DEPARTMENT OF HEALTH

Minnesota Rules, Chapter 4732 X-ray Revision

PROPOSED NON-MEDICAL CABINET X-RAY SYSTEMS, 1.0

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

Subpart 1. **Applicability.** A registrant's non-medical cabinet x-ray system must comply with this subpart. Certified non-medical cabinet x-ray system must also comply with applicable requirements of Code of Federal Regulations, title 21, section 1020.40, or successor requirements.

X-RAY SYSTEMS

Subp. 2. **Safety Device.** A registrant is responsible for the safety device requirements for cabinet x-ray systems. A cabinet x-ray system safety device must:

A. prevent insertion of any part of the human body through:

(1) any port into the primary beam; and

(2) any aperture.

Subp. 3. **Warning Lights.**

A. A visible warning light labeled with the words "X-RAY ON", or other visible warning indicator that indicates the cabinet 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.

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

Commented [BB(2]: CA; 30337

Commented [BB(3]: 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

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

Subp. 5. **Controls and indicators.** All non-medical cabinet x-ray systems must provide:

A. A key-actuated [safety switch] control to prevent x-ray generation with the key removed.

B. A key-actuated [safety switch] control to initiate and terminate the generation of x-rays other than by functioning of a safety interlock or the main power control.

C. Two independent means which indicate when x-rays are being generated, unless the x-ray generation period is less than one-half second, in which case the indicators shall be activated for one-half second, and which are discernible from any point at which initiation of x-ray generation is possible. Failure of a single component of the cabinet x-ray system shall not cause failure of both indicators to perform their intended function. One, but not both, of the indicators required by this subdivision may be a milliammeter labeled to indicate x-ray tube current. All other indicators shall be legibly labeled "X-RAY ON".

Commented [BB(4]: 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(5]: 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
TX(289.228), AL (420-3-26-.11)

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

Commented [TP(7]: This CFR provision is wordy and unclear. Looking for Focus Group input.

D. Additional means other than milliammeters which indicate when and only when x-rays are being generated, unless the x-ray generation period is less than one-half second in which case the indicators shall be activated for one-half second, as needed to insure that at least one indicator is visible from each door, access panel, and port, and is legibly labeled "X-RAY ON".

Commented [TP(8]: This CFR provision is wordy and unclear. Looking for Focus Group input.

Subp. 6. **Safety Interlocks.**

Commented [JC(9]: CFR; 1020.40, (c)(4), OH has, AK has this

A. Each door of a cabinet x-ray system must have a minimum of two safety interlocks. One, but not both are required interlocks shall be such that door opening results in physical disconnection of the energy supply circuit on the high-voltage generator, and such disconnection shall not be dependent upon any moving part other than the door.

Commented [BB(10]: Ohio; 3701:1-68-06, A(4)a,b,c,d Same: NJ

B. Each access panel must have at least one safety interlock.

C. Following interruption of x-ray generation by the functioning of any safety interlock, use of a control panel provided in accordance with paragraph (c)(6)(ii) of this section shall be necessary for resumption of x-ray generation.

Commented [BB(11]: ANSI; N43.3, 7.5.4

Commented [JC(12]: Need to coordinate this CFR reference with MDH rule.

D. Failure of any single component of the cabinet x-ray system must not cause failure of more than one required safety interlock.

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 system.

Commented [JC(13]: CFR; 1020.40, (C)(2), NJ

Subp. 8. **Ground fault.** An accidental electrical grounding of an electrical conductor must not result in the generation of x-rays.

Commented [JC(14]: 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.

Commented [JC(15]: CFR; 1020.40, (c)(8)
Ohio; 3701:1-68-06, 6(e)
CA; 30337, NJ

A. All cabinet 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 symbol and the words "CAUTION RADIATION – THIS EQUIPMENT PRODUCES IONIZING RADIATION WHEN ENERGIZED".

Commented [JC(16]: ANSI N43.2—2001; 6.2.2.1.5

B. All cabinet x-ray systems must be placed adjacent to each [beam] port and labeled with "CAUTION – DO NOT INSERT ANY PART OF THE BODY WHEN SYSTEM IS ENERGIZED - X-RAY HAZARD".

Commented [BB(17]: CA; 30337

Subp. 10. **Safety device evaluation**. An operator must evaluate a cabinet x-ray safety device upon [initial] installation and every six months (180 days). A safety device evaluation must include the interlocks, warning lights, and required emergency shut-off switches.

Commented [JC(18]: SSRCR; 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 tags and labels are legible and visible.

B. If a cabinet 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. Registrant must maintain a safety device evaluation record. The record must include:

(1) date of evaluations;

(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. A cabinet x-ray system that is locked out and tagged "DO NOT USE" by the RSO is exempt from this part.

E. A cabinet 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. 11. **Radiation emission limit.** Radiation emitted from the 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 [JC(19]: CFR, 1020.40m (c)(1)
Ohio; 3701:1-68-06, A(1)
CA; 30337, NJ

Commented [JC(20]: Should the radiation emission limit provision be consistent (ie – less detailed) with closed-beam analytical x-ray systems? The following language is from the Non-medical analytical x-ray systems rule draft:
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.

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 which produce the maximum x-ray exposure at the external surface; and

C. The door(s) and access panel(s) are fully closed as well as fixed at any other position(s) which will allow the generation of x-ray radiation.

Subp. 12. **Additional controls and indicators for cabinet x-ray systems designed to admit humans.** Cabinet x-ray systems designed to admit humans must:

A. Provide a control within the cabinet for preventing and terminating x-ray generation, which cannot be reset, overridden or bypassed from the outside of the cabinet.

B. Not allow the initiation of x-ray exposure from within the cabinet.

C. Audible and visible warning signals within the cabinet which are actuated for at least 10 seconds immediately prior to the first initiation of x-ray generation after closing any door designed to admit humans. Failure of any single component of the cabinet x-ray system must not cause failure of both the audible and visible warning signals.

D. A visible warning signal within the cabinet must remain actuated when and only when x-rays are being generated, unless the x-ray generation period is

Commented [JC(21]: CFR; 1020.40, (c)(7), AK same as this
Ohio; 3701:1-68-06, B, (1,2,3,4,5,6,7)

Commented [BB(22]: Do we need to include this in subpart 9?

Section F, Ohio

Commented [BB(23]: ANSI; N43.3, 7.5.2

less than one-half second in which case the indicators shall be activated for one-half second.

E. Signs must indicate the meaning of the warning signals required according to this subpart and:

(1) Must contain instructions for the use of the control provided pursuant to subpart 10 A.

(2) Must be legible, visible, and illuminated when the main power control is in the "on" position.

F. A means for a person within the enclosure to be able to egress at all times.

G. In addition to subpart 9, the safety systems in this subpart must be tested for proper operation:

(1) The audible and visible warning signals must be checked daily;

(2) The control for x-ray prevention and termination must be checked monthly;

(3) If the safety system(s) in this subpart do not function as designed, then the safety system(s) must be:

a. Labeled immediately as defective; and

b. Removed from service until the safety device is corrected.

(4) This subpart does not apply to a cabinet system that is lock-out/tag-out by a registrant and tagged "DO NOT USE".

Subp. 13. **Additional requirements for x-ray cabinet inspection systems.** Cabinet x-ray systems designed for the inspection of baggage and [industrial quality control] must:

Commented [JC(24]: CFR; 1020.40 (c)(10)
AK same as this
Ohio; 3701:1-68-06, C(1,2,3)

Commented [JC(25]: For inspecting food products on similar conveyor belt systems.

A. At the control area, an operator must be immediate attendance at all times and must be able to view the ports and doors during exposure.

B. Enable the operator to terminate the exposure or preset succession of exposures at any time for exposures of one-half second or greater duration.

C. Allow for completion of the exposure or preset succession of exposures of less than one-half second duration and must enable the operator to prevent additional exposures.

Subp. 14. **Radiation survey**. A registrant is responsible for performing a survey of cabinet x-ray systems that comply with the radiation emission requirements under subpart 12. A radiation survey must be performed:

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

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

Commented [BB(27]: ANSI; N43.3, 8.1, 8.6

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 a bypass of a safety device or interlock;

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

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

Commented [JC(28]: ANSI; N43.3, 8.2

CONDITIONS OF OPERATIONS

Subp. 15. **Safety Procedures.** A registrant must develop and comply with operating procedures for cabinet x-ray systems that include step-by-step instructions to accomplish the task.

Commented [JC(29]: 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) (2) equipment alignment;

(3) (3) routine maintenance by the registrant;

(4) (4) bypassing a safety device;

(5) (5) Lock out/tag out; and

Commented [JC(30]: Are subitems (1) and (2) needed?

(6) (6) Record retention procedures.

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 written approval from the radiation safety officer (RSO).

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

Subp. 16. **Bypassing a safety system.** A registrant is responsible for the requirements of this subpart.

A. A registrant must follow operating procedures under subpart 15 for bypassing a safety system.

B. An operator is prohibited from bypassing a safety device, interlock, or removing shielding unless an operator obtains 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:

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

(2) for a specified 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 cabinet x-ray system; and

(2) at the control switch.

Commented [BB(31]: NJ,

Commented [JC(32]: SSRCR; page H8, Section H.6. (H) (2) TX(289.228), AL (420-3-26-.11);

Commented [JC(33]: Is this needed?

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

Commented [JC(34]: ANSI; N43.3, 9.2.3

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

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 collimators or beam stops.

Subp. 18. **Records.**

Commented [JC(35]: 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)