DEPARTMENT OF HEALTH

Minnesota Rules, Chapter 4732 X-ray Revision

FLUOROSCOPIC X-RAY SYSTEMS, 1.0

OPERATION OF FLUOROSCOPIC X-RAY SYSTEMS FOR HUMAN USE, 1.0

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.####.

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

G. 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.

H. 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) copper mesh; or

Commented [BB(1]: Advisory Committee:
These come from MDH's current rule in ch. 4732.
Are the correct testing parameters identified in item C?
SSRCR: *An evaluation of high contrast resolution and low contrast resolution in both fluoroscopic and spot-film modes.*

(2) 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.

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

Subp. 25. **Shielding plan.** A registrant with a stationary, mobile, or a portable fluoroscopic x-ray system must comply with the shielding plan requirements under part 4732.####.

Subp. 26. **Supervision of fluoroscopy.**

A. The use of fluoroscopic x-ray equipment is prohibited unless a qualified practitioner working within his or her scope of practice is physically present in the room, except for maintenance or quality assurance activities and training courses.

B. A qualified practitioner who supervises fluoroscopic examinations must:

(1) be authorized to supervise fluoroscopic examinations by a registrant's radiation safety committee;

(2) obtain and document 40 hours of clinical experience supervised by a qualified practitioner who meets the requirements of this subpart; and

(3) complete 40 hours of:

a) didactic education; or

b) training or education that meet the requirements of subpart 28, item A.

Commented [JC(2]: Advisory Committee: Discussion point. MDH understands that not all fluoroscopy x-ray systems have these safety features.

Commented [JC(3]: Reference to dose levels part.

Commented [JC(4]: Reference to shielding plan requirements.

Advisory Committee: Discuss proposed provision for mobile equipment 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 [TP(5]: Advisory Committee discussion: Registered Radiologic Assistant (RRA)

Subp. 27. **Qualified operator qualifications.** The operation of a fluoroscopic x-ray system for use on humans is limited to:

A. a qualified practitioner who:

(1) is performing within the qualified practitioner's scope of practice; and

(2) meets the training requirements under this part.

B. an individual who passed the examination in radiography from the American Registry of Radiologic Technologists (ARRT) and holds a valid certification, and only under the personal supervision of the qualified practitioner who meets the conditions under subpart 26;

C. a medical resident in training, and only under the personal supervision of the qualified practitioner who meets the conditions under subpart 26; and

D. a radiologic technologist student in training and only under the personal supervision of a qualified practitioner who meets the conditions under subpart 26; and

E. a grandfathered x-ray operator who has original documentation from the commissioner or the examination provider of passing the examination that was required before January 1, 2008.

Subp. 28. **Training requirements; fluoroscopic x-ray systems.** An individual qualified to operate or supervise fluoroscopic x-ray systems must complete at least eight hours of initial training.

A. The training must include, at a minimum:

(1) basic properties of radiation including:

a) a brief history of fluoroscopy;

b) x-ray production;

c) inverse square law;

d) penetration of radiation through matter;

e) the fluoroscopic imaging chain; and

f) image intensifiers versus flat panel image receptors.

(2) biological effects of x-ray including:

a) the interaction of radiation with tissue;

b) radiosensitivity;

c) stochastic versus deterministic radiation effects;

d) effects of radiation on the skin and hair;

e) radiation cataractogenesis; and

f) radiation effects in utero.

(3) radiation protection methods for patients and occupational staff including:

a) cardinal rules of radiation protection;

b) managing operator dose during fluoroscopy;

c) selecting and using personal protective equipment;

d) monitoring occupational dose; and

e) dose limits and ALARA considerations.

(4) units of measurement and dose, including dose-area product values and air kerma;

(5) factors affecting fluoroscopic outputs including:

a) radiation quantities and units; and

b) dose rate limits.

(6) high level control options;

(7) dose management including dose reduction techniques, monitoring, and recording:

a) factors affecting patient dose;

b) importance of collimation;

c) advanced dose management techniques;

d) case studies;

e) special considerations for pregnant patients; and

f) fluoroscopic x-ray system-based dose optimization.

(8) principles and operation of the all fluoroscopic x-ray system to be used including:

a) anatomy of fluoroscopic x-ray systems;

b) the anti-scatter grid;

c) modes of operations of fluoroscopic x-ray systems;

d) electronic magnification;

e) automatic exposure control; and

f) recursive filtering.

(9) fluoroscopic and fluorographic outputs of each mode of operation on the system to be used clinically;

(10) methods to reduce patient dose using advanced imaging and recording features; and

(11) procedures for recording and monitoring patient dose including:

a) fluoroscopy time;

b) kerma area product;

c) reference air kerma;

d) measuring the peak skin dose;

e) notification levels; and

f) dose metrics and patient follow-up.

B. An individual qualified to operate or supervise fluoroscopic x-ray systems must be trained in site-specific operating procedures of the fluoroscopic x-ray system in use, including the use of any dose-reduction capability and the radiation output rates for various modes of operation.

C. An individual qualified to operate or supervise fluoroscopic x-ray systems must complete one hour of hands-on fluoroscopic x-ray system training demonstrating application of topics required under this subpart.

D. The eight hours of fluoroscopic training required under item A must be approved by the commissioner under part 4732.####.

Commented [TP(6]: Advisory Committee discussion: SSRCR: The training required in this subsection provided by a QMP or another individual approved by the Agency.

E. An individual authorized to operate or supervise fluoroscopic x-ray systems after the effective date of this rule part must comply with the training requirements under this part before performing fluoroscopy.

F. An individual authorized to operate or supervise fluoroscopic x-ray systems before the effective date of this rule part must comply with the training requirements under this subpart no later than two years after the effective date of this rule part.

Subp. 29. **Ongoing training required.**

A. Qualified practitioners who supervise or operate fluoroscopic x-ray systems and qualified operators who operate fluoroscopic x-ray systems must complete ongoing training every two years.

B. For qualified practitioners who supervise or operate fluoroscopic x-ray systems and qualified operators who operate fluoroscopic x-ray systems, a registrant must:

(1) provide a two hour in-service training that covers all the topics required under subpart 28, item A; or

(2) provide evidence of continuing education that covers all the topics required under subpart 28, item A.

Subp. 30. **Conditions of operation.**

Commented [JC(7]: Similar: NE, AK, VA

A. All fluoroscopic images must be viewed and interpreted by a qualified practitioner.

B. Fluoroscopic x-ray systems must not be used as a positioning tool for radiographic examinations.

Subp. 31. **Radiation safety committee; fluoroscopy.**

Commented [JC(8]: **Subp. 69. Radiation safety committee**. "Radiation safety committee" means a representative group of qualified individuals in a CT or fluoroscopic facility that is responsible for the ongoing review and management of protocols, quality control, equipment testing review, and quality assurance program.

A. A registrant using fluoroscopic x-ray systems must establish a radiation safety committee that meets the requirements of this subpart.

B. A registrant's existing radiation safety committee may be used to meet the requirements of this subpart if the committee's membership complies with item F.

C. The required members under item F must meet quarterly.

D. A radiation safety committee may meet in person or remotely using electronic technology.

E. A record of each radiation safety committee meeting must include the date, names of individuals in attendance, minutes of the meeting, and any actions taken.

F. Required members minimally include:

(1) a qualified practitioner overseeing the fluoroscopy x-ray systems;

(2) a qualified medical physicist;

(3) a radiation safety officer; and

(4) a qualified operator who operates fluoroscopy x-ray systems.

Subp. 32. **Radiation safety committee; responsibilities.**

A. A registrant's radiation safety committee must establish and implement site-specific written or electronic policies that include:

(1) information necessary to estimate the radiation dose to the skin if the peak skin dose, cumulative air kerma, or dose area product are not displayed on the fluoroscopic x-ray system;

(2) substantial radiation dose levels, when exceeded, require an investigation and patient follow-up;

(3) actions to be taken for cases when a substantial radiation dose level is exceeded that include:

a) patient follow-up; and

Commented [JC(9]: MDH intends to add definition. **Substantial radiation dose level**" (SRDL) means an appropriately-selected dose used to trigger additional dose-management actions during a procedure and medical follow-up for a radiation level that might produce a clinically-relevant injury in an average patient.

b) notification to the commissioner when the dose levels meet the requirements of a medical event;

(4) notifying the referring physician when substantial radiation dose levels are exceeded that require actions to be taken for patient safety;

(5) specific examinations that require a spacer cone to comply with subpart 13;

(6) specific examinations and conditions that prevent the use of lead equivalent material under subpart 39, item B;

(7) the eight-hour fluoroscopy training that the registrant is using to comply with subpart 28; and

(8) reviewing the registrant's site-specific policies in this subpart at an interval not to exceed 12 months.

B. A registrant's radiation safety committee must follow nationally recognized standards when establishing policies for substantial radiation dose levels.

C. A registrant's radiation safety committee must verify training is completed for the qualified practitioner and qualified operator.

D. If the registrant revises policies required in the subpart, the registrant must maintain the previous documentation after the revision for review upon inspection

Subp. 33. **Radiation safety committee; document review.**

A. A registrant's radiation safety committee must review and maintain the following written or electronic documentation for a qualified practitioner:

(1) required supervision of fluoroscopy training under subpart 26;

Commented [JC(10]: Subp. 13. **Source-to-skin distance.**

Commented [JC(11]: Following nationally recognized standards for SRDLs is an SSRCR protocol. F5(o)(vi)(1)(d), p. F40

(2) verification that the a qualified practitioner is working within the qualified practitioner's scope of practice;

(3) certificate of completion of the eight-hour fluoroscopy training under subpart 28, item A, that has been approved by the commissioner;

(4) one hour of hands-on fluoroscopic x-ray system training; and

(5) fluoroscopic site-specific training in this part.

B. A registrant's radiation safety committee must review and maintain the following written or electronic documentation for a qualified operator:

(1) a list identifying all qualified operators by first and last name;

(2) certificate of completion of the eight-hour fluoroscopy training under subpart 28, item A, that has been approved by the commissioner;

(3) one hour of hands-on fluoroscopic x-ray system training; and

(4) fluoroscopic site-specific training in this part.

C. A registrant's radiation safety committee must review and maintain the following written or electronic documentation:

(1) fluoroscopic x-ray system quality control, equipment testing, service reports, and corrective actions;

(2) exceeded substantial radiation dose level investigations and follow-up; and

(3) medical event notifications.

Subp. 34. **Prohibited uses.** A registrant must prohibit the exposure of an individual to the useful beam from fluoroscopic x-ray systems according to this subpart.

A. A registrant must prohibit the exposure of an individual to the useful beam from fluoroscopic x-ray systems except when authorized by a qualified practitioner for healing arts purposes;

B. A registrant must prohibit the exposure of an individual to the useful beam for:

(1) training;

(2) demonstration; and

(3) other non-healing arts purposes.

C. The following fluoroscopic x-ray systems are prohibit for use:

(1) hand-held fluoroscopic x-ray systems;

(2) photofluorographic x-ray systems;

(3) fluoroscopic x-ray systems for fitting shoes and apparel; and

(4) fluoroscopic x-ray systems manufactured before February 25, 1978.

Subp. 35. **Ordering of fluoroscopic examinations.**

A. A registrant must have an order for diagnostic fluoroscopic examination.

B. An order for a fluoroscopic examination must be:

(1) authorized by a qualified practitioner working within the qualified practitioner's scope of practice; and

(2) available to the qualified operator at the time of the examination, except if the order is a verbal order.

C. A qualified practitioner must authenticate a verbal order within 48 hours of a fluoroscopic examination.

D. An order for a fluoroscopic examination must include:

(1) the identification of the patient;

(2) the identification of the individual ordering the examination;

(3) the clinical indications for the examination;

(4) the anatomical part to be examined; and

(5) the examination to be performed.

Subp. 36. **Utilization data.**

A. A registrant using fluoroscopic x-ray systems must maintain utilization data of radiation output information in the event that the radiation dose to the skin must be estimated using the policy under subpart 32, item A, subitem 1.

B. The record of radiation output may be maintained in electronic or written form and must include:

(1) a patient identifier;

(2) type of examination;

(3) the date the examination was performed;

(4) the first and last name of the qualified operator who is operating the fluoroscopic x-ray system;

(5) the first and last name of all individuals who remain in the room during an x-ray examination; and

(6) the peak skin dose, cumulative air kerma, or dose area product used if the information is available on the fluoroscopic x-ray system.

C. If the peak skin dose, cumulative air kerma, or dose area product under item B, subitem (6) are not displayed on the fluoroscopic x-ray system, the registrant must use the following to estimate the radiation dose to the skin:

(1) fluoroscopic mode, such as high-level or pulsed mode of operation;

(2) cumulative fluoroscopic exposure time; and

(3) number of images or recorded exposures.

Subp. 37. **Off-site use of a mobile or portable fluoroscopic x-ray system.** A registrant must document the date and location when a registrant's qualified operator uses a registrant's mobile or portable fluoroscopic x-ray system at a location that is not listed on the registrant's equipment registration.

Subp. 38. **Medical event.** A registrant must notify the commissioner after the discovery of a medical event under part 4732.####.

Commented [JC(12]: Reference to medical event subpart (TBD).

Subp. 39. **Protection from radiation.** A registrant is responsible for the radiation protection requirements in this subpart.

Commented [JC(13]: Similar: NE, AK, VA, NC, MI, NJ, IL, WA, FL, AL

A. In a room where fluoroscopic x-ray systems are being used, an individual must be protected with personal protective equipment lead equivalent shielding of at least 0.50 mm by:

(1) wearing a full apron and thyroid; or

(2) remaining behind a full body mobile shield.

B. Fluoroscopic table designs must not permit any portion of an individual's body to be exposed to radiation emanating from above or below the table top unless the

radiation has passed through not less than a total of 0.50 mm lead equivalent material. Lead equivalent material includes drapes, self-supporting curtains, or viewing shields.

Subp. 40. **Records.**

Commented [JC(14]: There will be one Records provision applicable to all registrants.