RHODE ISLAND GOVERNMENT REGISTER

PUBLIC NOTICE OF PROPOSED RULEMAKING

DEPARTMENT OF HEALTH

Title of Rule: Radiation Safety Requirements for Industrial Radiation Machines (216-RICR-40-20-6)

Rule Identifier: 216-RICR-40-20-6

Rulemaking Action: Proposed Amendment

Important Dates:

Date of Public Notice: January 24, 2022

Hearing Date: February 7, 2022

End of Public Comment: February 23, 2022

Rulemaking Authority:

R.I. Gen. Laws § 23-1.3-5

Summary of Rulemaking Action:

This is a technical revision to correct several internal cross references.

Additional Information and Public Comments:

All interested parties are invited to request additional information or submit written or oral comments concerning the proposed amendment until February 23, 2022 by contacting the appropriate party at the address listed below:

Paula Pullano

Department of Health

3 Capitol Hill

Room 410

Providence, RI 02908-5097

Paula.Pullano@health.ri.gov

Public Hearing:

A public hearing, in accordance with R.I. Gen. Laws § 42-35-2.5, to consider the proposed amendment shall be held at which time and place all persons interested therein will be heard. This hearing is subject to R.I. Gen. Laws Chapter 42-46, Open Meetings.

Public Hearing Information:

Date: February 7, 2022

Time: 10:00 A.M.

Location: Zoom Link to Come Providence, RI, 02908

The place of the public hearing is accessible to individuals with disabilities. If communication assistance (readers/interpreters/captioners) is needed, or any other accommodation to ensure equal participation, please call 401-222-3395 or RI Relay 711 at least three (3) business days prior to the meeting so arrangements can be made to provide such assistance at no cost to the person requesting. For questions regarding available parking, please contact the agency staffperson listed above.

Regulatory Analysis Summary and Supporting Documentation:

In development of this rule, consideration was given to:
1)Alternative approaches;

2)Overlap or duplication with other statutory and regulatory provisions; and

3)Significant economic impact on small business
No alternative approach, duplication or overlap was identified based on available information. RIDOH has determined that the benefits of the rule justify its costs.

For full regulatory analysis or supporting documentation contact the agency staffperson listed above.

STATE OF RHODE ISLAND
RHODE ISLAND DEPARTMENT OF HEALTH
CONCISE STATEMENT OF PROPOSED NON-TECHNICAL AMENDMENTS
(AMENDMENTS TO AN EXISTING REGULATION)

In accordance with the Administrative Procedures Act, R.I. Gen. Laws § 42-35-1.7(b)(8), the following is a concise statement of proposed non-technical amendments to Part 1, Part 2, Part 3, Part 4, Part 5, Part 6, Part 7, Part 8, Part 9, Part 10, Part 11, Part 12, Part 13 and Part 15 of 216-RICR-40-20, *Radiation*.

Regulation	**Rationale/Summary of Change**
§ 1.2 (A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. Part 20
§ 2.2 (A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. Part 19
§ 3.10(A)(4)	Revised to require submission of RCA Form 2579 in lieu of an equivalent USFDA form which is being phased out.
§ 3.13(C)(1)(c)	Corrects internal cross reference to another section in Part 3
§ 3.13(D)	Corrects internal cross reference to another section in Part 3
§ 3.14(C)	Corrects internal cross reference to another section in Part 3
§ 3.14(D)(1)	Corrects internal cross reference to another section in Part 3
Part 4 (Title)	Title of this Part has been revised to reflect the incorporation of additional requirements regarding fluoroscopically guided interventional procedures. All changes to Part 4 implement the most current revisions to Part F of the Suggested State Regulations for the Control of Radiation (SSRCR) published by the Conference of Radiation Control Program Directors, Inc. (CRCPD).
§ 4.1(B)	Clarifies that use of X-ray equipment must be under the supervision of an individual authorized by and licensed in accordance with applicable provisions of the R.I. Gen. Laws to engage in the healing arts or veterinary medicine
§ 4.1(C) &(D)	Deleted and consolidated with § 4.1(B).
§ 4.1.1(B) &(C)	Added to incorporate two additional documents by reference
§ 4.2(A)(30)	Corrects a spelling error
§ 4.2(A)(92)	"Protective garment" replaces "protective apron" for consistency with other changes
§ 4.3.1(A) and (B)	Specifies that administrative controls must include an effective radiation safety program.
§ 4.3.1(C) to (G)	Reflects the incorporation of additional administrative controls specified in the most current revision to Part F of the SSRCR.
§ 4.3.2(A)	Language added to allow limited operation of noncompliant X-ray equipment after review by a Qualified Medical Physicist

Regulation	Rationale/Summary of Change
§ 4.3.3(C) to (F)	Clarifies required training that must be completed before an individual is allowed to operate fluoroscopic X-ray equipment.
§ 4.3.3(H)	Clarifies required training that must be completed before an individual is allowed to operate dental X-ray equipment.
§ 4.3.4(A)	Clarifies information that has to be readily available to an operator of an X-ray system.
§ 4.3.6(A)	Clarifies safety precautions for individuals (other than patient) who are in the room where an X-ray is being taken.
§ 4.3.7	Deleted to address changes in "best practices".
§ 4.3.9	Clarifies safety precautions when a patient or image receptor must be provided with auxiliary support while an X-ray is being taken.
§ 4.3.10(D)	Deleted and consolidated with other Quality Control requirements in § 4.10.1
§ 4.3.10(E) and (G)	Language revised to reflect the most current revision to Part F of the SSRCR.
§ 4.3.10(F), (H) and (I)	Deleted to reflect the most current revisions to Part F of the SSRCR.
§ 4.3.10(J) and (K)	Language added to reflect the most current revisions to Part F of the SSRCR.
§ 4.3.13	Clarifies retention period for maintenance records and associated information
§ 4.3.14(A)(4)	Removes text which refers to a deleted section.
§ 4.3.14(D)	Clarifies record retention requirements for veterinary X-ray facilities
§ 4.3.15(C)	Language revised to synchronize wording with equivalent requirements in § 5.3.12(E)(1)(b) and 10 C.F.R. 35.3047
§ 4.4.3	Revised to reflect different labeling requirements for systems manufactured before 10 June 2006
§ 4.4.7	Deletes information on dental X-ray systems which has been moved to § 4.14
§ 4.4.10	Clarifies requirements regarding technique factors and kVp accuracy
§ 4.4.13	Clarifies requirements regarding use of calibrated dosimetry systems
§ 4.4.14(F)	Requires information pertaining to a radiation medical event be maintained as part of a patient's permanent medical record
§ 4.5.2	Language revised for consistency with other sections of this Part
§ 4.5.3	Clarifies training required before an individual can operate fluoroscopy equipment
§ 4.5.6	Language revised for consistency with other sections of this Part
§ 4.5.7	Language revised to reflect the most current revisions to Part F of the SSRCR.
§ 4.5.11	Deleted to reflect the most current revisions to Part F of the SSRCR.

Regulation	Rationale/Summary of Change
§ 4.5.12	Language revised to reflect the most current revisions to Part F of the SSRCR
§ 4.5.13	Language added to reflect the most current revisions to Part F of the SSRCR regarding fluoroscopically-guided interventional (FGI) procedures.
§ 4.5.14(B)	Language revised to correct internal cross-reference
§ 4.5.16	Language revised for consistency with other sections of this Part
§ 4.6.1	Clarifies applicability of section to various types of X-ray systems
§ 4.6.2(C)(3)	Language revised to correct internal cross-reference
§ 4.6.2(D)	Clarifies operator protection requirements for veterinary X-ray systems
§ 4.6.3(A)	Removes language that is duplicated in another part of the regulations
§ 4.6.3(C)(4)	Language revised to correct internal cross-reference
§ 4.6.4(G)	Requires use of manual collimation standards when PBL is disabled
§ 4.6.5	Language revised to reflect the most current revisions to Part F of the SSRCR
§ 4.6.6	Language revised to reflect the most current revisions to Part F of the SSRCR
§ 4.6.9	Removes language that is duplicated in another part of the regulations
§ 4.6.11	Removes requirement that is superseded by MQSA standards in § 4.8
§4.6.12(A)(3)	Language deleted to reflect the most current revisions to Part F of the SSRCR
§ 4.6.14	Language revised to reflect the most current revisions to Part F of the SSRCR
§4.6.15(A)	Removes requirement that is now included in § 4.14
§4.6.15(C)	Removes requirement that is superseded by MQSA standards in § 4.8
§4.7.1(A)	Language added to reflect the most current revisions to Part F of the SSRCR
§4.7.1(F)&(G)	Language deleted to reflect the most current revisions to Part F of the SSRCR
§ 4.7.3	Language revised to reflect the most current revisions to Part F of the SSRCR
§ 4.7.5	Language added to reflect the most current revisions to Part F of the SSRCR
§ 4.7.6	Language added to reflect the most current revisions to Part F of the SSRCR
§ 4.7.7	Language added to reflect the most current revisions to Part F of the SSRCR
§ 4.7.8	Language added to reflect the most current revisions to Part F of the SSRCR
§ 4.9	Language revised to reflect the most current revisions to Part F of the SSRCR

Regulation	Rationale/Summary of Change
§ 4.10	Language revised to consolidate QA/QC requirements in a single section to reflect the most current revisions to Part F of the SSRCR
§ 4.13	Language revised to reflect the most current revisions to Part F of the SSRCR
§ 4.14	New section added to consolidate all dental X-ray system requirements in a single section to reflect the most current revisions to Part F of the SSRCR
§ 5.3.12(E)(1)(b)	Synchronize wording with equivalent requirements in 10 C.F.R. 35.3045
§ 5.4.2(A)(4)	Language revised to remove obsolete cross-reference to another section of this Subpart
§ 5.4.4	Language added to clarify that "records" refers to "records of surveys"
§§ 5.5.2 & 5.5.3	Synchronize wording with equivalent requirements in 10 C.F.R. 35.3047
§ 5.6.17(F)	Review interval revised to synchronize with equivalent requirements in 10 C.F.R. 35.642
§ 5.6.18(A)	Corrects internal cross-reference to another section of this Part
§ 5.7.1	Corrects internal cross-reference to another section of this Part
§ 5.7.4(B)	Corrects internal cross-reference to another section of this Part
§§ 5.11.11(D) & (H)	Corrects internal cross-references to other sections of this Part
§§ 6.5(D)(1) & (D)(2)	Corrects internal cross-references to other sections of this Part
§ 6.6(A)(1)	Corrects internal cross-reference to another section of this Subchapter
§ 7.2.1(A)	Revises incorporate on by reference date to 2021 to capture updates to 10 C.F.R. § 30.34 published in the Federal Register [83 FR 33046]. This C.F.R. section is already incorporated by reference in § 7.6.3
§ 7.2.2(A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. Part 31
§ 7.2.3(A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. § 32.72 published in the Federal Register [83 FR 33046 & 83 FR 57231]. This C.F.R. section is already incorporated by reference in §§ 7.6.3 and 7.6.16(A).
§ 7.2.3(B)	Corrects typo regarding portions of 10 C.F.R Part 32 that are not being incorporated by reference.
§ 7.2.4(A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. Part 33
§ 7.2.5(A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. Part 40
§ 7.2.5(B)	Corrects typo regarding portions of 10 C.F.R Part 40 that are not being incorporated by reference.
§ 7.2.6(A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. Part 70

Regulation	Rationale/Summary of Change
§ 7.2.6(C)	Incorporates the provisions of 10 C.F.R. § 150.11(b) by reference.
§ 7.4.10	Revises wording for consistency with U.S. Nuclear Regulatory Commission usage.
§ 7.6.7(B)	Language added to further clarify when a license amendment is required
§ 7.6.8	Revise language to remove duplicate reference
§ 7.6.13	Revises paragraph numbering for consistency with other sections in this Part
§ 8.2(A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. Part 37 published in the Federal Register [83 FR 57231]. These 10 C.F.R. Part 37 sections are already incorporated by reference in §§ 8.6.4 and 8.6.6.
§ 8.4.4(B)	Updates mailing address
§ 8.5.9	Adds a specific incorporation by reference citation for reporting of certain events
§ 9.2(A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. Part 35 published in the Federal Register [83 FR 33046, 85 FR 33527 and 85 FR 44685]. These 10 C.F.R. Part 35 sections are already incorporated by reference in §§ 9.3, 9.4.7, 9.5.5, 9.5.10, 9.5.11(A), 9.5.12(A), 9.5.13(A), 9.5.18, 9.6.4, 9.7.2, 9.7.4(A), 9.7.5, 9.8.1, 9.8.4, 9.8.5, 9.8.6, 9.8.7, 9.9.1, 9.9.7, 9.9.9, 9.9.10, 9.10.1, 9.10.2, 9.11.1, 9.11.4, 9.11.15, and 9.11.17.
§ 9.2(B)	Identifies 10 C.F.R. Part 35 amendments published in the Federal Register [83 FR 33046] which are not incorporated by reference.
§ 9.4.3(B)(2)	Implements 83 FR 33046 requirements for training & qualifications of Associate Radiation Safety Officer and Ophthalmic Physicist as part of a radioactive materials license application.
§ 9.4.3(B)(4)	Corrects internal cross-reference to another section of this Subchapter
§ 9.4.5(A)(2)	Clarifies utilization of a Visiting Ophthalmic Physicist without requiring a radioactive materials license amendment [related to 83 FR 33046 amendments].
§ 9.4.5(A)(9) and (A)(10)	Implements 83 FR 33046 requirements for obtaining a radioactive materials license amendment prior to performing certain specified activities.
§ 9.4.6(A)(1) (A)(5) & (A)(6)	Implements 83 FR 33046 requirements for certain notifications that must be submitted to the RI Radiation Control Agency.
§ 9.5.1(A)(2)	Implements a requirement for written management approval to utilize a Visiting Ophthalmic Physicist [related to 83 FR 33046 amendments].
§ 9.5.1(B)	Implements 83 FR 33046 requirements for approval of Associate Radiation Safety Officer.
§ 9.5.1(C)	Eliminates unnecessary language [related to 83 FR 33046 amendments].
§ 9.5.1(K)	Implements 83 FR 33046 recordkeeping requirements for approval of Associate Radiation Safety Officer.

Regulation	Rationale/Summary of Change
§ 9.5.4(B)(5)	Implements 83 FR 33046 requirements regarding the contents of a written directive for permanent implant brachytherapy.
§ 9.5.4(B)(6)	Renumbers current § 9.5.4(B)(5) as § 9.5.4(B)(6)
§ 9.5.6 and § 9.5.6(D)	Clarifies utilization of a Visiting Ophthalmic Physicist [related to 83 FR 33046 amendments] and corrects internal cross-reference to other section of this Part
§ 9.5.6(E) & (F)	Renumbers current § 9.5.6(D) and (E) as § 9.5.4(E) and (F) respectively.
§ 9.5.9(A)	Implements 83 FR 33046 requirements regarding the definition of a misadministration.
§ 9.5.9(G)(3)	Implements 85 FR 33527and 85 FR 44685 requirements regarding the use of a social security number to identify an individual in a misadministration report.
§ 9.5.10	Implements 83 FR 33046 requirements regarding training for an Associate Radiation Safety Officer.
§ 9.5.11(B)	Corrects internal cross-reference to another section of this Subchapter
§ 9.5.16(F)(1)	Corrects internal cross-reference to another section of this Part
§ 9.7.4(B), (C) and (D)	Implements 83 FR 33046 recordkeeping requirements regarding elution of radionuclide generators.
§ 9.11.15	Implements 83 FR 33046 requirements regarding full-inspection servicing of teletherapy and gamma stereotactic radiosurgery units.
§ 9.5.19(A)	Clarifies wording to indicate that the dose limits established in § 1.8 are being referenced
§ 9.5.19(B)	Corrects internal cross-reference to another section of this Part
§ 9.6.3(B)	Clarifies rcord maintenance requirement for consistency with § 9.6.2(B)
§ 9.6.8(F)	Clarifies wording regarding detection limit for consistency with other applicable NRC guidance
§ 9.6.8(H)	Corrects internal cross-reference to another section of this Part
§ 9.6.9(E)	Corrects internal cross-reference to another section of this Part
§ 9.7.6(D)	Corrects internal cross-reference to another section of this Subchapter
§ 9.11.6(B)	Clarifies wording to link recordkeeping requirements with surveys required under § 9.11.6(A)
§ 9.11.7(B)	Clarifies wording to link recordkeeping requirements with surveys required under § 9.11.7(A)
§ 9.11.8(B)	Clarifies wording to link recordkeeping requirements with surveys required under § 9.11.8(A)
§ 9.11.9(B)	Clarifies wording to link recordkeeping requirements with surveys required under § 9.11.9(A)
§ 9.11.15(B)	Clarifies wording to link recordkeeping requirements with surveys required under § 9.11.15(A)
§ 9.12.1	Header is removed and contents of section are collapsed into § 9.12

Regulation	Rationale/Summary of Change
§ 10.2(A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. Part 34 published in the Federal Register [85 FR 15347]. These 10 C.F.R. Part 34 sections are already incorporated by reference in §§ 10.6.6 and 10.7.7.
§ 10.6.3(C) (2)	Corrects internal cross-reference to another section of this Part
§ 10.6.3(C) (4)	Corrects internal cross-reference to another section of this Part
§ 10.6.3(H)	Corrects internal cross-reference to another section of this Part
§ 10.7.1(A) (7), (8) & (9)	Corrects internal cross-references to other sections of this Part
§ 10.7.10(A)	Corrects internal cross-reference to another section of this Part
§ 10.7.2(A)(9)	Corrects internal cross-reference to another section of this Part
§ 10.7.3(A)(2)	Corrects internal cross-reference to another section of this Part
§ 11.2(A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. Part 39 published in the Federal Register [85 FR 15347]. This 10 C.F.R. Part 39 section is already incorporated by reference in § 11.6.3.
§ 11.7.2(A)(9)	Corrects internal cross-reference to another section of this Part
§ 11.7.3(A)(2)	Corrects internal cross-reference to another section of this Part
§ 12.2(A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. § 71.97 published in the Federal Register [83 FR 57231]. This C.F.R. section is already incorporated by reference in § 12.8.9.
§ 12.2(B)	Revises incorporation by reference date to 2021 to capture updates to 39 C.F.R. § 111.1
§ 12.2(C)	Identifies an additional subsection of 71 C.F.R. 101 that is not incorporated by reference
§ 12.8.8	Corrects section title for consistency with 10 C.F.R. 71.95
§ 12.9.1	Clarifies that RCA and not NRC is responsible for certificate approval.
§ 13.4.7(A) & (B)	Corrects internal cross-references to another section of this Subchapter
§ 15.5.7(C) (11)(c)	Language added to clarify that Category 3K also includes all other use of unsealed radioactive material not authorized for commercial distribution.

216-RICR-40-20-6

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.