Department of Health

Adopted Permanent Rules Relating to Ionizing Radiation

Rules as Adopted

4730.1510 REGISTRANT'S SAFETY REQUIREMENTS.

[For text of subps 1 to 3, see M.R.]

Subp. 4. **Procedure and safety instruction.** All individuals who operate an X-ray system shall be initially instructed and annually retrained in facility-specific and system-specific safe operating procedures, emergency procedures for malfunctioning equipment, and quality assurance procedures. Written safety procedures for the facility and X-ray systems shall be provided by the registrant to the individuals specified in subpart 3 including:

[For text of items A to C, see M.R.]

[For text of subps 5 to 7, see M.R.]

Subp. 8. **Holding.** When a patient, film cassette, or intraoral film must be provided with auxiliary support during a radiation exposure, items A to E apply.

[For text of items A to C, see M.R.]

D. No individual shall be used routinely to hold intraoral film, film cassettes, or patients. In those cases where the patient must hold the film cassette, any portion of the body, other than the area of clinical interest struck by the useful beam, shall be protected by not less than 0.5 millimeter lead equivalent material.

[For text of item E, see M.R.]

[For text of subp 9, see M.R.]

Subp. 10. **Radiological practice standards.** Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be used.

[For text of items A to E, see M.R.]

F. The darkroom for film development must be tested

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for film fog at least every three months; any time fog is suspected; whenever there is a change in film speed or a change of safelight bulb or filters; or any time the integrity of any seal around the processor, other equipment, or the darkroom may have been compromised. The amount of fog (increase in optical density) for a two-minute fog test must not exceed 0.04 for facilities doing mammographic film development and 0.08 for all other radiographic film development.

(1) All film must be processed to achieve optimal sensitometric performance.

(2) The film manufacturer's published recommendations for processing time and temperature must be followed.

(3) Chemicals must be mixed according to the chemical manufacturer's recommendations.

[For text of item G, see M.R.]

H. Diagnostic radiographic systems subject to part 4730.1850, other than fluoroscopic, dental intraoral, dental panoramic, and computed tomography systems must not be used in procedures where the source-to-skin distance is less than 30 centimeters (11.8 inches).

[For text of item I, see M.R.]

[For text of subps 11 to 13, see M.R.]

4730.1655 REQUIRED QUALITY ASSURANCE PROGRAM PROCEDURES.

[For text of subps 1 and 2, see M.R.]

Subp. 3. **Quality control measurements for all diagnostic X-ray facilities.** Each registrant operating a diagnostic radiographic facility must implement the quality assurance measures specified in items A to C.

[For text of items A and B, see M.R.]

C. The registrant and the registrant's employees must be familiar with the contents and recommendations of any of the following applicable publications:

(1) NCRP report 99, "Quality Assurance for Diagnostic Imaging Equipment," (December 30, 1988);

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(2) "Quality Assurance Program for Diagnostic Radiology Facilities," by Roger L. Burkhart, Ph.D., United States Department of Health, Education and Welfare, public health service, food and drug administration, publication number 80-8110 (February 1980);

(3) "A Basic Quality Assurance Program for Small Radiology Facilities," by Roger L. Burkhart, Ph.D., United States Department of Health, Education and Welfare, public health service, food and drug administration, publication number 83-8215 (1983).

The registrant may incorporate portions of the publications specified in this subpart into the facility's quality assurance manual described in subpart 2, item A. The publications are available at the Biomedical Library of the University of Minnesota, Minneapolis, Minnesota, or through the Minitex interlibrary loan system.

4730.1691 DIAGNOSTIC QUALITY CONTROL TESTS FOR A QUALITY ASSURANCE PROGRAM.

[For text of subpart 1, see M.R.]

Subp. 2. **Automatic processing.**

TEST TYPE	MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A. Darkroom fog	Quarterly	≤ 0.08 O.D. increase in density (measured at approximately 1.00 O.D.) after 2 minutes using film exposed on-site at the time of test. For mammography the O.D. increase must be ≤ 0.04.
B. Sensitometry and densitometry	Before processing first film of the day	Density ± 0.15 O.D. using film exposed on-site at time of test. As of July 1, 1993, veterinary facilities are not required to perform this test
C. Temperature check	At the time of sensitometry	Follow manufacturer's recommendations.

Subp. 3. **Manual processing.**

	MINIMUM TEST	MINIMUM PERFORMANCE

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TEST TYPE	INTERVAL	CRITERIA
A. Darkroom fog	Quarterly	≤ 0.08 O.D. increase in density (measured at approximately 1.00 O.D.) after 2 minutes using film exposed on-site at time of test
B. Sensitometry and densitometry	Before processing first film of the day	Density ± 0.15 O.D. using film exposed on-site at time of test. As of July 1, 1993, veterinary facilities are not required to perform this test
C. Temperature check	Before processing each batch of film	Follow manufacturer's time and temperature chart

Subp. 4. **All diagnostic radiographic tubes; required when applicable.**

TEST TYPE	MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A. SID accuracy	Biennially	± 2% of measured value
B. X-ray and light field alignment	Biennially	± 2% of SID any one direction, ± 3% of SID, both directions (total)
C. X-ray and bucky alignment	Biennially	± 2% of SID
D. Collimator dial accuracy	Biennially	± 2% of SID
E. Reproducibility	Biennially	Coefficient of variation ≤ 5%
F. mR/mAs	Biennially	± 10% of baseline (Baseline should be as low as reasonably achievable without degrading image quality)
G. Linearity	Biennially	± 10% over clinical range
H. Timer accuracy	Biennially	Single Phase - Use Table 4730.1692 Three Phase - ± 5% of setting
I. Half-value layer	Biennially	Use part 4730.1750, subpart 6, item A
J. kVp accuracy	Biennially	± 5% of indicated kVp for noncertified equipment. For certified equipment follow manufacturer's specified limits
K. Phototimer reproducibility,	Biennially	± 5% of average exposure

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if present

Subp. 5. **For facilities with fluoroscopes and C-arm fluoroscopes, except radiation therapy simulators.**

[The proposed amendments to items A to F are withdrawn at .. S.R. ..]

G.	Fluoroscopic high contrast and distortion	~~Biennially~~ Annually	15 centimeter (six inch) intensifier: center 40 and edge 35 (wires per inch) copper mesh; 23 centimeter (nine inch) intensifier: center 35 and edge 30 (wires per inch) copper mesh

Subp. 6. **For facilities with mammography systems.**

TEST TYPE		MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A.	Same test types and minimum performance criteria as Diagnostic Radiographic Tubes as specified in subpart 4, unless listed below		
B.	kVp accuracy	Annually	± 1 kVp of indicated kVp
C.	Glandular dose (50% glandular and 50% adipose tissue composition)	Annually	A. ≤ 400 millirads for a single view screen film 4.5 cm compressed breast; cranial caudal view; or B. ≤ 100 millirads for a single screened film without grid
D.	Mammographic low and high contrast resolution (phantom image quality). The phantom image must meet the technical specifications for a breast phantom of the American College of Radiology as described in "ACR Mammography Accreditation Program," July 7, 1992. This specification is incorporated by reference, is not subject to frequent change, and is available from the Minnesota Department of Health, Barr Library, or the Minitex interlibrary loan system.	Quarterly	Using the ACR phantom or equivalent that evaluates image quality in the 1.0 to 1.6 optical density range, the system must be capable of producing images of the phantom in which the following are visualized: (1) the three largest masses with thicknesses of 2.0 millimeters, 1.0 millimeters, and 0.75 millimeters; (2) the three largest speck groups with diameters of 0.54 millimeters, 0.40 millimeters, and 0.32 millimeters; and (3) the four largest fibers with thicknesses of 1.56 millimeters, 1.12 millimeters, 0.89 millimeters, and 0.75 millimeters.

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E. Phototimer reproducibility	Annually	± 5% of average exposure

[For text of subps 7 to 9, see M.R.]

Subp. 10. For facilities with interventional study or vascular imaging systems.

TEST TYPE	MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A. Same test types and minimum performance criteria as Diagnostic Radiographic Tubes as specified in subpart 4, unless indicated in this subpart		
B. Same test types and minimum performance criteria as fluoroscopes and C-arm fluoroscopes as specified in subpart 5, unless indicated in this subpart		
C. Film changer screen-film contact	Semi-annually	No significant difference between static and dynamic conditions
D. Low and high contrast resolution	Semi-annually	No significant difference between static and dynamic conditions
E. Optical density of films over duration of filming run	Semi-annually	< ± 0.2 O.D. difference
F. Cinefluorographic exposure rates (use cinefluorographic tests, minimum frequency and minimum performance criteria in subpart 9, item A)		
G. Cinefluorographic low and high contrast resolution	Semi-annually	No degradation from fluoroscopic measurements
H. Ancillary special procedures equipment	Follow recommendations of equipment manufacturer	Meet recommendations of equipment manufacturer
I. The tests specified in subparts 4 and 5	Annually	

Subp. 11. For facilities with dental intraoral systems.

TEST TYPE	MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A. Film processing	Before the first film	Between 0.75 and 1.05 O.D. on the test

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	of the day	tool or follow test tool manufacturer's recommendations
B. Filtration (HVL)	Biennially	Use part 4730.1750, subpart 6, item A
C. Radiation exposure at end of cone	Biennially	Use part 4730.1950, subpart 4, item D
D. Timer reproducibility and accuracy	Biennially	±10% of indicated timer setting
E. kVp accuracy	Biennially	±5% of indicated kVp for noncertified equipment. For certified equipment follow manufacturer's specified limits
F. Reproducibility	Biennially	Coefficient of variation $\leq$ 5%
G. Fog test	Quarterly	Use criteria in subpart 2, item A for automatic processing; subpart 3, item A for manual processing

Subp. 12. **For facilities with dental extraoral systems including panoramic systems.**

TEST TYPE	MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A. Film processing		Use automatic and manual processing as specified in subparts 2 and 3. A step wedge or dose normalizing and monitoring device may be used in place of the sensitometry and densitometry test in subparts 2, item B, and 3, item B.
B. Same test types and minimum performance criteria as Diagnostic Radiographic Tubes in subpart 4.		
C. Fog test	Quarterly	Use criteria in subpart 2, item A for automatic processing; subpart 3, item A for manual processing

Source: Derived from NCRP 99, Tables A.1 to A.10.

4730.1750 GENERAL EQUIPMENT REQUIREMENTS FOR ALL DIAGNOSTIC RADIOGRAPHIC SYSTEMS.

[For text of subps 1 to 14, see M.R.]

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Subp. 15. **Additional requirements applicable only to certified X-ray systems.** Only diagnostic radiographic systems incorporating one or more certified components must comply with the requirements in this subpart which relate to those certified components.

[For text of items A and B, see M.R.]

C. Deviation of technique factors for kVp must be those the manufacturer has specified for that system. For other technique factors, the deviation must have a coefficient of variation of no more than five percent.

[For text of items D and E, see M.R.]

4730.1950 INTRAORAL DENTAL RADIOGRAPHIC SYSTEMS.

[For text of subps 1 to 3, see M.R.]

Subp. 4. **Safety controls.** The registrant must ensure that the safety controls in this subpart are followed.

A. Intraoral film holders and bite blocks must be used. Film must not be routinely held by hand.

[For text of item B, see M.R.]

C. The exposure at the end of the cone must not exceed the values listed in Table 4730.1950:

TABLE 4730.1950

kVp	"D" Speed Film ESE (milliroentgens)	"E Speed Film" ESE (milliroentgens)
50	425 - 575	220 - 320
55	350 - 500	190 - 270
60	310 - 440	165 - 230
65	270 - 400	140 - 200
70	240 - 350	120 - 170
75	170 - 260	100 - 140
80	150 - 230	90 - 120
85	130 - 200	80 - 105
90	120 - 180	70 - 90
95	110 - 160	60 - 80
100	100 - 140	50 - 70

Notes:

(1) Exposures are specified as free-in-air exposures without backscatter.

(2) The indicated kVp is often significantly different from the actual kVp. The kVp must be tested at the time the output per film is measured to determine the correct exposure range to be applied.

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4730.2050 VETERINARY MEDICINE RADIOGRAPHIC INSTALLATIONS.

Subpart 1. **Applicability.** This part applies to X-ray systems used for diagnostic veterinary medicine radiography and applies in addition to the requirements in parts 4730.0100 to 4730.1750.

A. Requirements for fluoroscopic veterinary medicine systems are covered in part 4730.2150.

B. Requirements for therapeutic veterinary medicine shall be the same as those in parts 4730.2350, 4730.2450, and 4730.2475.

C. Requirements for dental intraoral veterinary medicine shall be the same as those in part 4730.1950.

Subp. 2. **Beam limitation.** Collimators must be provided to restrict the useful beam to the area of clinical interest and must provide the same degree of protection as is required of the tube housing.

A. If a variable-aperture beam limiting collimator is used, the projected light and X-ray field must not exceed the smallest dimension of the X-ray film cassette by greater than two percent of the distance of the X-ray tube to the film (SID) in any direction.

B. A method must be provided to:

(1) indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor;

(2) align the center of the X-ray field with respect to the center of the image receptor to within two percent of the SID; and

(3) indicate the SID to within two percent.

C. If a fixed dimension beam limiting collimator is used, it must meet the additional requirements in this item.

[For text of subitems (1) to (3), see M.R.]

(4) The requirements in part 4730.1850, subpart 3, items D and E.

D. In the case of horizontal beam x-rays, a mechanical cassette holding device must be used to ensure that

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no part of the body of the individual steadying the cassette is exposed to primary beam x-rays.

E. If necessary, and any involved individual is properly attired in protective apron and gloves of at least 0.5 mm lead equivalency, this does not preclude the operation of the radiographic system by one of the individuals holding the animal patient using a foot switch.

[For text of subp 3, see M.R.]

4730.2150 FLUOROSCOPIC X-RAY SYSTEMS.

[For text of subps 1 to 10, see M.R.]

Subp. 11. **Control of scattered radiation.** The procedures in this subpart must be used to control scattered radiation from all fluoroscopes.

A. When a fluoroscopic table with an undertable X-ray tube is used, the bucky opening must be shielded to attenuate the scattered radiation by at least 70 percent. Drapes must be attached to the intensifier tower to attenuate scattered radiation by 70 percent.

[For text of items B to D, see M.R.]

[For text of subp 12, see M.R.]

REPEALER. Minnesota Rules, part 4730.1475, is repealed.

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