



Registration Conditions for Personnel Security Screening Systems Using X-Rays

Table of Contents

Table of Contents	1
a. Scope.....	1
b. Definitions	2
c. System Categories.....	3
i. <i>General-use systems</i>	3
ii. <i>Limited-use systems</i>	4
d. Dose Limitation	4
i. <i>Dose to scanned individuals for general-use systems</i>	4
ii. <i>Dose to scanned individuals for limited-use systems</i>	4
iii. <i>Dose to bystanders, operators, or other employees</i>	5
iv. <i>Shielding</i>	5
e. System Requirements.....	5
i. <i>Indicators</i>	5
ii. <i>Controls</i>	5
iii. <i>Safety interlocks</i>	6
f. Operating Requirements	7
i. <i>Operating procedures</i>	7
ii. <i>Information to be provided to screened individuals</i>	7
iii. <i>Personnel training</i>	8
iv. <i>Preventive Maintenance</i>	8
v. <i>Radiation Surveys</i>	9

a. Scope

Under the provisions of R 333.5039(2) and R 333.5511 of the *Ionizing Radiation Rules Governing the Use of Radiation Machines*, use of personnel security screening systems using x-rays shall be subject to the requirements of these registration conditions. In addition to these registration conditions, owners and operators of these systems are subject to the applicable requirements of Part 1– “General Provisions”, Part 2 – “Registration of Radiation Machines”, and Part 3 – “Standards for Protection Against Radiation for Users of Radiation Machines” of the *Rules*.

MIOSHA-RSS-117 (Rev 5/16)
Authority; 1978 PA 368, as amended

The Michigan Department of Licensing and Regulatory Affairs will not discriminate against any individual or group because of race, sex, religion, age, national origin, color, marital status, disability, or political beliefs. You may make your needs known to this agency if you need assistance with reading, writing, hearing, etc., under the *Americans with Disabilities Act*.

The devices subject to these registration conditions are unique in that they intentionally expose people to ionizing radiation for non-medical purposes. Personnel security screening systems should only be used in the legitimate search for concealed weapons and contraband, plus related activities, such as training and service. Use of these systems for unnecessary or frivolous activities is contrary to the requirements of these registration conditions and the intended use of the applicable systems.

These registration conditions are based on ANSI/HPS N43.17-2009 and apply both to backscatter and transmission technology body scanners.

b. Definitions

Access panel: 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.

As low as reasonably achievable (ALARA): The practice of making every reasonable effort to maintain exposures to radiation as far below the dose limits in the rules as is practical, consistent with the purpose for which the registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of registered radiation machines in the public interest.

Backscatter system: A security screening system that makes use of radiation scattered or deflected from an object or person to form an image of the scattering object or person.

Bystander: Any person other than the individual being screened who is not directly associated with operation of the system.

General-use system: A personnel screening system that is not capable of delivering a reference effective dose greater than 0.25 μSv (25 μrem) per screening. Given proper justification and certain restrictions, general-use systems may be operated without specific controls that would limit the number of individuals scanned or the number of scans per individual in a year.

Inspection zone: The general area established by the facility for the purpose of limiting or controlling access to the area where the screening will be performed. This includes but is not limited to any ingress, egress, gate, portal, traffic path, and areas, access to which is restricted due to the presence of radiation. The ambient dose equivalent outside of the inspection zone shall not exceed 20 μSv (2 mrem) in any 1 hour.

Limited-use system: A personnel screening system that is capable of delivering a reference effective dose greater than 0.25 μSv (25 μrem) per screening. Limited-use systems require additional controls and documentation to ensure that annual individual dose limits are not exceeded. A personnel screening system shall not be capable of delivering a reference effective dose greater than 10 μSv (1 mrem) per screening.

Mode of operation: A selectable set of technique factors or machine settings that is pre-determined by the manufacturer for a specific purpose.

Reference Effective Dose (E_{REF}): A quantity based on measurable parameters used for setting dose limits. The reference effective dose shall be determined from measurements of the half-value layer (HVL) and air kerma (or exposure) using one of the equations (1) or (1a) below.

$$E_{REF} = K_a \times C \quad (\text{eq.1})$$

where

E_{REF} is the reference effective dose in Sv, K_a is the measured air kerma in Gy, and C in Sv/Gy is given by

$C = 0.125 \times \text{HVL in mm of Al}$ or

$C = 1.14$, whichever is smaller.

Or, when using traditional units the equivalent equation is

$$E_{REF} = X \times C_R \quad (\text{eq. 1a})$$

where

E_{REF} is the reference effective dose in rem, X is the measured exposure in R, and

C_R in rem/R is given by

$C_R = 0.110 \times \text{HVL in mm of Al}$ or

$C_R = 1.00$, whichever is smaller.

Screening: The sum of radiation exposures or scans necessary to image objects concealed on all sides of the body as intended by the system design under normal conditions. Examples: 1) for backscatter systems a screening typically consists of four scans, one from each side; 2) for transmission systems a screening typically consists of one scan; 3) for portal systems a screening consists of a complete pass through the inspection zone.

Technique factors: 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.

Transmission system: A security screening system using the conventional means of radiographic imaging in which x-rays pass through a target (e.g., person or container) and create shadow-grams of enclosed objects (e.g., contraband) based on their radiation attenuating properties.

c. System Categories

Personnel screening systems are divided into two categories based on their radiation output. Dose limitation requirements for each system category are described in section (d).

i. *General-use systems*

General-use systems guarantee a high degree of radiation safety due to the extremely low doses delivered and engineering controls incorporated into them. The probability of any one individual receiving a cumulative effective dose in excess of the allowed annual limit from a general-use system is extremely low.

Therefore, general-use systems require few administrative controls and may be operated without the need for tracking the number of individuals scanned or the number of scans per individual in a year.

ii. *Limited-use systems*

Limited-use systems require additional administrative controls in order to ensure that members of the public are not subjected to a cumulative effective dose in excess of the allowed annual limit. Limited-use systems may be suitable when additional security measures are necessary and when a general-use system is not adequate. These systems shall be used with discretion in terms of the number of scans per individual in a year or shall be used with rigorous administrative controls that guarantee the same dose limitation per screening as general-use systems.

d. Dose Limitation

i. *Dose to scanned individuals for general-use systems*

The radiation dose delivered to a human subject shall be kept ALARA while meeting the desired detection performance. Under maximum operating parameters, the reference effective dose shall not exceed 0.25 μSv (25 μrem) per screening. In addition, the reference effective dose received by individuals from a facility shall not exceed 250 μSv (25 mrem) over a 12-month period

If the nature of the screening operation is such that one or more adult individuals may be screened routinely more than twice each day by the same facility (e.g., as in routine screening of employees), the facility shall keep records to show that either:

- (1) The number of screenings received by any individual does not exceed 1,000 per 12-month period; or
- (2) The reference effective dose multiplied by the number of screenings does not exceed 250 μSv (25 mrem) over a 12-month period for any individual.

ii. *Dose to scanned individuals for limited-use systems*

The radiation dose delivered to a human subject shall be maintained ALARA while meeting the desired detection performance. The reference effective dose shall not exceed 10 μSv (1 mrem) per screening.

Administrative controls are required for the operation of all limited-use, full-body scanners. Administrative controls shall be in the form of documented procedures that ensure that the effective dose to any individual screened shall be limited to 250 μSv (25 mrem) in any 12-month period. This shall be accomplished by keeping records to demonstrate that the reference effective dose multiplied by the number of screenings to any individual in a 12-month period does not exceed 250 μSv (25 mrem).

iii. *Dose to bystanders, operators, or other employees.*

An inspection zone shall be established around the personnel security screening system where bystanders are prohibited during the operation of the device. A means shall be provided for any operator responsible for initiating a scan to maintain full visual surveillance of the inspection zone. Radiation doses outside of this inspection zone shall not exceed 20 μSv (2 mrem) in any one hour. The system should be positioned and operated such that personnel at any work station do not exceed a dose of 1 mSv (100 mrem) per year.

iv. *Shielding.*

Under maximum operating parameters, the leakage dose rate at any point 30 cm from any external surface of the device, excluding the beam exit surface, shall not exceed 2.5 μSv (0.25 mrem) in any one hour. For units that employ a shutter or beamstop, this limit shall also apply to the beam exit surface while the shutter is closed or the beam is aligned with the beamstop.

e. System Requirements

i. *Indicators.*

- a. There shall be at least one indicator, clearly visible from any location from which a scan can be initiated, that indicates when a scan is in progress.
- b. There shall be at least one lighted indicator clearly visible from the inspection zone. For portal systems the indicator shall be visible from any approach to the inspection zone to indicate that a scan is in progress.
- c. For any x-ray system that normally keeps high voltage applied to the x-ray tube at times other than during a scan, there shall be at least one lighted “x-ray on” indicator at the control console where x-rays are initiated indicating when x-rays are being produced.

ii. *Controls.*

- a. Power to the system shall be controlled by a key switch. The key shall be captured (unable to be removed) whenever it is in a position that allows exposures to be initiated. Turning on the key switch shall never result in the external emission of radiation.
- b. Each system shall have a means for the operator to initiate the emission of radiation other than the function of an interlock or the main power control.
- c. Each system shall have a means for the operator to terminate the emission of radiation other than the function of an interlock.
- d. Means shall be provided to ensure that operators have a clear view of the scanning area. This can be a direct, mirror view, or real-time video of the scanning area. Engineering controls should be provided to ensure that

individuals do not reenter the scanning area from the exit while x-rays are being produced (e.g., one way turnstile).

- e. Technique factors for each mode of operation shall be preset by the manufacturer and shall not be alterable by the system operator. If there is more than one mode, prior to each scan, a mode indicator shall be clearly visible to the operator.
- f. The following warning label shall be permanently affixed or inscribed on the x-ray system at the location of any controls used to initiate x-ray generation: “CAUTION: X-RAYS PRODUCED WHEN ENERGIZED.”
- g. X-ray emission shall automatically terminate after a preset time or exposure.

iii. Safety interlocks.

- a. Failure of any single component of the system shall not cause failure of more than one safety interlock.
- b. A tool or key shall be required to open or remove access panels. Each access panel to the x-ray source shall have at least one safety interlock to terminate the x-ray production when opened.
- c. For stationary-subject systems, the scanning motion of the x-ray beam relative to the subject shall be interlocked and the exposure shall terminate when the rate of motion of the beam in any direction falls below a preset minimum speed. The minimum speed shall be chosen so that the dose during the exposure period is within the applicable limit.
- d. Operational interlocks shall terminate the primary beam in the event of any system problem that could result in abnormal or unintended radiation emission. This shall include, but is not limited to, 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.
- e. In the event of a malfunction, the system shall terminate radiation exposure rapidly enough so that no location on the subject’s body shall receive an ambient dose equivalent exceeding 250 μSv (25 mrem), regardless of the size of the exposed area.
- f. Following interruption of x-ray production by the functioning of any safety interlock, resetting the interlock shall not result in the production of x-rays. Use of the normal control sequence shall be necessary for resumption of x-ray generation.
- g. For portal systems, the minimum walking or driving velocity through the inspection zone shall be determined by the manufacturer. The minimum speed shall ensure that the dose during the exposure period is within the

applicable limit. Motion sensors shall monitor the speed of pedestrians or vehicles through the inspection zone (in the forward direction) and the radiation exposure shall terminate when the speed drops below the minimum.

f. Operating Requirements

i. *Operating procedures.*

The facility shall document its procedures for operating the system that are consistent with the manufacturer's operations manual. The procedures shall include the following topics:

- (1) Warnings of potential safety hazards (such as unauthorized modification of the system).
- (2) These registration requirements.
- (3) Operational procedures and training needed to use the system safely.
- (4) Preventive maintenance requirements for safe operation.
- (5) Technique factors for each operating mode and beam quality of the primary beam.
- (6) The reference effective dose per screening measured by the manufacturer. This information shall include a definition of "screening" for the system (e.g., number of scans required).
- (7) Identification of the area around the system where the ambient dose equivalent is greater than 20 μSv (2 mrem) in 1 hour of operation at the maximum throughput. This is the minimum boundary of the inspection zone.
- (8) Identification of the area around the system where the ambient dose equivalent is greater than 0.5 μSv (50 μrem) in 1 hour of operation at the maximum throughput. This is the recommended area of exclusion for work stations occupied full-time.

ii. *Information to be provided to screened individuals.*

The facility shall inform each individual being screened that the system emits ionizing radiation and that more information is available. Posters, signs, and handouts are examples of appropriate means to provide this information. At a minimum, the screening subject shall be informed of the following:

- (1) The estimated effective dose from one screening is less than 0.25 μSv (25 μrem) (for general-use systems).
-OR-
The estimated effective dose from one screening (for limited-use systems).

- (2) An example shall be provided to compare the dose to a commonly known source of radiation, such as:

“The radiation from one screening is roughly equivalent to 1 hour of exposure to the average naturally occurring background radiation” (for general-use systems).
-OR-
“The radiation dose from one screening is roughly equivalent to 1 to 2 days of exposure to the average naturally occurring background radiation” (for limited-use systems).
- (3) The system conforms to radiation safety requirements of the Michigan Department of Licensing and Regulatory Affairs.

iii. *Personnel training.*

All personnel associated with the operation of the system shall receive appropriate training sufficient to operate the system in conformance with these conditions. This training shall include:

- (1) Familiarity with the information being provided to the individual being scanned.
- (2) Radiation safety training, including:
 - (a) Types of radiation
 - (b) Sources and magnitude of common exposures
 - (c) Units of measurement
 - (d) Time, distance, and shielding
 - (e) Concept of ALARA
 - (f) Biological effects of radiation and radiation risks
 - (g) 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) Rights of declared pregnant workers.
- (7) Regulatory requirements.
- (8) Supervised practical operations.

iv. *Preventive Maintenance*

The operating institution shall follow the manufacturer's recommended maintenance schedule. Preventive maintenance shall be performed by qualified personnel.

v. *Radiation Surveys*

Radiation surveys shall verify subject dose, radiation leakage, inspection zone, radiation area, and any other parameters specified by the manufacturer. Surveys shall be performed:

- (1) Upon installation.
- (2) At least once every 12 months.
- (3) After any maintenance that affects the radiation shielding, shutter mechanism, or x-ray production components.
- (4) After any incident that may have damaged the system in such a way that unintended radiation emission occurs.