Whole Body X-ray Transmission Security Scanner Radiation Protection Guidance

Prepared by

The Federal Provincial Territorial Radiation Protection Committee

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PURPOSE

This document has been developed by the Federal Provincial Territorial Radiation Protection Committee (FPTRPC) to provide radiation protection guidance for the installation and use of whole body X-ray transmission security scanners (WBXTSSs). It provides an overview of the basic design and performance of WBXTSSs and provides information on Canadian legislative and regulatory frameworks that apply to these devices. Information on radiation dose to scanned individuals is given, in addition to radiation protection principles, and information on dose criteria and other radiation protection guidelines. This document presupposes that appropriate justification procedures have been applied, and is intended to provide information and guidance on radiation safety aspects of WBXTSSs. This guidance document is largely in alignment with the American National Standards Institute (ANSI) standard entitled "Radiation Safety for Personnel Security Screening Systems Using X-ray or Gamma Radiation" (ANSI/HPS N43.17-2009) (1). This standard can be referred to for further details on radiation protection guidelines, as referenced within this guidance document.

WHO THIS GUIDANCE IS FOR

This guidance is intended for all parties involved with the installation and use of WBXTSSs. This may include organizations carrying out whole body X-ray transmission security scanning, Provincial/territorial and federal radiation protection authorities, equipment manufacturers, equipment owners, equipment operators, equipment servicing personnel, and the public.

SCOPE

This document applies to radiation safety of WBXTSSs with respect to dose limits, and furthermore keeping doses as low as reasonably achievable below these limits (optimization). This document does not address whether the use of WBXTSSs is justified (i.e. does more good than harm). Rather, in applying the guidance in this document, it is presupposed that appropriate justification procedures have already been applied.

The process of justification allows the determination of whether a human exposure to ionizing radiation should be undertaken or not. Justification of planned human radiation exposures requires that the benefits to the exposed individual or society outweigh the radiation risks. The justification process requires considerations of factors which will be specific to each potential use situation. International Commission on Radiological Protection (ICRP) 125, "Radiological Protection in Security Screening" (2) provides guidance on the principle of justification. Additional guidance on justification can be found under International Atomic Energy Agency (IAEA) General Safety Requirements (GSR) Part 3 Requirement 10 (3), and in IAEA General Safety Guide (GSG)-5 (4).

INTRODUCTION

Whole body X-ray transmission security scanners (WBXTSSs) are used for detection of prohibited items (e.g. weapons, drugs), primarily in correctional institutions. Unlike backscatter X-ray technology that only detects objects inside clothing or on the surface of the body, transmission scanners can detect objects that are swallowed or hidden inside body cavities and orifices. While various technologies exist, the scanner devices known to FPTRPC to be prevalent in Canada require that the individual stands on a platform positioned between an X-ray tube and a linear array of detectors. The individual is then scanned as the moving platform passes through a vertical fan-shaped beam of X-rays, and a whole body radiographic image is generated.

The scanners typically have selectable scan settings, based on the size of the individual to be scanned, and the types of objects or prohibited materials to be detected through screening. Choice of setting(s) can impact the radiation dose received by the scanned individual. The settings consist of different combinations of X-ray tube voltage, current, and scan time. For instance, the higher the X-ray current and/or the longer the scan time, the higher the radiation dose will be. Of the scanner devices known to FPTRPC to be prevalent in Canada, X-ray tube voltage ranges from 100 kV to 110 kV, current ranges from 1 mA to 1.5 mA, and scan time ranges from 8 seconds to 16 seconds among the available scan settings. Filtration is also applied to the X-ray beam in these devices in order to limit the amount of low-energy X-rays the scanned individual is exposed to, as low-energy X-rays contribute to radiation dose without

contributing to image quality. Total filtration is generally in the range of 4-8 mm aluminum equivalent (5).

These security X-ray devices differ from medical X-ray devices in that their use does not offer a health benefit to the individual being scanned. Their use must be appropriately justified, and once justified, optimization procedures and dose limitation must be applied (as per the ICRP's system of radiological protection). While radiation doses to scanned individuals, operators, and bystanders from these devices are expected to be quite low (e.g. maximum of a few microSieverts (μ Sv) per scan to a scanned individual (see section on "Radiation Dose to Scanned Individuals"), and often negligible doses to operators and bystanders), it is important to ensure that appropriate radiation safety systems and procedures are in place so that radiation doses remain as low as reasonably achievable (ALARA), beyond just meeting dose limits.

APPLICABLE LEGISLATION AND AUTHORITIES

Responsibility for radiation protection is shared across multiple levels of government in Canada.

Radiation Emitting Devices Act

Health Canada administers the <u>Radiation Emitting Devices Act</u> and its <u>Regulations</u>, which govern the sale, lease, importation, and advertising of radiation emitting devices in Canada at the federal level. The Radiation Emitting Devices Regulations set out radiation safety standards for labelling, construction and performance of radiation emitting devices for prescribed classes of devices.

While the *Radiation Emitting Devices Regulations* do not prescribe specific standards applicable to WBXTSSs, it is the responsibility of manufacturers, importers, and distributors to ensure that their products comply with the applicable requirements of the Act, including the provisions outlined in paragraph 4 (b), and section 5.

- Paragraph 4(b) requires that no person shall sell, lease or import into Canada a radiation emitting device if the device creates a risk to any individual of genetic or personal injury, impairment of health or death from radiation by reason of the fact that it
 - (i) does not perform according to the performance characteristics claimed for it,
 - (ii) does not accomplish its claimed purpose, or
 - (iii) emits radiation that is not necessary in order for it to accomplish its claimed purpose.
- Section 5, which applies only in relation to representations relating to the emission of radiation, states no person shall label, package or advertise a radiation emitting device

in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its design, construction, performance, intended use, character, value, composition, merit or safety.

Provincial and territorial requirements

In Canada, the provinces and territories, through their respective legislation, and along with professional associations, may establish rules governing safe installation and use of X-ray equipment and any protocols and safety requirements for operators of X-ray equipment. Guidance in this document may be applied or taken into consideration by provinces and territories in establishing radiation safety requirements. For further information on regulatory requirements in provinces and territories, a list of provincial and territorial radiation protection authorities is available at the following link: https://www.canada.ca/en/health-canada/services/environmental-workplace-health/radiation/federal-provincial-territorial-radiation-protection-committee.html#a4

Canada Labour Code

Note that federal facilities do not fall under jurisdiction of the provincial and territorial regulations. Federally regulated employers/employees are subject to workplace health and safety requirements set out in the *Canada Labour Code* and the *Canada Occupational Health and Safety Regulations* (COHSR).

Part XIX of the COHSR, entitled *Hazard Prevention Program*, addresses obligations concerning the identification of hazards, the assessment of those hazards, the choice of preventative measures, and employee education. Employers are required to develop, implement and monitor a program for the prevention of hazards in the work place in consultation with the policy committee, work place health and safety committee or health and safety representative, as applicable. The guidance set out in this document may be taken into consideration in administering these requirements of the COHSR.

For additional information about the *Canada Labour Code* and the COHSR, it is recommended that you contact the Labour Program of Employment and Social Development Canada, which is responsible for the enforcement of this legislation: http://www.labour.gc.ca/eng/contact/index.shtml

RADIATION DOSE TO SCANNED INDIVIDUALS

While the science of low dose radiation is evolving, the current radiation protection risk model assumes that any radiation exposure may cause some deleterious health effects, the probability of which is proportional to the dose; therefore, any procedure involving exposures to ionizing radiation must be carefully managed. The radiological protection community recommends application of the ALARA (As Low As Reasonably Achievable) principle. This approach to

radiation protection manages and controls exposures to personnel and the general public to as low as is reasonably achievable, taking into account social and economic factors.

The dose that a scanned individual receives depends on a number of factors, such as image quality setting (e.g. X-ray tube voltage, current, and time settings), and how frequently an individual is scanned. As per a review of scientific literature from various countries, doses to screened individuals have been reported to be between 0.1-6 μ Sv per screening (6-11) (with the lowest dose system being used for regular inmate screening for contraband, and the highest dose being used to identify concealment of special objects, such as diamonds, when screening mine workers). These dose estimates are either more direct estimates of effective dose (e.g. through Monte Carlo simulation, or through weighted summation of organ doses as measured with thermoluminescent dosimeters (TLDs)), or estimates of quantities that are used in place of effective dose (e.g. ANSI reference effective dose, ambient dose equivalent (H*(10)), or personal dose equivalent (H_p(10))).

For single whole body security scans, a radiation dose to a scanned individual that is a few microSieverts at most is comparable to a typical effective dose for a medical diagnostic X-ray of an extremity (e.g. hand, foot) (1 μ Sv), or an intra-oral dental x-ray (5 μ Sv). It is a small fraction of the effective dose from a chest X-ray (100 μ Sv), and a very small fraction of the effective dose from a computed tomography procedure (1.5-20 mSv) (12). (Note that these examples are primarily intended to give an idea of the order of magnitude of radiation doses for such procedures. Actual values may differ due to factors such as patient size or specific technologies used.)

For radiation protection purposes, FPTRPC recommends calculating the ANSI reference effective dose as per the method described in ANSI/HPS N43.17-2009 (1) in order to estimate the dose to a scanned individual from WBXTSS devices (see "Radiation Protection Guidelines for Whole Body Scanners"). This is a standardized method that provides a means for air kerma measurements to be converted to estimates of effective dose for comparison against applicable limits. Note that as effective dose is not a directly measurable quantity, operational quantities or approximations of effective dose are needed for comparison against the dose limit/constraints. Further guidance on measurable dose quantities can be found in the ANSI standard mentioned above.

RADIATION PROTECTION PRINCIPLES FOR WHOLE BODY X-RAY TRANSMISSION SECURITY SCANNERS

There are three main principles that the ICRP deems fundamental for the system of protection. FPTRPC would like to emphasize these principles as they are applicable in planned exposure situations (amongst other exposure situations), including in the case of WBXTSSs. The principles are outlined in ICRP 103 (13) as follows:

- "The principle of justification: Any decision that alters the radiation exposure situation should do more good than harm."
- "The principle of optimisation of protection: the likelihood of incurring exposures, the number of people exposed, and the magnitude of their individual doses should all be kept as low as reasonably achievable, taking into account economic and societal factors."
- "The principle of application of dose limits: The total dose to any individual from regulated sources in planned exposure situations other than medical exposure of patients should not exceed the appropriate limits recommended by the Commission."

ICRP 125, "Radiological Protection in Security Screening" (2) goes over the principles of justification, optimisation of protection, and dose limitation for planned exposure situations in the context of using ionizing radiation for security screening. It provides key considerations under ICRP's system of protection for the exposure of an individual to devices including WBXTSSs.

Examples of radiological protection considerations for optimisation and dose limits for security screening using ionizing radiation mentioned in ICRP 125 are as follows:

- **Optimization of protection:** Considerations include:
 - o "the number of exposures necessary to accomplish the screening objective,
 - the dose per exposure,
 - \circ $\;$ and the avoidance of additional (or repeated) exposures."
 - dose constraints for "individuals being screened, individuals who are not being screened but may be in the vicinity of the screening, and individuals who operate and maintain the screening system."
- Dose Limitation:
 - "The exposure of an individual to be screened for security purposes is considered to be public exposure."

Considerations about vulnerable populations

Because of the low dose nature of the scans, the justification and optimization processes applied are expected to be protective of all members of the population, meaning vulnerable populations (e.g. pregnant persons, children) do not need to be considered separately in risk assessment for occasional scanning (2, 5). However, it should be noted that the reference effective dose is based on an adult reference individual, and so for more frequent (e.g. routine) scanning of children, additional analysis is recommended (1). Note these factors are largely based on considerations of radiation-induced health effects or risks. There may be other factors that may prevent certain subgroups of the population from being scanned (e.g. privacy concerns, psychological or physical conditions).

RADIATION PROTECTION GUIDELINES FOR WHOLE BODY SCANNERS

The following outlines FPTRPC's recommended guidance on dose criteria and other radiation protection guidelines for WBXTSSs, and is aligned with international standards where noted. The words *must* and *should* in these guidelines have been chosen with purpose. The word *must* indicates a requirement that is essential to meet current standards of protection, while *should* indicates an advisory recommendation that is highly desirable and is to be implemented where applicable.

- 1) For a facility, WBXTSSs must be operated such that it is ensured that annual full body effective dose received by scanned individuals, operators, and other members of the public remains below 1 mSv (13). Note that in order to be compliant with ANSI/HPS N43.17-2009 (1), the full body effective dose to a scanned individual must not exceed 250 μSv over a 12-month period for a facility, though the ANSI standard states it is recognized that the need for security may sometimes call for the 250 μSv annual limit to be exceeded. It is recommended that an annual effective dose of 250 μSv be considered an "action level", where if this level is exceeded, scan protocols should be reviewed to ensure that dose settings per screening, in addition to the number of scans for an individual, are not in excess of what is required for the necessary security outcome.
- 2) The dose per screening procedure must not exceed 10 µSv as per the "Limited use systems" limit in section 6.1.2 of the ANSI standard. This limit is in terms of "reference effective dose", for which the ANSI standard provides a method of calculation based on measured air kerma and half value layer (HVL) (see section 6.1.3 of the standard).
- 3) In order to ensure that the annual full body effective dose limit is not surpassed within a facility and that doses are kept ALARA,
 - a. Cumulative dose for each scanned individual who is at risk of exceeding 250 μSv in a year for a facility must be tracked. (Note that especially for device models or settings that result in higher-range doses, and with heavy usage patterns, it is possible for individual doses to approach the radiation dose limit criteria above.)

- b. The number of scans per individual, and the exposure level of each scan, must not be increased beyond what is necessary for achieving the intended security outcome.
- c. Appropriate distance and/or shielding must be applied during installation of the control panel where the operator stands to ensure doses to the operator are below the 1 mSv annual limit and remain ALARA.
- d. An exclusion zone of 2 m radius should be established around the scanner that prevents other members of the public from approaching the scanner. The boundary of the exclusion zone should be visible to workers and members of the public. Note that while this distance is expected to offer conservative protection against radiation exposure, this should be independently verified by measurements of a radiation survey conducted by someone with radiation protection expertise as exposure situations may differ between scanner models and setups.
- 4) Acceptance testing must be conducted upon installation to confirm manufacturer specifications are met.
- 5) Operators must complete radiation safety training as provided by the distributor/manufacturer. Radiation safety training must at minimum include:
 - a. The safe operation of the device
 - b. Proper positioning for screened individuals
 - c. Radiation protection procedures and measures for non-screened personnel/public
 - d. Any routine manufacturer-specified quality assurance procedures
 - e. Other relevant training topics as per section 8.2.5 of the ANSI standard

Note that individuals must **not** be scanned with X-rays for training purposes.

- 6) An ongoing quality assurance program must be implemented, with quality control tests as recommended by the manufacturer, including frequency and pass criteria for the tests. If quality control tests are not available from the manufacturer, at minimum the following tests should be conducted to ensure manufacturer specifications are met:
 - a. Function of any X-ray exposure interlocks, indicators, or other radiation safety features that can be practically verified by the operator (Daily)
 - b. Radiation output (Dose per screening procedure) and reproducibility (Annually)
 - c. X-ray beam collimation to receptor (Annually)

d. Leakage radiation and radiation survey (Annually)

Note that individuals must **not** be scanned with X-rays for quality assurance purposes.

7) For shielding requirements, refer to ANSI standard section 6.3. For other device construction, function, labelling, and operating requirements, refer to ANSI standard sections 7 and 8 regarding "limited use" systems.

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