

Minnesota Rules, Chapter 4732 X-ray Revision

DRAFT CABINET X-RAY SYSTEMS, 2.0

Summary of Changes

MDH made a number of changes to the cabinet x-ray system rule draft v1.0 based on the industrial focus group's review and feedback at the January 4, 2018 meeting. The changes are described below and refer to this version (2.0).

Subp. 1. Applicability.

- Revised applicability statement to include "other known cabinet x-ray systems" and listed examples

Subp. 5. Controls and indicators.

- **Item A.** Deleted "safety switch" and added "key or password-actuated control..."
- **Item B.** Deleted "A key-actuated safety switch" and added "An exposure control..."
- **Item C.** Revised by dividing into subitems
- **Item D.** Revised for clarity/plain language

Subp. 9. Labeling.

- **Item A.** Deleted "IONIZING RADIATION" and added "or words having similar meaning"
- **Item B.** Added "or words having similar meaning"

Subp. 10. Safety device evaluation.

- Added "For purposes of this subpart, a safety device evaluation includes the safety device under subpart 2, interlocks, warning lights, and additional safety controls under subpart 13"
- **Item C.** Deleted "(4) survey instrument model and serial numbers;" and "(5) survey instrument current calibration date;"

Subp. 11. Radiation emission limit.

- Syntax edits

Subp. 12. Radiation protection survey.

- Changed “radiation survey” to “radiation protection survey”
- **Item A.** Added “or relocation”
- Deleted bypass and visual inspection provisions
- Renumbered [formerly subpart 14]

Subp. 13. Additional safety controls and indicators for cabinet x-ray systems designed to admit humans.

- Modified headnote to “safety controls” and where it appears in subpart
- Syntax and form edits
- Renumbered [formerly subpart 12]

Subp. 14. Baggage inspection and industrial quality control.

- Revised headnote from “Additional requirements for cabinet inspection systems” for clarity
- Renumbered [formerly subpart 13]

Subp. 15. Safety and emergency procedures.

- Added “and emergency” to headnote and where it appears in subpart
- **Item A.** Deleted provisions involving routine maintenance, bypassing a safety device, and record retention procedures

Subp. 16. Repair or modification.

- New subpart

Subp. 17. Exemption to use service provider for cabinet x-ray system repair or modification.

- New subpart

***MDH deleted original Subp. 16. Bypassing a safety system.**

4732.#### CABINET X-RAY SYSTEMS

Subpart 1. Applicability.

- A. A registrant's non-certified cabinet x-ray system must comply with this part.
- B. A registrant's certified cabinet x-ray system must comply with this part and applicable requirements of Code of Federal Regulations, title 21, section 1020.40, or successor requirements.
- C. For purposes of this part, other known cabinet x-ray systems must comply with this part. Examples of known cabinet x-ray systems include fluorescence x-ray (closed beam), breast specimen x-ray, certified cabinet x-ray, package x-ray, particle size analyzer, or ion-implant.

Commented [JC(1): Advisory Committee:
1. Industrial focus group advised MDH that some equipment types were missing and questioned where they should be included.
2. MDH is requesting feedback on this item C and possibly including electron beam welding here.

X-RAY SYSTEMS

Subp. 2. Safety device. A registrant is responsible for the requirements for cabinet x-ray systems. A cabinet x-ray system safety device must prevent the insertion of any part of the human body through:

- A. any port into the useful beam; and
- B. any aperture.

Subp. 3. Warning lights and devices.

- A. A visible warning light labeled with the words "X-RAY ON", or other visible warning indicator that demonstrates the cabinet x-ray system is producing

Commented [JC(2): CFR; Ports and apertures 1020.40(c)(3) Ohio; 3701:1-68-06, A (2,3)

Commented [JC(3): CA; 30337

Commented [JC(4): Ohio; page 1 3701:1-68-04, (A) (2) ANSI N43.2-2001; 6.2.2.1.3 AK, FL, IN, ME, NM, AL (420-3-26-.11): same and includes fail-safe CA; 30337, NJ,NC

ionizing radiation, must be located near a switch that energizes an x-ray tube, and illuminated only when the tube is energized.

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

Commented [BB(5)]: 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. 4. Beam ports. Unused beam ports on radiation producing housing must be secured in the closed position to prevent opening.

Commented [JC(6)]: SSRRC; 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
TX(289.228), AL (420-3-26-.11)

Subp. 5. Controls and indicators. A cabinet x-ray system must be equipped with:

Commented [JC(7)]: Ohio; 3701:1-68-06, A (6) a,b,c,d
CA; 30337

- A. a key-actuated control to prevent x-ray generation with the key removed; or
- B. a password control to prevent x-ray generation; and
- C. an exposure control to initiate and terminate the generation of x-rays other than by functioning of a safety interlock or the main power control.
- D. two independent indicators are required when x-rays are being generated where:
- (1) the failure of a single component of the cabinet x-ray system must not cause the failure of both indicators to perform their intended function;
- (2) one, but not both, of the indicators may be a milliammeter. All other indicators must be legibly labeled "X-RAY ON"; and

- (3) indicators must be activated the entire period of time when x-rays are generated. If x-rays are generated for less than 0.5 seconds, then the indicator must illuminate for at least 0.5 seconds; and
- (4) at least one x-ray generation indicator must be visible and discernible from each door, access panel, or port.

Subp. 6. Safety interlocks.

- A. Each door of a cabinet x-ray system must have a minimum of two safety interlocks where:
- (1) one, but not both of the required interlocks, result in the physical disconnection of the energy supply circuit on the high-voltage generator when a door is opened; and
- (2) results in physical disconnection of the energy supply circuit is not dependent upon any moving part other than the door.
- B. Each access panel must have at least one safety interlock.
- C. If the exposure has been interrupted, then a reset from the control panel is required.
- D. The failure of one safety interlock must not cause the failure of any other safety interlock.

Commented [JC(8)]: CFR; 1020.40, (c)(4), OH has, AK has this

Commented [BB(9)]: Ohio; 3701:1-68-06, A(4)a,b,c,d Same: NJ

Commented [JC(10)]: ANSI; N43.3, 7.5.4

Subp. 7. Floors. A cabinet x-ray system must have a permanent floor. Any support surface to which a cabinet x-ray system is permanently affixed may be deemed the floor of the cabinet x-ray system.

Commented [JC(11): CFR; 1020.40, (C)(2), NJ

Subp. 8. Ground fault. An accidental electrical grounding of an electrical conductor must not generate x-rays.

Commented [JC(12): CFR; 1020.40, (c)(5)
Ohio; 3701:1-68-06, A(5)-similar
CA; 30337

Subp. 9. Labeling. A registrant is responsible for labeling cabinet x-ray systems according to this subpart. A cabinet x-ray system must be labeled:

Commented [JC(13): CFR; 1020.40, (c)(8)
Ohio; 3701:1-68-06, 6(e)
CA; 30337, NJ

A. near any switch that energizes an x-ray tube with a visible and discernible sign with the words "CAUTION – X-RAYS PRODUCED WHEN ENERGIZED", or words having similar meaning.

Commented [JC(14): ANSI N43.2—2001; 6.2.2.1.5

B. adjacent to each port with a visible and discernible sign bearing the words "CAUTION – DO NOT INSERT ANY PART OF THE BODY WHEN SYSTEM IS ENERGIZED - X-RAY HAZARD", or words having similar meaning.

Commented [BB(15): CA; 30337

Subp. 10. Safety device evaluation. A registrant is responsible for the safety device evaluation of a cabinet x-ray safety device upon installation and every six months (up to 180 days). For purposes of this subpart, a safety device evaluation includes the safety device under subpart 2, interlocks, warning lights, and additional safety controls under subpart 13.

Commented [JC(16): SSRRCR; page H6, Section H.6
(j) Ohio; page 3, 3701:1-68-04, Section (C) (3), D
ANSI; N43.3, 8.7

A. The evaluation must verify that:

- (1) all cabinet x-ray safety devices are functioning as designed; and
- (2) all labels are visible and discernible.

B. If a cabinet x-ray safety device is not functioning as designed, then the cabinet x-ray system must be:

- (1) labeled immediately as defective; and
- (2) removed from service until the safety device is repaired.

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

- (1) the dates of evaluations;
- (2) a list of the safety devices evaluated;
- (3) results of the evaluation;
- (4) the name of the individual performing the evaluation; and
- (5) corrective actions recommended and performed for any safety device that fails the required evaluation.

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

E. When a cabinet 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 the six-month interval.

Subp. 11. Radiation emission limit. Radiation emitted from a cabinet x-ray system must not exceed an exposure of 0.5 milliroentgen (0.005 mSv) in one hour at any point 5 centimeters outside the external surface when:

Commented [BB(17)]: Ohio; page 3, 3701:1-68-04, Section (C) (3) (b)

Commented [BB(18)]: ANSI; N43.3, 8.7.4

Commented [JC(19)]: CFR, 1020.40m (c)
(1) Ohio; 3701:1-68-06, A(1)
CA; 30337, NJ

- A. measurements are averaged over a cross-sectional area of ten square centimeters with no linear dimension greater than 5 centimeters;
- B. the cabinet x-ray system is operated at combinations of x-ray tube potential, current, beam orientation, and conditions of scatter radiation that produce the maximum x-ray exposure at the external surface; and
- C. all doors and access panels are fully closed as well as fixed at any other position that may generate x-ray radiation.

Subp. 12. Radiation protection survey. A registrant is responsible for performing a radiation protection survey of cabinet x-ray systems that complies with the radiation emission requirements under subpart 11. A radiation survey must be performed:

- A. upon installation or relocation of the equipment;
- B. after any change to the components in the system; and
- C. with radiation survey instruments used according to part 4732.####.

Subp. 13. Additional safety controls and indicators for cabinet x-ray systems designed to admit humans. A cabinet x-ray system designed to admit humans must:

- A. provide a control within the cabinet for preventing and terminating x-ray generation that cannot be reset, overridden, or bypassed from the outside of the cabinet;
- B. prohibit the initiation of x-ray exposure from within the cabinet;

Commented [JC(20)]: SSRCR; page H7, Section H.6. (e) Ohio; 3701:1-68-06, E TX(289.228) AL (420-3-26-.11),NJ

Commented [BB(21)]: ANSI; N43.3, 8.1, 8.6

Commented [JC(22)]: CFR; 1020.40, (c)(7), AK same as this Ohio; 3701:1-68-06, B, (1,2,3,4,5,6,7)

- C. have audible and visible warning signals within the cabinet that are activated for at least 10 seconds prior to the first initiation of x-ray generation after closing any door designed to admit humans. The failure of any single component of the cabinet x-ray system must not cause failure of both the audible and visible warning signals;
- D. have a visible warning signal within the cabinet that remains activated when x-rays are being generated. If the x-ray generation period is less than one-half second, then the indicators must be activated for one-half second;
- E. have signs that indicate the meaning of the required warning signals according to this subpart and must:
- (1) contain instructions for the use of the control under items C and D; and
 - (2) be visible, discernible, and illuminated when the main power control is in the "on" position; and
- F. provide a means for a person to egress at all times when in an enclosure;
- G. The safety controls and indicators in this subpart must be tested as follows:
- (1) the audible and visible warning signals must be tested and checked daily. A registrant is not required to document and maintain a record of this daily test;
 - (2) the control for x-ray prevention and termination must be checked monthly;
- and

Commented [JC(23)]: CFR – sec 7

Commented [JC(24): Advisory Committee:
MDH is looking for feedback on certified vs non-certified cabinet x-ray systems.

Commented [JC(25)]: Ohio

- (3) if any safety control or indicator in this subpart does not function as designed, then a cabinet x-ray system must be:
 - a) labeled immediately as defective; and
 - b) removed from service until the safety device is repaired.
- (4) A registrant's cabinet x-ray system that is locked out and tagged "DO NOT USE" is exempt from this subpart.

Subp. 14. Baggage inspection and industrial quality control. A registrant's cabinet x-ray system designed for the inspection of baggage and **industrial quality control** must meet the requirements of this subpart.

A. At the control area, an operator of a cabinet x-ray system must be:

- (1) in immediate attendance at all times; and
- (2) able to view the ports and doors during exposure.

B. An operator of a cabinet x-ray system must be able to:

- (1) terminate the exposure or preset succession of exposures at any time for exposures of 0.5 seconds or greater duration;
- (2) complete the exposure or preset succession of exposures of less than 0.5 seconds duration; and
- (3) prevent additional exposures.

Commented [JC(26): CFR; 1020.40 (c)(10)
AK same as this
Ohio; 3701:1-68-06, C(1,2,3)

Commented [JC(27): For inspecting food products
on similar conveyor belt systems.
FG: Term is ok; covers a broad base

CONDITIONS OF OPERATIONS

Subp. 15. Safety and emergency procedures. A registrant must develop and comply with operating and emergency procedures for a cabinet x-ray system that include instructions.

Commented [BB(28)]: SSRCR; page H4, in definitions Louisiana; page 233, in definitions FL, IN, IA; procedures not listed

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

- (1) sample insertion and manipulation;
- (2) equipment alignment;
- (3) equipment malfunctions;
- (4) locked out and tagged systems; and
- (5) daily testing under subpart 13, item G.

B. No individual may operate a cabinet 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.

Commented [BB(29)]: NJ,

C. Operating procedures must be available to an operator of a cabinet x-ray system.

Subp. 16. Repair or modification. Only qualified personnel may install, repair, or make modifications to a registrant's cabinet x-ray system.

Commented [BB(30)]: ANSI; N43.3, 9.2.3

A. The x-ray power source must be locked out and tagged for shutdown before repair or modification to a cabinet x-ray system.

B. The x-ray power source must be off, and remain off, before an operation that involves:

(1) removing covers, shielding materials, or x-ray source housing; or

(2) modifications to collimators or beam stops.

Subp. 17. Exemption to use service provider for cabinet x-ray system repair or modification.

- A. A registrant is exempt from using a service provider to repair or make modifications to a registrant's cabinet x-ray system under subpart 16 if the individual performing the repair or modification on the registrant's cabinet 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 cabinet x-ray system.
- C. A registrant must maintain documentation of manufacturer training under part 4732.#### and have documentation of manufacturer training available for review by the commissioner at the time of the inspection.

Subp. 18. Records.

Commented [BB(31)]: 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. SSRRCR; page H9, Section H.6 (j)