DEPARTMENT OF HEALTH

Minnesota Rules, Chapter 4732 X-ray Revision

PROPOSED NON-MEDICAL ANALYTICAL X-RAY SYSTEMS, 1.0

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

Subpart 1. **Applicability.** A registrant's analytical x-ray system used to determine the properties of materials must comply with this part.

X-RAY SYSTEMS

Subp. 2. **Safety device.** A registrant is responsible for the safety device requirements for analytical x-ray systems.

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 primary beam path; or

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

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

(1) have a system 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.

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 [BB(5]: ANSI N43.2-2001; 6.2.2.3.1

Subp. 3. **Warning Lights.**

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 located near a switch that energizes an x-ray tube and illuminated only when the tube is energized.

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

Subp. 4. **Warning devices.** A registrant is responsible for the warning devices requirements for open beam analytical x-ray system.

A. An x-ray tube "on-off" status must be located near the radiation source housing. This requirement may be met if the warning lights, required under subpart 3, are readily discernible and viewable by anyone near the primary beam.

B. A shutter "open-closed" status must be located near each port on the radiation-producing equipment housing if the primary beam is controlled with a shutter. This requirement may be met if the status light at the control panel is readily discernible and viewable by anyone near the primary beam.

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

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 [BB(8]: 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.

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

Commented [TP(9)]: 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…."

Subp. 5. **Beam ports.** Unused beam ports on radiation producing housings must be secured in the closed position to prevent opening.

Commented [JC(10)]: 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

Subp. 6. **Shutters.** For an open-beam analytical x-ray configuration, 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.

Commented [JC(11)]: 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

Subp. 7. **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 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:

Commented [JC(12)]: SSRCR; page H6, Section H.6 (c) (i), Rhode Island.
ANSI N43.2-2001; 6.2.2.1.6
IA; has first paragraph

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;

Commented [BB(13)]: GA; same

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

Commented [BB(14)]: GA, KY; same

Commented [VC(15)]: SSRCR; page H9, H.6. (H) (iv)

C. be a fail-safe design.

Commented [JC(16)]: ANSI N43.2-2001; 6.2.2.3.4

Subp. 8. **Labeling.** A registrant is responsible for labeling analytical x-ray systems according to this subpart.

Commented [BB(17)]: Minnesota; 4732.0385, subpart 4
AZ, FL, LA, ME - same

A. All analytical x-ray systems must be labeled near any switch that energizes an x-ray tube with a readily visible and discernible sign bearing the radiation

Commented [BB(18)]: ANSI N43.2-2001; 6.2.2.1.5

symbol and the words "CAUTION RADIATION - THIS EQUIPMENT PRODUCES IONIZING RADIATION WHEN ENERGIZED".

B. Open beam analytical x-ray systems 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".

Subp. 9. **Safety device evaluation**. An operator must evaluate an analytical x-ray safety device upon [initial] installation and every six months (180 days). A safety device evaluation must include the interlocks, shutters, warning lights, warning devices, and required emergency shut-off switches.

A. The evaluation must verify that:

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

(2) all tags and labels are legible and visible.

B. If an analytical x-ray 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 corrected.

C. C. A registrant must maintain a safety device evaluation record. The record must include:

(1) date of evaluations;

Commented [JC(19]: 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. SSRCR has that as an option in their testing if you would like to add that?

Commented [BB(20]: IL, KY; has testing monthly, Section 380.50

Commented [TP(21]: SSRCR; page H9, Section H.6 (j)

(2) a list of [all] the safety devices evaluated;

(3) results of the evaluation;

(4) survey instrument model and serial numbers;

(5) survey instrument current calibration date;

(6) the individual performing the evaluation; and

(7) corrective actions recommended and performed for any safety device that fails the required evaluation.

D. An analytical x-ray system that is locked out and tagged "DO NOT USE" by the RSO is exempt from this subpart.

E. An analytical x-ray system that is returned to service after being locked-out and tagged must be evaluated before use if the date of the last safety device evaluation exceeds the six-month interval.

Subp. 10. **Radiation emission limit**. All analytical x-ray systems 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 tube rating.

Commented [BB(22]: SSRCR; page H6, Section H.6. (c)(ii)
ANSI N43.2-2001; 6.2.2.1.8
FL, IN, IA - under radiation Source housing- slightly diff

Commented [JC(23]: Definition needed?
FDA 1020.30 – Tube rating chart
Tube rating chart means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=1020.30

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 five centimeters measured outside at the nearest accessible surface.

C. Open-beam analytical x-ray systems 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 could result in a dose to an individual in excess of the dose limits outlined in 4732.0430 (current public dose). This limit must be met at the maximum tube rating.

Subp. 11. Generator cabinet or high voltage source radiation dose rate limits.

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.

B. The radiation emission for closed beam analytical x-ray systems must comply with subpart 10, item B.

SHIELDING (AREA) REQUIREMENTS

Subp. 12. **Radiation survey.** A registrant is responsible for performing a survey of analytical x-ray systems that comply with the radiation emission requirements under subpart 10. A radiation survey must be performed:

Commented [BB(24]: 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)

Commented [JC(25]: Add as a definition – ANSI 43.8/ SSRCR

Commented [BB(26]: SSRCR; page H13, Section H.8. (f)
ANSI N43.2-2001; 6.2.2.2 Section has different values.
IA, NM has this under Radiation levels

Commented [JC(27]: MDH may consider moving Item C to the part covering radiation levels.

Commented [BB(28]: SSRCR; page H7, Section H.6. (d)
AK, FL, IN, IA, LA, ME, NM : same

Commented [BB(29]: ANSI N43.2-2001; 6.2.2.1.1

Commented [BB(30]: SSRCR; page H6/H7, Section H.6. (c)(ii) References H.7. (d)
SSRCR; page H11, Section H.7. (d)

Commented [JC(31]: SSRCR; page H7, Section H.6. (e)
AZ, FL, IA. LA, NM are similar; MDH added after bypass

A. upon installation of the equipment, and at an interval not to exceed 12 months;

B. after any change to the local components in the system, including the initial arrangement, number, or type;

C. after any maintenance that requires the disassembly, removal, or repair of a local component in the system;

D. during maintenance, calibration, and other procedure that requires the presence of a primary x-ray beam while any local component in the system is disassembled or removed;

E. after bypass of a safety device or interlock;

F. when a visual inspection of the analytical x-ray systems reveals an abnormal condition, according to subpart 12; and

G. radiation survey instruments must be used according to 4732.####.

Commented [JC(32]: ANSI N43.2-2001; 7.2.1

CONDITIONS OF OPERATION

Subp. 13. **Safety Procedures.** A registrant must develop and comply with operating procedures for analytical x-ray systems that include step-by-step instructions to accomplish the task.

Commented [BB(33]: SSRCR; page H4, in definitions
Louisiana; page 233, in definitions
FL, IN, IA - procedures not listed

A. Operating procedures may be maintained in electronic or written form and must include:

(1) sample insertion and manipulation;

(2) equipment alignment;

(3) routine maintenance by the registrant;

(4) bypassing a safety device;

(5) Lock out/tag out; and

(6) Record retention procedures.

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 written approval from the radiation safety officer (RSO).

C. Operating procedures must be available to all operators of analytical x-ray systems.

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. **Bypassing a safety device.** A registrant is responsible for the requirements of this subpart.

A. A registrant must follow the procedures under subpart 12 for bypassing a safety device.

B. An operator is prohibited from bypassing a safety device, interlock, or removing shielding unless the operator obtains the approval from the RSO.

C. An approval for bypassing a safety device under Item A may be in electronic or written form and must be:

Commented [JC(34]: MDH to develop and specify record retention procedures

Commented [BB(35]: SSRCR; page H8, section H.6. (h)
FL, IN are the same

Commented [JC(36]: GA - similar

Commented [BB(37]: Arkansas; page 3-161, RH-1612. c.2.A
IA, LA, NM - similar

Commented [BB(38]: SSRCR; page H8, Section H.6. (H)(2)
FL, GA. IA , LA , GA are similar; MN has more detail

(1) authorized or signed, and dated by the RSO; and

(2) for a specific and limited period of time.

D. When a safety device or interlock is bypassed, a sign bearing the words "SAFETY SYSTEM NOT WORKING," must be placed:

(1) on the radiation source housing; and

(2) at the control switch.

E. A registrant must maintain utilization data when bypassing a safety device or interlock. Utilization data may be maintained in electronic or written form and must include:

(1) date(s) of the alteration;

(2) type of alteration;

(3) name of the individual who made the alteration;

(4) length of time the unit remained in the altered condition;

(5) name of the individual who restored the unit to normal operation; and

(6) post bypass survey that is authorized or signed by the RSO.

Subp. 16. **Repair or modification.** A qualified service provider must install, repair, or make modifications to a registrant's analytical x-ray system.

Commented [BB(39]: Ohio; page 2, 3701:1-68-04 (B)(3) SSRCR. P. H9
IN, IA ; similar

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.

Commented [BB(40]: ANSI N43.2-2001; 7.4.2, - Does NOT include lock-out/tag-out

B. A qualified service provider must verify that the x-ray source is off, and will remain off, before an operation that involves removing the covers, shielding

materials, x-ray source housings, modifications to shutters, collimators, or beam stops.

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

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

B. An operator must be in immediate attendance at all times when the 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.

Subp. 18. Records.

Commented [BB(41]: SSRCR; page H12, Section H.8. (g)

Commented [BB(42]: SSRCR; page H12, Section H.8. (h) GA - similar

Commented [JC(43]: 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)