

X-RAY WHOLE BODY IMAGING SYSTEMS FOR NON-MEDICAL USE IN PENNSYLVANIA

Whole body imaging systems that detect all types of dangerous or illegal substances such as guns, liquid explosives, drugs, copper wires, plastics, etc., are now being marketed in the United States. These systems are designed to handle the high-level security needs of prisons, border crossings, jails, and government facilities. Based on unique technology, this low radiation dose X-ray screening system detects many types of illegal substances and weapons both internally and on the body. The X-rays traverse through the body, similar to a medical X-ray, so even objects that have been swallowed or hidden in body cavities may be visible.

The general-use system dose received by an individual being scanned is less than 25 microrem (μrem) per scan. A microrem is a unit that measures the biological effects of radiation. Here are some effective radiation doses for comparison:

- Natural background radiation = 5-10 $\mu\text{rem}/\text{hour}$
- Single dental X-ray = 500 μrem
- Chest X-ray = 2 mrem
- Aircraft flight from New York-Los Angeles = 3-5 mrem

Registration of Whole-Body Scanners

Whole Body Scanners that utilize an X-ray tube must be registered as a radiation-producing machine with the Department of Environmental Protection (DEP) within 30 days of acquisition.

Whole Body Scanner Use in Screening

More importantly, an X-ray system used for detection of explosives, weapons, or illegal items may not be used on human beings without specific permission of the DEP. See 25 Pa. Code § 227a.52 (relating to radiation-producing devices used in individual security screening).

DEP will consider efficacy as a factor in evaluating screening procedures outside of healing arts. The request for approval to use whole body imaging systems for non-medical use should include the following:

- A commitment to compliance with all regulations pertaining to the possession and operation of radiation-producing equipment in 25 Pa. Code Article V (relating to radiological health).
- A written radiation safety program based on accepted radiation protection principles, including keeping exposures as low as reasonably achievable (ALARA). The program shall be developed, documented, and implemented. The radiation protection program shall be reviewed at least annually. (Reference: 10 CFR 20.1101)
- A written plan for equipment evaluation and preventative maintenance in accordance with 25 Pa. Code Section 227a.52(2) and 227a.52(10).
- In addition to X-ray scanner operation training by the manufacturer, the operators shall receive at least two (2) hours of radiation safety training. The Radiation Safety Officer (RSO) shall have eight (8) hours of training in radiation safety which shall include X-ray physics, biological effects, units of measure, safety standards, and protection regulations. All operators and RSO shall receive annual radiation safety refresher training.
- Procedures shall be in place to maintain control of the device at all times to prevent operation by an unauthorized user. (Reference: 25 Pa. Code Section 219.132)

- A description of the population to be examined in the screening program in accordance with 25 Pa. Code Section 221.13(b)(4). This should also include an approximation of the frequency of screening activities, for example, how often an individual will be scanned.
- The X-ray scanner shall not be used to scan individuals who are known or declared to be pregnant.
- Prior to initial use of the scanner, a complete radiological survey shall be performed by a Qualified Expert (QE) and submitted to DEP for review and approval. The survey shall include, at a minimum, the typical exposure to the individual scanned, the equipment operator, and background exposure. A general-use personnel screening system must deliver a referenced effective dose equal to or less than 25 μ rem per scan.
- The typical exposure to an individual scanned shall be measured annually by a QE.
- The X-ray scanner(s) shall be installed in a location(s) outside of routinely occupied areas.
- An inspection zone shall be established around the X-ray scanner where bystanders are prohibited during operation of the scanner. The operator must have full visual surveillance of this zone.
- Access to the operation of the X-ray scanner shall be maintained by individually assigned passwords or biometric fingerprint.
- A radiation-producing device must be labeled with a readily visible and discernible sign or signs bearing the radiation symbol and the words: "CAUTION RADIATION—THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED," or words having a similar intent, near every switch that energizes an X-ray tube in accordance with 25 Pa Code Section 227a.12.

DEP concurs with The American National Standards Institute (ANSI) Standard N43.17-2009 recommendation that individuals who may have repeat security screenings not receive an effective dose greater than 25 mrem in any one year at the registrant's or licensee's facility. Logs and records shall be maintained with identifying information of the individual, the reference effective dose, and the dates and number of times when each individual was screened.

This list of requirements and recommendations is not exhaustive. Contact the Bureau of Radiation Protection at 717-787-3720.

For more information, visit www.dep.pa.gov.