DEPARTMENT OF HEALTH

Minnesota Rules, Chapter 4732 X-Ray Revision

DRAFT NON-MEDICAL ANALYTICAL X-RAY SYSTEMS, 2.0 (03/09/2018)

Summary of Changes

MDH made a number of changes to the Non-Medical Analytical X-ray Systems rule draft based on the industrial focus group's review and feedback at the December 5, 2017 meeting. Substantive changes to version 1.0 are described below.

Subp. 1. Applicability.

- Deleted "used to determine properties of materials"

Subp. 2. Safety device.

- Replaced "primary x-ray beam" with "useful beam" where it appeared

Subp. 3. Warning lights and devices.

- Revised headnote by inserting "and devices"

Subp. 4. Warning devices.

- Deleted this subpart; incorporated provisions into Subp. 17. **Additional requirements; open beam analytical systems.**

Subp. 4. Beam ports. (formerly Subp. 5)

- Renumbered

Subp. 5. Shutters. (formerly Subp. 6)

- Renumbered
- Removed "configuration" and replaced with "system"

Subp. 6. Radiation source housing. (formerly Subp. 7)

- Renumbered

Subp. 7. Labeling. (formerly Subp. 8)

- Renumbered

Subp. 8. Safety device evaluation. (formerly Subp. 9)

- Renumbered
- Form and syntax edits

Subp. 9. Radiation emission limit (formerly Subp. 10)

- Renumbered

Subp. 10. Generator cabinet or high voltage source radiation emission limits. (formerly Subp. 11)

- Renumbered

Subp. 11. Radiation protection survey. (formerly Subp. 12)

- Renumbered
- Revised headnote by inserting "protection"
- Deleted items C, D, E, and F.

Subp. 12. Area Survey. [new]

- New subpart containing items C, D, and F from subpart 11

Subp. 13. Safety procedures.

- Deleted "that includes step-by-step instructions to accomplish the task"and inserted "and emergency"
- **Item A.** Inserted "and emergency"; deleted subitems (4) and (6)
- **Item B.** Inserted "electronic authorization or"
- **Item C.** Inserted "and emergency" and "at the control panel"

Subp. 15. Bypassing a safety device.

- Deleted this subpart

Subp. 15. Repair or modification. (formerly Subp. 16)

- Renumbered
- Deleted "service provider" and replaced with "personnel"

Subp. 16. Training requirements; qualified personnel. [new].

- Deleted this subpart

Subp. 17. Additional requirements; open-beam analytical x-ray systems.

- Replaced "primary x-ray beam" with "useful beam" where it appeared

4732.#### NON-MEDICAL ANALYTICAL X-RAY SYSTEMS

Subpart 1. **Applicability.** A registrant's analytical x-ray system must comply with this part.

X-RAY SYSTEMS

Subp. 2. **Safety device.** A registrant is responsible for the requirements of this subpart.

A. An open-beam analytical x-ray system safety device must:

(1) prevent the entry of any portion of an individual's body into the useful beam; or

(2) provide an automatic shut-off feature that prevents any part of an individual's body from being exposed to the useful beam.

B. A closed-beam analytical x-ray system safety device must:

(1) have an enclosure for the radiation source, sample or object, detector, and analyzing crystal; and

(2) be enclosed in a chamber, or coupled chambers, that cannot be entered by any part of the body during normal operation.

Subp. 3. **Warning lights and devices.**

A. A visible warning light labeled with the words "X-RAY ON, or other visible warning indicator, that indicates the analytical x-ray system is producing ionizing radiation, must be:

(1) located near a switch that energizes an x-ray tube; and

(2) illuminated only when the tube is energized.

Commented [JC(1): SSRCR; page H4 (definitions area)

Commented [BB(2): SSRCR; page H12, Section H.8

Commented [BB(3): ANSI N43.2-2001; 6.2.2.2.3

Commented [BB(4): SSRCR; page H11, Section H.7

Commented [JC(5): ANSI N43.2-2001; 6.2.2.1.3

Commented [BB(6): Ohio; page 1 3701:1-68-04, (A) (2)
ANSI N43.2-2001; 6.2.2.1.3
AK, FL, IN, ME, NM: same and includes fail-safe

B. Warning devices must be labeled so that the purpose is easily identified. For analytical x-ray systems installed after the effective date of this part, a warning device must have a fail-safe design.

Subp. 4. **Beam ports.** Unused beam ports on radiation source housings must be secured in the closed position to prevent opening.

Subp. 5. **Shutters.** For an open-beam analytical x-ray system, each beam port on the radiation source housing must be equipped with a shutter that cannot be opened unless either a collimator or a coupling has been connected to the beam port.

Subp. 6. **Radiation source housing.** When the x-ray tube housing is the primary shielding for the x-ray tube, and is intended to be opened for normal use or maintenance, the x-ray tube housing must be equipped with an interlock that shuts off the high voltage to the x-ray tube if the housing is opened or is disassembled. All interlocks must:

A. not be used to deactivate the x-ray tube or analytical x-ray system, unless in an emergency or during a test of the interlock system;

B. require a reset from the control panel after triggering any interlock;

C. be a fail-safe design.

Subp. 7. **Labeling.** A registrant is responsible for labeling an analytical x-ray system according to this subpart.

A. An analytical x-ray system must be labeled near any switch that energizes an x-ray tube with a visible and discernible sign bearing the radiation symbol and the words "CAUTION RADIATION - THIS EQUIPMENT PRODUCES

Commented [TP(7]: Iowa; Ch 45, page 24, Section 45.5(3) (b) (3)
AK, IN, KY, LA,NM - similar, effective date different
ME- similar, has "installed after effective date of these regulations, must have…."

Commented [JC(8]: SSRCR; page H13, Section H.8 (d)
ANSI N43.2-2001; 6.2.2.2.2
FL, GA, IL, IN, IA, LA, ME, NM; similar to MN

Commented [JC(9]: SSRCR H.8 (p. 13);
Arkansas; page 3-159, RH-1612.b. (5) –same
FL, IN, IA, LA, ME ; same
NM; similar
ANSI N43.2-2001; 6.2.2.2.2

Commented [JC(10]: SSRCR; page H6, Section H.6 (c) (i), Rhode Island.
ANSI N43.2-2001; 6.2.2.1.6
IA; has first paragraph

Commented [JC(11]: SSRCR; page H9, H.6. (H) (iv) – for items A and B

Commented [BB(12]: GA; same

Commented [BB(13]: GA, KY; same

Commented [JC(14]: ANSI N43.2-2001; 6.2.2.3.4

Commented [JC(15]: MN 4732.0385, subpart 4
AZ, FL, LA, ME - same

Commented [BB(16]: ANSI N43.2-2001; 6.2.2.1.5

IONIZING RADIATION WHEN ENERGIZED", or other words having similar meaning.

B. An open beam analytical x-ray system must be labeled at or near the x-ray exit beam port to identify the location of the beam with the words “CAUTION - HIGH INTENSITY X-RAY BEAM", or other words having similar meaning.

Subp. 8. **Safety device evaluation**. A registrant is responsible for an evaluation of a safety device of an analytical x-ray system:

A. upon installation; and

B. at intervals not to exceed 180 days.

C. A safety device evaluation includes:

(1) the safety device under subpart 2;

(2) the shutters;

(3) the warning lights; and

(4) the warning devices.

D. A safety device evaluation must verify that:

(1) all analytical x-ray system safety devices are functioning as designed; and

(2) all labels are visible and discernible.

E. If an analytical x-ray system safety device is not functioning as designed, then it must be:

(1) labeled immediately as defective; and

(2) removed from service until the safety device is repaired.

Commented [JC(17]: SSRCR; page H6, Section H.6 (j); and

Ohio; page 3, 3701:1-68-04, Section (C) (3)
Safety System components.
SSRCR; page H.9. Section H.6 (J)(2) taking out of service completely or proper admin controls established.

Commented [JC(18]: NC, DE, IL: 3 months

F. A registrant must maintain a record of safety device evaluations for an analytical x-ray system. The record must include:

(1) the dates of evaluations;

(2) a list of the safety devices evaluated;

(3) the results of the evaluations;

(4) the name of the individual performing the evaluations; and

(5) corrective actions recommended and performed for any safety device that fails the evaluations.

G. When an analytical x-ray system is returned to service after being locked-out and tagged, it must be evaluated before use if the date of the last safety device evaluation exceeds 180 days.

H. An analytical x-ray system that is locked out and tagged "DO NOT USE" by the radiation safety officer is exempt from this subpart.

Subp. 9**. Radiation emission limits**. An analytical x-ray system must meet the following radiation emission limits.

A. Each x-ray tube housing must be so constructed that, with all shutters closed, the leakage radiation measured at a distance of 5 centimeters from the x-ray tube housing surface does not exceed 2.5 mrem (0.025 mSv) per hour. This limit must be met at the maximum operating parameters.

B. Closed-beam analytical x-ray systems must not exceed a dose rate of 0.5 mrem (0.005 mSv) in one hour at a distance of 5 centimeters measured outside at the nearest accessible surface.

Commented [JC(19]: SSRCR; page H9, Section H.6 (j)

Commented [BB(20]: SSRCR; page H6, Section H.6. (c)(ii)
ANSI N43.2-2001; 6.2.2.1.8
FL, IN, IA - under radiation source housing

Commented [BB(21]: SSRCR; page H6/H7, Section H.6. (c)(ii) References H.7. (d)
ANSI N43.2-2001; 6.2.2.3.2; has 0.25 mrem/hr
SSRCR; page H11, Section H.7. (d)

C. An open-beam analytical x-ray system must be located and arranged to include sufficient shielding or access controls such that no radiation emission exists in any area surrounding the local component group which may result in a dose to an individual in excess of the dose limits outlined under part 4732.#### . The public dose limit must be met at the maximum operating parameters.

Commented [BB(22]: SSRCR; page H13, Section H.8. (f)
ANSI N43.2-2001; 6.2.2.2 Section has different values.
IA, NM – See Radiation levels

Commented [JC(23]: Public dose limit

Subp. 10. **Generator cabinet or high voltage source radiation emission limits.**

Commented [BB(24]: SSRCR; page H7, Section H.6. (d)
AK, FL, IN, IA, LA, ME, NM : same

A. Each x-ray generator or high voltage source must be supplied with a protective cabinet which limits leakage radiation to 0.25 mrem (2.5 µSv) per hour at a distance of five centimeters measured at the nearest accessible surface.

Commented [BB(25]: ANSI N43.2-2001; 6.2.2.1.1

B. The radiation emission for a closed beam analytical x-ray system must comply with subpart 9, item B.

Commented [BB(26]: SSRCR; page H6/H7, Section H.6. (c)(ii) References H.7. (d)
SSRCR; page H11, Section H.7. (d)

SURVEY REQUIREMENTS

Subp. 11. **Radiation protection survey.** A registrant is responsible for performing a radiation protection survey of an analytical x-ray system that complies with the radiation emission requirements under subpart 9.

Commented [JC(27]: SSRCR; page H7, Section H.6.
(e) AZ, FL, IA. LA, NM are similar

A. A radiation protection survey must be performed:

1) upon installation or relocation of the equipment; and

Commented [JC(28]: ANSI N43.2-2001; 7.2.1

2) after any change to the local components of analytical x-ray system, including the initial arrangement, number, or type.

B. All radiation survey instruments used to perform a radiation protection survey must be calibrated according to part 4732.####.

Subp. 12. **Area survey.** A registrant is responsible for performing an area survey of an analytical x-ray system that complies with the radiation emission requirements under subpart 9.

A. An area survey must be performed:

(1) after any maintenance that requires the disassembly, removal, or repair of a local component of the analytical x-ray system; and

(2) during maintenance, calibration, and other procedure that requires the presence of a useful beam while any local component of the industrial system is disassembled or removed.

B. All radiation survey instruments used to perform an area survey must be calibrated according to part 4732.####.

CONDITIONS OF OPERATION

Subp. 13. **Safety Procedures.** A registrant must develop and comply with operating and emergency procedures for an analytical x-ray system.

Commented [JC(29]: SSRCR; page H4, in definitions
Louisiana; page 233, in definitions
FL, IN, IA - procedures not listed

A. Operating and emergency procedures must include:

(1) sample insertion and manipulation;

(2) equipment alignment;

(3) routine maintenance by the registrant; and

(4) locked out and tagged.

B. No individual may operate an analytical x-ray system in any manner other than that specified in the operating procedures unless the individual has obtained electronic authorization or written approval from the radiation safety officer.

C. Operating and emergency procedures must be available at the control panel to an operator of an analytical x-ray system.

D. Operating and emergency procedures may be maintained in electronic or written form.

Subp. 14. **Posting.** A registrant must post a sign bearing the radiation symbol and the words "CAUTION-X-RAY EQUIPMENT" in each area or room that contains an analytical x-ray system.

Subp. 15. **Repair or modification.** Only qualified personnel must repair, or make modifications to a registrant's analytical x-ray system.

A. The x-ray source power switch must be locked out and tagged for routine shutdown before repair or modification to an analytical x-ray system.

B. A qualified personnel must verify that the x-ray source is off, and remains off, before an operation that involves removing the covers, shielding materials, x-ray source housings, modifications to shutters, collimators, or beam stops.

Subp. 16. **Training requirements; qualified personnel.**

A. A registrant is exempt from using qualified personnel to repair or make modifications to a registrant's analytical x-ray system under subpart 15 if the qualified personnel performing the repair or modification on the registrant's

Commented [BB(30): SSRCR; page H8, section H.6. (h)
FL, IN are the same

Commented [BB(31): SSRCR, Sec. I.10 (f),
Similar: MI;450(8), OK, OR, TN, DE, MA

Commented [BB(32): Arkansas; page 3-161, RH-1612. c.2.A
IA, LA, NM - similar

Commented [BB(33): Ohio; page 2, 3701:1-68-04 (B)(3)
SSRCR. P. H9
IN, IA ; similar

Commented [BB(34): ANSI N43.2-2001; 7.4.2, - Does not include lock-out/tag-out

Commented [JC(35): Added after 12/5 meeting

analytical x-ray system has received training from the x-ray system manufacturer.

B. An individual who has received training from the manufacturer under item A may not train other individuals to repair or make modifications to a registrant's analytical x-ray system; and

C. A registrant must:

(1) maintain documentation of qualified personnel manufacturer's training under item A;

(2) have a current list of qualified personnel on-site; and

(3) have all documentation under this subpart available for review by the commissioner at the time of the inspection.

Subp. 17. **Additional requirements; open-beam analytical x-ray systems.**

A. A registrant must provide protective measures when the useful beam is not intercepted by the detector device under all conditions of operation to avoid exposure to any individual from the useful beam. Protective measures include auxiliary shielding or administrative procedures.

B. An operator must be in immediate attendance at all times when an analytical x-ray system is in operation except when:

(1) the area is locked; or

(2) the equipment is secured against unauthorized or accidental entry.

Commented [JC(36]: SSRCR; page H12, Section H.8. (g)

Commented [BB(37]: SSRCR; page H12, Section H.8. (h) GA - similar

C. An x-ray tube "on-off" status must be located near the radiation source housing. This requirement may be met if the warning indicators required under subpart 3 are visible and discernible by anyone near the useful beam.

D. A shutter "open-closed" status must be located near each port on the radiation-source housing if the useful beam is controlled with a shutter. This requirement may be met if the status light at the control panel is visible and discernible by anyone near the useful beam.

E. Warning devices must be labeled so that the purpose is easily identified. For equipment that is installed after the effective date of this part, a warning device must have a fail-safe design.

Subp. 18. **Records.**

Commented [JC(38]: SSRCR; Page H12, Section H.8 (b)
AZ, IA; combined lights and devices
FL; similar, page VII-1

IA, TX, IN, OH, include 'if the primary beam is controlled in this manner' after A. and B.

Commented [TP(39]: Iowa; Ch 45, page 24, Section 45.5(3) (b) (3)
AK, IN, KY, LA,NM - similar, effective date different
ME- similar, "installed after effective date of these regulations, must have…"

Commented [JC(40]: There will be one records provision applicable to all registrants.

Records of safety device tests, check dates, findings and corrective actions must be available for inspection and maintained. SSRCR; page H9, Section H.6 (j)

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