2.5]
	80	2.3 [2.9]

90	2.5 [3.2]
100	2.7 [3.6]
110	3.0 [3.9]
120	3.2 [4.3]
130	3.5 [4.7]
140	3.8 [5.0]
150	4.1 [5.4]

*X-ray systems manufactured before June 10, 2006, are not in brackets. X-ray systems manufactured on or after this date are in brackets.

C. To determine a half-value layer at a kVp (x-ray tube potential) that is not listed under item B, a qualified medical physicist or a service technician who is under the general supervision of a qualified medical physicist must:

(1) make a linear interpolation or extrapolation; and

(2) include this determination in the calibration report under part 4732.####.

D. For capacitor energy storage equipment, compliance must be determined with the maximum selectable quantity of charge per exposure.

E. The half-value layer of the useful beam must be measured with all the materials in the beam that normally are present between the source and the patient.

F. For purposes of this subpart, half-value layer means the thickness of a specified material that absorbs the beam of radiation to such an extent that the exposure rate is reduced to one-half of its original value. The contribution of all scattered

radiation, other than any that might be present initially in the beam concerned, is considered excluded.

Subp. 20. **Equipment performance evaluation; beam size test.**

A. The fluoroscopic beam size must comply with subpart 4.

B. The fluoroscopic image size error between fluoroscopic beam size and observed image size must be no more than:

(1) ± 3% of SID in length or width; or

(2) ± 4% of SID for total length and width.

C. The actual spot-film size vs. indicated error between actual fluoroscopic beam size at image receptor and indicated image size must be no more than:

(1) ± 3% of SID in length or width; or

(2) ± 4% of SID for total length and width.

Subp. 21. **Equipment performance evaluation; kVp accuracy test.**

A. A registrant's fluoroscopic x-ray system must meet manufacturer's specifications for the kilovolt peak.

B. The manufacturer specifications required under item A must be available for:

(1) use by a qualified medical physicist or a service technician who is under the general supervision of a qualified medical physicist; and

(2) review by the commissioner at the time of inspection.

C. If the manufacturer's specifications under item B are not available, then the indicated kilovolt peak of a registrant's fluoroscopic x-ray system must be accurate to within ± 5% of the indicated settings.

Subp. 22. **Equipment performance evaluation; image resolution test.**

A. The image resolution must meet the manufacturer's specifications.

B. The manufacturer specifications under item A must be available for:

(1) Use by a qualified medical physicist or a service technician under the general supervision of a qualified medical physicist; and

(2) Review by the commissioner at the time of inspection.

C. If the manufacturer's specifications under item B are not available then the fluoroscopic high contrast resolution and distortion must be:

(1) six inch (15 cm) intensifier: center 30 and edge 24 (wire per inch); or

(2) copper mesh; nine inch (23 cm) intensifier.

Subp. 23. **Equipment performance evaluation; safety controls.** An evaluation of the operation of the five-minute timer, warning lights, interlocks, and collision sensors.

SHIELDING

Subp. 24. **Shielding requirements.** A registrant operating a stationary or a mobile fluoroscopic x-ray system must maintain the dose levels so that they do not exceed the limits under parts 4732.#### to 4732.####;

Commented [BB(53]: Advisory Committee: Are the correct testing parameters identified in item C? These come from MDH's current rule in ch. 4732.
SSRCR: *An evaluation of high contrast resolution and low contrast resolution in both fluoroscopic and spot-film modes.*

Commented [JC(54]: Advisory Committee: Discussion point. MDH understands that not all fluoroscopy x-ray systems have these safety features.

Commented [JC55]: Based on 4732.0365, subparts 1, 2 Consistent with SSRCR

Commented [JC(56]: Advisory Committee: Discuss proposed provision for mobile shielding from Wisconsin and other states.

Mobile and portable x-ray systems used continuously for greater than one week in the same location shall meet the requirements of stationary systems.
(WI, 157.77)

Commented [JC(57]: Reference to dose levels.