

## Minnesota Rules, Chapter 4732 X-ray Revision

DRAFT SECURITY SCREENING X-RAY SYSTEMS, 1.0

### 4732. ##### SECURITY SCREENING X-RAY SYSTEMS.

#### Subpart 1. **Applicability.**

A. A registrant's security screening x-ray system for full body imaging must comply with the requirements of this part.

B. For purposes of this part:

(1) subject means an individual who is in the custody of a correctional or detention facility licensed under Minnesota Statutes, section 241.021; and

(2) security benefit means the use of a security screening x-ray system on a subject to identify contraband items concealed within or on all sides of a subject's body.

**Subp. 2. Leakage radiation.** When the x-ray tube is operated at its maximum rated tube current for the maximum kilovoltage, the leakage dose must not be greater than 2.5  $\mu$ Sv (0.25 mrem) in any one hour at any point 30 centimeters from any external surface. For units that employ a shutter or beamstop, this limit must also apply to the beam exit surface while the shutter is closed or the beam is aligned with the beam stop. For purposes of this subpart, external surface means the outside surface of the enclosure containing all associated ionizing radiation sources.

**Subp. 3. Safety devices or interlocks.** A registrant is responsible for the safety device or interlock requirements of this subpart for a security screening x-ray system

**Commented [TP(1):** Michigan\_ANSI: 6.3

**Commented [JC(2): Advisory Committee:** Is this meant for security screening systems, or for portal systems not regulated under this part?

**Definition:**

Beam exit surface means the surface of the outer system assembly from which the direct x-ray beam emanates. This may be a flat surface or the outer surface of a port or collimator. The subject being scanned is exposed through this surface. Systems with more than one radiation source may have more than one beam exit surface.

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A. All position locking, holding, and centering devices on security screening x-ray system components must function as designed by the manufacturer.

Commented [TP(3)]: Ohio

B. Failure of any single component of the security screening x-ray system must not cause failure of more than one safety interlock.

Commented [TP(4)]: MI; ANSI 7.2.1 (h)

C. A tool or key must be required to open or remove access panels. Access panels to the x-ray source and detector must be provided with at least one safety interlock. For purposes of this subpart, an access panel means any panel designed to be removed or opened for maintenance or service purposes that when removed or opened affects the radiation leakage pattern or allows intrusion into the radiation field.

Commented [JC(5)]: MI; ANSI 7.2.1 (i)

D. For stationary-subject systems, the scanning motion of the x-ray beam relative to the subject must be interlocked and the exposure must terminate when the rate of motion of the beam in any direction falls below a preset minimum speed. The minimum speed must be chosen so that the dose during the exposure period is within the applicable limit.

Commented [BB(6)]: ANSI 7.2.1 (j)

E. Operational interlocks must terminate the useful beam in the event of any security screening x-ray system malfunction that may result in abnormal or unintended radiation emission. Examples of system malfunction include unintended stoppage of beam motion, abnormal or unintended x-ray source output, computer safety system malfunction, termination malfunction, and shutter or beam stop mechanism malfunction.

Commented [BB(7)]: ANSI 7.2.1 (l)

F. In the event of a system malfunction, a security screening x-ray system must terminate radiation exposure so that no location on the subject's body receives

Commented [BB(8)]: ANSI 7.2.1 (m)

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an ambient dose equivalent exceeding 250  $\mu$ Sv (25 mrem), regardless of the size of the exposed area.

G. In the event of a system malfunction that results in termination of exposure, use of the normal control sequence must be reset for a new scan.

Subp. 4. Radiation exposure control. A registrant is responsible for the radiation exposure control requirements of a security screening x-ray system.

A. An x-ray control must:

(1) have a key switch to prevent x-ray generation with the key removed, or a password;

(2) be incorporated into each security screening x-ray system so that an exposure can be terminated by a security screening operator at any time; and

(3) have a means to terminate the exposure at a preset time interval or exposure.

B. A security screening x-ray system designed to control the exposure output using multiple modes of operation must indicate the selected mode before each scan.

Subp. 5. Beam-on indicators. A registrant is responsible for the beam-on indicator requirements of this subpart for a security screening x-ray system.

A. There must be at least one indicator visible from any location where a scan can be initiated that indicates when a scan is in progress.

B. An "X-RAY ON" indicator that lights only when a scan is in progress must be provided. The "X-RAY ON" indicator must be visible:

Commented [BB(9)]: Similar: ANSI 7.2.1 (e)

Commented [BB(10)]: A, B, C are all from MI ANSI 7.2.1 (a)

Commented [BB(11)]: ANSI 7.2.1 (b)

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- (1) at the control panel;
- (2) to all security screening operators; and
- (3) to anyone approaching the inspection zone.

C. For a security screening x-ray system that normally keeps high voltage applied to the x-ray tube at times other than during a scan, there must be at least one lighted "X-RAY ON" or other visible warning indicator that demonstrates the security screening x-ray system is producing ionizing radiation at the control panel where x-rays are initiated indicating when x-rays are being produced.

Commented [JC(12)]: This language from MI. In addition to ANSI.

D. The following warning label must be permanently affixed or inscribed on the security screening x-ray system at the location of any controls used to initiate x-ray generation: "CAUTION: X-RAYS PRODUCED WHEN ENERGIZED".

Commented [JC(13)]: ANSI, 7.2.2

Subp. 6. **Technique factors.** A registrant is responsible for the technique factors requirements of this subpart for a security screening x-ray system.

Commented [BB(14)]: Taken from MI

- A. Technique factors for a security screening x-ray system may not be adjustable and must be preset by the manufacturer for each mode of operation.
- B. Technique factors means the x-ray settings including:
  - (1) the peak kilovoltage applied to the x-ray tube;
  - (2) the electric current passing through the x-ray tube; and
  - (3) the scan time.

Subp. 7. **Equipment preventative maintenance.** A registrant using a security screening x-ray system is responsible for preventative maintenance under this part.

- A. A service provider must complete preventative maintenance on a security screening x-ray system according to the manufacturer specifications:

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- (1) at installation before first subject use; and
- (2) at intervals not to exceed 12 months (365 calendar days), from the date of the previous preventative maintenance.

B. A registrant may have a grace period of 30 calendar days to comply with the preventative maintenance requirement under item A(2).

C. If a registrant's security screening x-ray system fails to meet any of the manufacturer's specifications under this subpart then a registrant must:

- (1) not use the security screening x-ray system; and
- (2) have a service provider calibrate the security screening x-ray system so that the operating parameter meets the requirements under item A.

D. A registrant must maintain the manufacturer specifications under item A for review by the commissioner.

**Subp. 8. Quality management system.** A registrant is responsible for developing, documenting, implementing, and maintaining written or electronic site-specific safety procedures, with the radiation safety officer that meet the requirements of this subpart.

A. Each registrant must implement a quality assurance program that includes safety procedures for:

- (1) interval requirements for the equipment preventative maintenance of the security screening x-ray system to comply with applicable rules of this chapter and manufacturer specifications;
- (2) when security screening x-ray system failures occur or when test results fall outside the tolerance limits;

**Commented [TP(15): Our proposed Definition: Subp. 12. Calibrate or Calibration.** "Calibrate or Calibration" means:

- A. to check, adjust, or systematically standardize to graduations of a quantitative measuring instrument; and
- B. equipment service adjustments to bring radiation-producing equipment into manufacturer's specifications and into compliance with this chapter.

**Commented [TP(16): Our proposed Definition: Subp. 62. Quality assurance program.** "Quality assurance program" means a registrant's site-specific set of activities that includes written procedures designed to reduce unnecessary radiation exposure by optimizing the performance of facility personnel and equipment.

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(3) facility-specific and system-specific safety control procedures according to subpart 21 for each type of security screening x-ray system;

**Commented [JC(17)]:** BB - Similar: IL,

(4) emergency procedures for responding to malfunctioning security screening x-ray systems;

(5) preventing unauthorized use or access to the security screening x-ray system;

(6) training ancillary personnel initially and annually on radiation safety training according to part 4732.#### [Radiation safety];

(7) protective garment integrity according to part 4732.####, subpart 20;

**Commented [JC(18)]:** Reference to REGISTRANT RESPONSIBILITIES

(8) declared pregnant workers;

(9) screening for pregnant subjects;

(10) subject protection for dose limitations under subparts 15 or 16;

(11) members of the public, ancillary personnel, or occupational workers:

a) to hold or assist patients;

b) to remain in the inspection zone during radiation exposure; and

c) subject identification.

**Commented [TP(19)]:** Ancillary personnel means all individuals who, in the course of employment in a year, are likely to receive an occupational dose in excess of 100 millirems (1.0 mSv) must be:  
(1) kept informed of the use of radiation;  
(2) instructed in the health protection problems associated with exposure to radiation, in precautions to procedures to minimize exposure, and in purposes and functions of protective devices employed

B. Each registrant must establish and implement an operative maintenance check program for a security screening x-ray system according to manufacturer specifications and part 4732.#### that includes:

**Commented [TP(20)]:** Reference to Quality Management Systems, quality control program subpart.

(1) documenting the primary and secondary security screening operators responsible for operative maintenance checks and an outline of their responsibilities;

(2) a description of the performance standards, with specific tolerance limits established for each operative maintenance check;

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- (3) a description of the method used to test each parameter;
- (4) a list of the security screening x-ray system parameters to be tested and a schedule of operative maintenance checks for the security screening x-ray system;

C. An operative maintenance check program for a security screening x-ray system must be performed on a daily basis, at a minimum, when subjects are being imaged. An operative maintenance check program must be performed:

- (1) by a security screening operator; and
- (2) prior to first subject use.

D. A registrant must maintain an operative maintenance check program under item B for:

- (1) a security screening operator; and
- (2) review by the commissioner.

E. Each registrant must implement an individual monitoring program that includes procedures for:

- (1) proper use of individual monitoring devices;
- (2) evaluating the required use of individual monitoring according to part 4732.####;
- (3) complying with occupational exposure limits according to part 4732.####;
- (4) providing an annual notification in writing to each current employee for radiation dose according to part 4732.####;
- (5) verifying that any employee receiving occupational exposure at multiple registrants does not exceed 5 rem per year;

**Commented [JC(21):** Reference to individual monitoring rule part

**Commented [BB(22):** Reference to individual monitoring rule part

**Commented [BB(23):** Reference to individual monitoring rule part

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(6) notifying the registrant's administrator when individuals are occupationally over-exposed to radiation according to part 4732.#### [Individual monitoring – Report to individual worker beyond occupational levels];

Commented [BB(24)]: OH wording

(7) for occupational exposure of declared pregnant workers according to part 4732.####;

Commented [JC(25)]: Reference to Dose Monitoring

(8) obtaining and maintaining employees' occupational doses;

(9) providing a report at the end of employment of a worker's dose of radiation according to part 4732.####; and

Commented [BB(26)]: Reference to Individual Monitoring rule part

(10) if minors are employed, maintaining occupational limits that must not exceed 500 millirem per year.

G. Each registrant must implement an ALARA program that includes procedures on personnel protection to include time, distance, and shielding according to this chapter.

(1) A registrant must use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).

(2) For purposes of this subpart, "as low as reasonably achievable" or "ALARA" means making every reasonable effort to maintain exposure to radiation as far below the dose limits as practical, consistent with the purpose for which the registered activity is undertaken, taking into account the state of technology, the economics of improvement in relation to benefits to the

Commented [TP(27)]: SSRCR definition and current 4732. During definition review it was proposed to be included in ALARA rule part.



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public health and safety, and other societal and socioeconomic considerations.

Subp. 9. Shielding requirements. A registrant must meet the shielding requirements under part 4732.####.

Subp. 10. Radiation protection survey.

Commented [JC(28)]: MI; ANSI 8.1.7

A. A radiation protection survey must be performed:

- (1) at installation by a qualified expert or a physicist assistant;
- (2) at intervals not to exceed 12 months;
- (3) after any maintenance or change that may affect the reference effective dose; and
- (4) after any incident that may have damaged the security screening x-ray system.

B. A radiation protection survey must verify:

- (1) reference effective dose;
- (2) radiation leakage;
- (3) inspection zone;
- (4) security screening radiation area; and
- (5) any other parameters specified by the manufacturer of the security screening x-ray system.

Commented [JC(29): Advisory Committee:  
Can these surveys be performed initially and annually by a service technician?

Or, do these surveys have to be performed by a QE or a service technician under the general supervision of a QE?

ANSI definition of reference effective dose”:

Reference effective dose,  $E_{ref}$ : A quantity based on measurable parameters used by this standard for setting dose limits. It is derived from the effective dose to the average adult as defined in ICRU Report 57 “ICUR 1998” and as modified by ICRP publication 103 (ICRP 2007). It is obtained from air kerma (or exposure) and HVL measurements as described in section 6.1.3 of this standard, “Determination of the Reference Effective Dose”.

Subp. 11. Security screening operator. An operator of a security screening x-ray system is limited to an individual who meets the training requirements under subpart 12.

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Subp. 12. Security screening operator training; initial and before first use. An individual operating a security screening x-ray system must be initially trained before first use on subjects and must comply with the requirements of this subpart.

A. A security screening operator must be trained on the operation and use

Commented [JC(30)]: ANSI 8.2.5 a

including:

- (1) operational checks;
- (2) operations of the x-ray system;
- (3) subject positioning;
- (4) interpretation of images;
- (5) procedures to be followed if the system is damaged or malfunctions; and
- (6) practical operational experience.

B. A security screening operator must be trained on radiation safety including:

Commented [JC(31)]: List is from ANSI 8.1.5

- (1) types of radiation;
- (2) sources and magnitude of common/typical exposures;
- (3) radiation units of measurement;
- (4) concept of time, distance, and shielding;
- (5) concept of ALARA;
- (6) biological effects of radiation;
- (7) radiation risks;
- (8) basic communication concepts; and
- (9) training on the engineering controls associated with ensuring that dose to subjects is limited and on the importance of these engineering controls.

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- C. For purposes of this subpart, engineering controls means documented, required, routine procedures aimed at controlling the radiation exposure received by subjects and verifying that dose limits are not exceeded under this part.
- D. A security screening operator must be trained on the manufacturer's operational features by:
- (1) a manufacturer; or
  - (2) a registrant's security screening operator that has received the training by a manufacturer.
- E. A security screening operator must be trained on:
- (1) quality management system in subpart 8;
  - (2) site-specific operating and emergency procedures;
  - (3) other safety hazards (e.g. unauthorized disassembly of the system);
  - (4) physical security procedures to prevent unauthorized use or access;
  - (5) operator awareness and control of inspection zones;
  - (6) how to use relevant radiation meters and personnel dosimetry, if applicable;
  - (7) rights of declared pregnant workers;
  - (8) applicable requirements of this chapter;
  - (9) prohibited uses under subpart 18;
  - (10) supervised practical operations; and
  - (11) familiarity with the information being provided to the subject being screened.
- F. A security screening operator must demonstrates competency and understanding of the training under items A, B, and E by passing a practical

**Commented [JC(32)]:** ANSI, 8.2.5  
Consistent with Industrial Radiography requirements.

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examination covering the requirements of this subpart. The examination must be administered by the registrant.

Subp. 13. **Additional training.** A registrant must provide additional training for a security screening operators at the time of any modification in radiation output:

- A. to the security screening x-ray system; or
- B. as a result of new software, security screening x-ray system, or technology.

Subp. 14. **Annual refresher training.** A registrant must provide annual in-service training for each security screening operator at intervals not to exceed 12 months (365 days). For purposes of this subpart, annual in-service training means a review conducted or provided by a registrant for operators of a security screening x-ray system on the training topics under subpart 12.

**Commented [JC(33)]:** ANSI, 8.2.5  
Consistent with Industrial Radiography

Subp. 15. **Dose limitations: general use security screening x-ray systems.** For general use security screening x-ray systems, a registrant is responsible for maintaining the reference effective dose limitations to a screened subject according to this subpart.

**Commented [JC(34)]:** ANSI: Full body scanner: Class A – general use 6.1.1.1:

- A. The reference effective dose received by a subject from one registrant must not exceed:
  - (1) 0.25  $\mu$ Sv (25  $\mu$ rem) per scan; and
  - (2) 250  $\mu$ Sv (25 mrem) over a 12-month period.
- B. If one or more subjects are screened routinely more than twice each day of the year by the same facility, then the registrant must keep records to document:
  - (1) the number of screenings received by a subject does not exceed 1,000 per 12-month period; or

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- (2) the reference effective dose multiplied by the number of scans does not exceed 250  $\mu$ Sv (25 mrem) over a 12-month period for any subject.

**Subp. 16. Dose limitations; limited use security screening x-ray systems.** For limited use security screening x-ray systems, a registrant is responsible for maintaining the reference effective dose limitations to a screened subject according to this subpart.

Commented [JC(35)]: ANSI: full body scanner: Class A-limited use 6.1.2.2:

A. The reference effective dose received by a subject from one registrant must not exceed:

- (1) 10  $\mu$ Sv (1 mrem) per scan; and
- (2) 250  $\mu$ Sv (25 mrem) over a 12-month period.

B. If one or more subjects are screened routinely more than twice each day of the year by the same facility, then the registrant must keep records to document:

- (1) the number of screenings received by a subject does not exceed 1,000 per 12 month period; or
- (2) the reference effective dose multiplied by the number of scans does not exceed 250  $\mu$ Sv (25 mrem) over a 12-month period for any subject.

**Subp. 17. Information to be provided to screened subjects.**

Commented [JC(36)]: MI; ANSI 8.2.4

A. A registrant must inform each subject being screened that the security screening x-ray system emits ionizing radiation. A registrant may use signs or fact sheets to provide this information to subjects being screened.

B. At a minimum, the scanned subject must be informed of the following for a limited use system:

- (1) the estimated effective dose from one scan is less than 10  $\mu$ Sv (1 mrem) per screening; and

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(2) an example must be provided to compare the dose to a commonly known source of radiation: "The radiation from one scan is roughly equivalent to that received from natural sources during a typical three-hour flight at 30,000 feet."

C. A registrant that is a correctional or detention facility must:

(1) inform an individual who was incarcerated of his or her right to request the total accumulated radiation exposure from all body scans during the individual's incarceration,

(2) notify the individual of this right when the individual is released from incarceration, and

(3) provide the information within 30 days of receiving the request.

Subp. 18. **Prohibited uses.** A registrant must prohibit the exposure of an individual to the useful beam from a security screening x-ray system:

A. for training;

B. for demonstration;

C. for screenings where no security benefit is obtained;

D. to anyone other than a subject;

E. to pregnant subjects; and

F. to minor subjects.

Subp. 19. **Utilization record.** A registrant that screens subjects must maintain a utilization record, in electronic or written form, including:

A. the name, date of birth, and identification of the subject scanned;

**Commented [JC(37)]:** Minn. Stat. 144.121, subd. 1a(d):

(d) For purposes of this section, a security screening system means radiation-producing equipment designed and used for security screening of humans who are in the custody of a correctional or detention facility, and used by the facility to image and identify contraband items concealed within or on all sides of a human body. For purposes of this section, a correctional or detention facility is a facility licensed under section 241.021 and operated by a state agency or political subdivision charged with detection, enforcement, or incarceration in respect to state criminal and traffic laws.

**Commented [BB(38)]:** NY

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- B. the name of the individual operating the security screening x-ray system;
- C. MN Department of Corrections offender identification number, if applicable;
- D. the time and date that each individual is screened;
- E. the reason each screening is conducted; and
- F. documentation of the number of scans to each subject that allows the tracking of subjects across different periods of incarceration during a 365-day period to comply with annual scanning limits for each individual.

Subp. 20. Protection from radiation. A registrant is responsible for the radiation protection requirements for an operator of a security screening x-ray system, ancillary personnel, and members of the public during a security screening x-ray system screening.

- A. A qualified expert, or a physicist assistant, must determine the inspection zone at installation.
- B. A qualified expert, or a physicist assistant, must place clear, identified markings that outline the inspection zone for individuals in the area.
- C. A security screening operator responsible for initiating the scan must be able to view, at all times, the screening area and the inspection zone.
- D. Radiation doses outside of the inspection zone must not exceed 20  $\mu$ Sv (2 mrem) in any one hour.
- E. A security screening x-ray system must be positioned and operated so that an individual at any work station does not exceed a dose of 1 mSv (100 mrem) per year.

Subp. 21. Safety control procedures.

Commented [TP(39)]: ANSI, 6.2 MI

Commented [JC(40)]: Similar: ANSI 7.2.1 (f)

Commented [JC(41)]: MI, Item D(3) (Dose Limitations)

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A. A registrant must establish and maintain safety control procedures for operating the security screening x-ray system that are consistent with the manufacturer's recommendations. The safety control procedures may be in written or electronic format.

B. The operating procedures must be available to the operator for each security screening x-ray system.

C. Safety control procedures for a security screening x-ray system must include:

(1) warnings of potential safety hazards;

Commented [BB(42): ANSI 7.5 (a)

(2) operational procedures and training;

Commented [BB(43): ANSI 7.5 (d)

(3) preventive maintenance requirements;

Commented [BB(44): ANSI 7.5(e)

(4) any restrictions of the operating technique factors or parameter for each mode of operation;

(5) the reference effective dose per screening measured by the qualified expert or physicist assistant that meets the requirements under subparts 15 and 16;

Commented [BB(45): ANSI 7.5 (h);  
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(6) a policy on the radiation protection requirements under subpart 20;

(7) a policy prohibiting the use of a security screening x-ray system where no security benefit is obtained;

Commented [TP(46): Ohio

(8) a policy requiring subjects undergoing screening to be positioned facing away from the source of radiation when using a transmission security screening x-ray system;

Commented [TP(47): Ohio

(9) a policy prohibiting the exposure of pregnant subjects;

Commented [TP(48):

(10) a policy prohibiting the exposure of minor subjects; and

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(11) a policy preventing subjects and individuals from reentering the scanning area from the exit while x-rays are being produced.

Commented [JC(50)]: Similar: ANSI 7.2.1 (f)

Subp. 22. Procedure for maximum annual scans. A registrant must establish and maintain written or electronic safety control procedures to limit the number of scans so that the effective dose is limited to an adult individual:

Commented [JC(51)]: ANSI

A. who is not screened more than twice each day; and

B. whose total scans in a 12-month period do not exceed 1,000.

Subp. 23. Posting. A registrant must post caution signs according to part 4732.####.

Subp. 24. Records. A registrant must maintain records under this part according to part 4732.####.

Commented [JC(52)]:  
Reference to RECORDS part.