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TITLE 216 – DEPARTMENT OF HEALTH

CHAPTER 40 – PROFESSIONAL LICENSING AND FACILITY REGULATION

SUBCHAPTER 20 – RADIATION

PART 6 – Radiation Safety Requirements for Industrial Radiation Machines

6.1 Authority

A. This Part is promulgated pursuant to the authority conferred under R.I. Gen. Laws § 23-1.3-5.

B. This Part establishes special requirements for the use of industrial radiation machines not otherwise covered by this Subchapter. The requirements of this Part are in addition to, and not in substitution for, other applicable requirements of this Subchapter.

C. Any notifications, reports or correspondence required by this Part shall be directed to the Agency using contact information specified in § 1.4 of this Subchapter.

6.2 Exemptions

Uses of portable/handheld fluorescence X-ray (open beam) devices that are manufactured without safety devices are exempt from the requirements of § 6.5(A) of this Part.

6.3 Definitions

A. Whenever used in this Part, the following terms shall be construed as follows:

1. “Act” means R.I. Gen. Laws Chapter 23-1.3 entitled "Radiation Control."

2. “Agency” means Rhode Island Radiation Control Agency (RCA), Center for Health Facilities Regulation – Radiation Control Program, Rhode Island Department of Health.

3. "Bomb detection radiation machine" means X-ray generating equipment used solely for the purpose of remotely detecting explosive devices. This definition does not include hand-held X-ray bomb detection equipment for the purposes of this Part.

4. "Cabinet X-ray system” means an X-ray system with the X-ray tube installed in an enclosure (hereinafter termed "cabinet") that is independent

of existing architectural structures except the floor. The cabinet X-ray system is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of radiation. Included are all X-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and in similar facilities. An X-ray tube used within a shielded part of a building, or X-ray equipment which may temporarily or occasionally incorporate portable shielding is not considered a cabinet X-ray system.

5. “Category A industrial radiation machine” means a device capable of generating or emitting fields of radiation in an open beam configuration during normal conditions of use. This includes, but is not limited to, portable/handheld fluorescence X-ray, fluoroscopy hand-held intensified, fluoroscopy X-ray, flash X-ray, flash X-ray for bomb detection, spectrography X-ray, diffraction X-ray and uncertified cabinet X-ray.

6. “Category B industrial radiation machine” means a device capable of generating or emitting fields of radiation where the beam is contained during normal conditions of use. This includes, but is not limited to, package X-ray, certified and certifiable cabinet X-ray, X-ray fluorescence units and similar devices.

7. "Certifiable cabinet X-ray system" means an existing uncertified X-ray system that has been modified to meet the certification requirements specified in 21 C.F.R. § 1020.40.

8. "Certified cabinet X-ray system" means an X-ray system which has been certified in accordance with 21 C.F.R. § 1010.2 as being manufactured and assembled pursuant to the provisions of 21 C.F.R. § 1020.40.

9. "Interlock" means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

10. "Leakage radiation" means all radiation coming from within the source housing, except the useful beam.

11. "Open-beam configuration" means an analytical X-ray system in which an individual could accidentally place some part of his body in the primary beam path during normal operation.

12. “Registrant” means any person who is registered with the Agency and is legally obligated to register with the Agency pursuant to this Subchapter and the Act.

13. “Registration” means registration with the Agency pursuant to this Subchapter and the Act.

6.4 General Requirements – All Industrial Radiation Machines

6.4.1 Radiation Levels

The local components of an industrial radiation machine shall be located and arranged and shall include sufficient shielding or access control such that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present in the area in excess of the dose limits given in § 1.8.1 of this Subchapter.

6.4.2 Warning Devices

A. The X-ray control shall provide visual indication whenever X-rays are produced.

B. All ancillary warning devices shall be labeled so that their purpose is easily identified and shall have fail-safe characteristics.

C. Posting. Each area or room containing industrial radiation machines shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words "CAUTION - X-RAY EQUIPMENT," or words having a similar intent.

D. Ports. Unused ports on industrial radiation machine source housings shall be secured in the closed position in a manner which will prevent inadvertent opening.

E. Labeling. Each registrant shall ensure that each industrial radiation machine is labeled in a conspicuous manner to caution individuals that radiation is produced when it is energized. This label shall be affixed in a clearly visible location on the face of the control unit. If the industrial radiation machine is not visible from the control unit, the industrial radiation machine shall have a visible indication that it is energized.

F. Radiation Source Housing. Each radiation source housing shall be equipped with an interlock that shuts off the tube if it is removed from the radiation source housing or if the housing is disassembled.

6.5 Additional Requirements – Category A Industrial Radiation Machines

A. Safety Device. A safety device shall be provided on all open-beam configurations which prevents the entry of any portion of an individual's body into the primary X-ray beam path or which causes the beam to be shut off upon entry into its path shall be provided on all open-beam configurations.

1. A registrant may apply to the Agency for an exemption from the requirement of a safety device. Such application shall include:

a. A description of the various safety devices that have been evaluated;

b. The reason each of these devices cannot be used; and

c. A description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices.

B. Warning Devices. Open-beam configurations shall be provided with a visible indication of:

1. X-ray tube status (ON - OFF) located near the radiation source housing, if the primary beam is controlled in this manner; and/or

2. Shutter status (OPEN - CLOSED) located near each port on the radiation source housing, if the primary beam is controlled in this manner.

C. Shutters. On open-beam configurations each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or a coupling has been connected to the port.

D. Surveys

1. Radiation surveys, as required by § 1.10.2 of this Subchapter, of industrial radiation machines sufficient to show compliance with ~~§ 6.4(A)~~ § 6.4.1 of this Part shall be performed:

a. Upon installation of the equipment, and at least once every twelve (12) months thereafter;

b. Following any change in the initial arrangement, number, or type of local components in the system;

c. Following any maintenance requiring the disassembly or removal of a local component in the system;

d. During the performance of maintenance and alignment procedures if the procedures require the presence of a primary X-ray beam when any local component in the system is disassembled or removed; and

e. Any time a visual inspection of the local components in the system reveals an abnormal condition.

f. Whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the radiation dose limits.

2. Radiation survey measurements shall not be required if a registrant can demonstrate, to the satisfaction of the Agency, compliance with ~~§ 6.4(A)~~ § 6.4.1 of this Part in some other manner.

E. Generator Cabinet. Each X-ray generator shall be supplied with a protective cabinet which limits leakage radiation measured at a distance of five (5) cm from its surface such that it is not capable of producing a dose in excess of one half (0.5) mrem (five (5) µSv) in any one (1) hour.

6.6 Additional Requirements – Category B Industrial Radiation Machines

A. All Category B industrial radiation machines shall be evaluated in accordance with the following requirements:

1. The registrant shall perform an evaluation of the radiation dose limits to determine compliance with §§ 1.8.1(A) and (B) ~~and (C)~~ of this Subchapter at intervals not to exceed twelve (12) months. The registrant shall ensure that radiation emitted five (5) centimeters from the external surface of the cabinet X-ray system does not exceed one half of one (0.5) millirem (five (5.0) µSv) in any one (1) hour;

2. Tests for proper operation of interlocks shall be conducted and recorded at intervals not to exceed twelve (12) months;

3. Records that demonstrate compliance with § 6.6(A) of this Part shall be maintained by the registrant for ten (10) years for inspection by the Agency.

B. Certified and Certifiable Cabinet X-ray Systems. Certified and certifiable cabinet X-ray systems, including those designed to allow admittance of individuals shall also be maintained in compliance with 21 C.F.R. § 1020.40, and no modification shall be made to the system unless prior Agency approval has been granted.

6.7 Operating Requirements

A. Procedures. Operating and safety procedures shall be written and made available to all industrial radiation machine operators. No individual shall be permitted to operate an industrial radiation machine in any manner other than that specified in the procedures unless such individual has obtained written approval of the radiation safety officer.

B. Bypassing. No individual shall bypass a safety device or interlock unless such individual has obtained the written approval of the radiation safety officer. Such approval shall be for a specified period of time. When a safety device or interlock has been bypassed, a readily discernible sign bearing the words "SAFETY DEVICE NOT WORKING," or words having a similar intent, shall be placed on the radiation source housing.

C. Repair or Modification of Industrial Radiation Machines. Except as specified in § 6.7(B) of this Part, no operation involving removal of covers, shielding materials or tube housing or modifications to shutters, collimators, or beam stops shall be performed without ascertaining that the tube is off and will remain off until safe conditions have been restored. The main switch, rather than interlocks, shall be used for routine shutdown in preparation for repairs.

6.8 Personnel Requirements

A. Instruction. No individual shall be permitted to operate or maintain an industrial radiation machine unless the individual has received instruction in and demonstrated competence in the following:

1. Identification of radiation hazards associated with the use of the industrial radiation machine;

2. Radiation warning and safety devices incorporated into the industrial radiation machine, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases;

3. Operating and safety procedures for the industrial radiation machine; and

4. Proper procedures for reporting an actual or suspected exposure in excess of the limits specified in § 1.8.1 of this Subchapter.

B. Instructions for Bomb Detection Radiation Machines. All personnel operating bomb detection radiation machines shall be trained in the set-up and operation of the radiation machine and in establishing a restricted area.

C. Individual Monitoring. In addition to the requirements of § 1.10.3(A)(1) of this Subchapter, finger dosimetric devices shall be provided to and shall be used by:

1. Industrial radiation machine workers using systems having an open-beam configuration and not equipped with a safety device; and

2. Personnel maintaining industrial radiation machines if the maintenance procedures require the presence of a primary X-ray beam when any local component in the X-ray system is disassembled or removed.

D. Reported dose values shall not be used for the purpose of determining compliance with § 1.7.1 of this Subchapter unless evaluated by an individual registered with the Agency to provide General Radiation Physics Services.

E. Records and Documentation. Records that demonstrate compliance with §§ 6.8(A) through (C) of this Part shall be maintained by the registrant for ten (10) years for inspection by the Agency. In addition to complying with the requirements of §§ 6.8(A) through (C) of this Part, records of individual monitoring results shall be maintained by the registrant in accordance with § 1.16.6 of this Subchapter.