IOWA DEPARTMENT OF PUBLIC HEALTH

Radiation Emitting Body Scanners For Security Related Purposes Regulatory Guide

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1.0 INTRODUCTION

1.1 PURPOSE OF GUIDE

Radiation from radiation emitting machines used on humans for nonmedical purposes is prohibited, unless it is approved by the Iowa Department of Public Health (IDPH) for security-related purposes. Full body scanners use a low dose x-ray system to scan a subject person for many types of items both internally and on the body.

This regulatory guide is provided to describe the type and extent of information for registration to possess radiation-emitting body scanners for security related purposes in Iowa.

You should carefully read this guide and other applicable rules in Iowa Administrative Code (IAC) 641-Chapters 38 through 40 and then complete the registration form. IDPH may request additional information to provide reasonable assurance that the applicant has established an adequate radiation protection program.

1.2 APPLICABLE REGULATIONS

Rules pertaining to this type of registration are found in the IAC 641-Chapters 38, 39, and 40. You may go to https://idph.iowa.gov/radioactivematerials/rules and follow the links to access these rules.

Note: Due to non-medical use of these machines and overlap with radioactive materials in other industrial machines, security-related radiation machines are managed by the Radioactive Materials Program within the Bureau of Radiological Health.

1.3 AS LOW AS REASONABLY ACHIEVABLE (ALARA) PHILOSOPHY

Sub rule 3 of 641-40.1(3) states "…Every reasonable effort should be made to maintain radiation exposures as low as reasonably achievable (ALARA)." As a registrant, you should consider the ALARA philosophy in the development of work plans involving radiation emitting equipment.

The success of an ALARA program depends on the cooperation of each person who works at your facility. Management should make a formal policy commitment to the ALARA philosophy and implement that commitment with the use and maintenance of radiation emitting equipment. Management needs to designate one or more responsible persons who will oversee the day-to-day operations of the radiation safety program, including the mandatory annual audit of the radiation safety program.

The operation of full body scanners intentionally exposes people to low doses of ionizing radiation for security screening purposes. While aspiring to the lowest dose achievable, IDPH recognizes that these machines can provide greater security and safety for a larger population as well as the screened individual.

2.0 REGISTRATION

IDPH registers radiation emitting equipment that is operational and in use. This includes full body scanners or security screening systems.

There are two (2) types of registrations – initial registration and annual renewal registration.

2.1 INITIAL REGISTRATION

Lettered paragraph "a" of IAC 641-39.3(2) states that each person having a radiation machine facility shall apply for registration of such facility with IDPH prior to the operation of a radiation machine facility.

Application for registration of full body scanners shall consist of a completed application that includes a current inventory of all radiation emitting equipment, and the registration fee based on per tube for industrial/nonmedical use type of x-ray machine described in IAC 641-38.8(1).

However, these machines, the operators, and their procedures need to be evaluated prior to use and to gain IDPH approval to ensure that the ALARA concept is being properly applied. In order to determine this justification IDPH will require the information in Appendix A provided by the registrant.

Security screening radiation machines are approved by Manufacturer/Model Number and by facility. The approval of a particular model at one location does not automatically grant approval at another location/facility/registrant. This is due to the operator training requirements and operational procedure requirement, as well as verification of shielding following installation by the manufacturer or service provider (both of which need to be registered with IDPH or have reciprocity with IDPH).

2.2 REGISTRATION RENEWAL

IDPH emails a courtesy notice of expiration two months prior to the annual expiration date of the certificate of registration. During renewal, ensure inventory (including serial numbers) is accurate and point of contact information is up to date. Late registration will be charged a fee (see section 10).

3.0 CONTACT PERSON

A contact person should be an individual who is responsible for the renewal of the registration and the primary point of contact to coordinate with other members of the facility. This individual -- usually the security manager, safety officer, or office administrator.

The contact person is typically responsible for sections 9 through 11 of this document.

4.0 RESPONSIBLE PERSON

The responsible person is the person responsible for the proposed radiation program. They should be able to answer questions about the equipment (including periodic maintenance requirements), manager of operators training, and maintainer of operating procedures. The responsible person should have independent authority to stop operations that are considered unsafe. The responsible person should be allowed sufficient time and commitment from management to fulfill certain duties and responsibilities to ensure that radiation emitting equipment are used in a safe manner.

The responsible person is typically responsible for sections 5 through 8 of this document. This person may or may not be the same individual as the contact person. If two or more different individuals are designated, they may share the duties and responsibilities. This arrangement should be clearly documented.

5.0 INDIVIDUAL USERS – TRAINING AND EXPERIENCE

Individuals who use the equipment must follow the manufacturer's instructions for the proper operation, storage, and maintenance of the equipment. These instructions appear both in the operator's manuals and on the machine labels. Manufacturers often provide this training during installation or servicing of the equipment. The registrant should maintain records that document the individual users' training. Although it is not required, annual refresher training on proper operations checks of the machine and appropriate radiation safety procedures are valuable tools to maintain safety awareness and to ensure that personnel do not mishandle radiation emitting equipment. Individuals who may be considered as users include but are not limited to contact persons, line workers, lead shift workers, maintenance workers, or others who work in the area where a piece of equipment is installed.

6.0 INSPECTION AND MAINTENANCE

Each registrant will need to develop, document, and implement a radiation protection program in compliance with IAC 641-40.10(1). Maintenance and pre-use inspections shall be in accordance with manufacturer's recommendations. Exceptions to the maintenance, including preventive maintenance, or pre-use inspection recommendations must be approved by IDPH.

7.0 ANNUAL AUDIT OF THE RADIATION SAFETY PROGRAM

An annual audit is required by IAC 641-40.10(3). It is essential that once problems are identified; they are corrected. IDPH will review a registrant's audit program and determine if corrective actions are thorough, timely, and sufficient to prevent recurrence. IDPH encourages registrants to regulate their own compliance. Normally self-identified violations that have been corrected by the registrant will not be cited.

Audits should include personnel training, inventory, operational checks (if appropriate), actual observations of machine use, identification of any problems, and resolution of those problems. Any equipment failure must be reported immediately to IDPH. A copy of a model audit checklist is included as Appendix A. However, this model may need to be modified for your specific operations

8.0 POSTINGS AND SIGNS

All machine labels must be clean and legible, and caution individuals that radiation is produced when energized. IDPH recognizes that in a manufacturing setting it may not be possible to maintain these conditions. However, it is appropriate to clean labels and check them for legibility any time the equipment is inventoried, or checked for operation.

IDPH "Notice to Employees" (available at idph.iowa.gov/radioactivematerials/forms) must be posted to allow individuals to observe it on the way to or from the area where equipment is used or stored. This can be posted on a bulletin board in the employee lounge, on the door to the area where the equipment is located, or on a notification bulletin board where other official documents (for example, Occupational Safety and Health Administration or the US Environmental Protection Agency information) are posted.

9.0 TRANSFER/DISPOSAL

When transferring or disposing of radiation equipment, you should notify IDPH in writing about equipment that has been disposed of and where it was sent. This notification may also be done during the registration renewal period. In either case, a copy of the receipt of transfer must be sent to IDPH.

10.0 REGISTRATION FEES

An annual registration fee must be paid in full as required by IAC 641-38.8(1) for all equipment. Fees for processed registrations are not refundable. Late fees of $25 a month are assessed starting 30 days after the due date.

11.0 REGISTRATION CORRECTIONS OR UPDATES

IAC 641-39.3(7) states that registrants shall notify IDPH in writing before making any change which would render the information contained in the application for registration no longer accurate. A registration can be corrected or updated by providing the correct information to IDPH. There is no fee to make these changes. Items about which IDPH should be informed include receiving or transferring a new device and changes in contact person, responsible person, name of the firm, address, or telephone number.

APPENDIX A

Security Screening Radiation Program Application Form

Complete this application along with the *Registration of Industrial & Medical Oncology Radiation Emitting Equipment* application form found on at idph.iowa.gov/radiological-health/xray-machines. Both forms are required.

IDPH utilizes standards developed by the Food & Drug Administration (FDA), National Council on Radiation Protection and Measurement (NCRP) and the American National Standards Institute (ANSI) as published by the Health Physics Society (HPS) in ANSI/N43/17-2002.

General-Use (GU): "General-use systems should adhere to an effective dose of 0.1 µSv [10 µrem] or less per scan, and can be used mostly without regard to the number of individuals scanned or the number of scans per individual in a year."

Limited-Use (LU): "Limited-use systems include all other ionizing radiation scanning systems that require effective doses per scan greater than 0.1 µSv [10 µrem] and less than or equal to 10 µSv [1 mrem]. These systems should be used with discretion in terms of the number of individuals scanned and the number of scans per individual in a year."

SCREENING SYSTEM APPROVAL DOCUMENT SUBMISSION

Type of Machine: General-Use (GU) / Limited-Use (LU) Full-Body / Partial-Body

For All (GU/LU applicants):

Name/Phone/Email of Contact Person: _____

Name/Phone/Email of Responsible Person: _____

____ Commitment to not screen pregnant, or may be pregnant, individuals.

____ Commitment to not screen minors (under 18 years old).

____ Commitment to manufacturer's operating and emergency procedures. Any deviations shall be submitted to IDPH for approval.

____ Submit annotated drawing of room, device placement, and adjacent rooms.

Current Screening method (if any): _____

_____

_____

_____

_____

Expected benefit of radiation to current screening method (if any): _____

_____

_____

_____

_____

Risk to facility if screener not approved: _____

_____

_____

_____

_____

Method to ensure radiation leakage from device as expected (dosimetry badges in area, survey of room with machine at power, etc):

_____

_____

_____

_____

Limited-Use (LU) applicants only:

Why is a LU machine required over a GU machine? _____

_____

_____

_____

_____

_____

Screening Modes: _____

Max Dose per Screening (typically higher BMI individauls): _____

Administrative controls to limit exposure to 25 millirems in a year, to include long-term record keeping (if >1 machine, must include how data from each machine is aggregated).

_____

_____

_____

_____

_____

_____

APPENDIX B

MODEL ANNUAL AUDIT CHECKLIST

AUDITS

A.	Were previous audits conducted at intervals not to exceed 12 months? [40.10(3)]	☐	N/A	☐	Yes	☐	No
B.	Were records of previous audits maintained? [40.81(136C)]	☐	N/A	☐	Yes	☐	No

ORGANIZATIONAL STRUCTURE

A.	If the mailing address or places of use changed, was IDPH notified?	☐	N/A	☐	Yes	☐	No
B.	If ownership changed or bankruptcy filed, was IDPH notified?	☐	N/A	☐	Yes	☐	No
C.	Responsible Person is identified?	☐	N/A	☐	Yes	☐	No
	1. Is the Responsible Person fulfilling their duties?	☐	N/A	☐	Yes	☐	No
	2. If the designated Responsible Person changed, was IDPH notified?	☐	N/A	☐	Yes	☐	No
D.	If the designated Contact Person changed, was IDPH notified?	☐	N/A	☐	Yes	☐	No

OPERATIONS AND PROCEDURES

A.	Have manufacturers or distributor's manuals for operation and maintenance been followed?	☐	N/A	☐	Yes	☐	No
B.	Are the actual uses of equipment consistent with the authorized uses?	☐	N/A	☐	Yes	☐	No
C.	Are procedures provided to IDPH during registration still being followed?	☐	N/A	☐	Yes	☐	No
D.	Are occupational exposure still being monitored?	☐	N/A	☐	Yes	☐	No
	1. Were occupational exposure results reviewed?	☐	N/A	☐	Yes	☐	No
	2. Was IDPH approval to discontinue dosimetry given?	☐	N/A	☐	Yes	☐	No
E.	Adherence to ANSI Standard N43.17-2009 still being implemented?	☐	N/A	☐	Yes	☐	No
	1. Anyone receive greater than 25 millirem in a year (1000 scans)?	☐	N/A	☐	Yes	☐	No

TRAINING AND INSTRUCTION TO WORKERS

A.	Did all workers receive training in accordance to the manufacturer's recommendations?	☐	N/A	☐	Yes	☐	No
	1. Has refresher training provided?	☐	N/A	☐	Yes	☐	No
	2. Are records maintained?	☐	N/A	☐	Yes	☐	No

MAINTENANCE

A.	Are repair and maintenance of components related to the radiological safety of the machine performed by the manufacturer, distributor?	☐	N/A	☐	Yes	☐	No

POSTINGS

A.	Is IDPH Notice to Employees posted in visible/open area?	☐	N/A	☐	Yes	☐	No
B.	Are labels, signs, and postings identifying radiation emitting equipment and lockout procedures/warnings clean and legible?	☐		☐		☐	

SIGN OFF

A.	Is the date of audit noted?	☐	N/A	☐	Yes	☐	No
B.	Are the dates the audit is covering noted?	☐	N/A	☐	Yes	☐	No
C.	Has the auditor signed audit?	☐	N/A	☐	Yes	☐	No

*Add additional pages with comments or descriptions of circumstances as deemed necessary.

SUMMARY OF REVISIONS

REVISION	SECTION	DESCRIPTION
1/17/2022	All	New regulatory guide