RHODE ISLAND GOVERNMENT REGISTER

PUBLIC NOTICE OF PROPOSED RULEMAKING

DEPARTMENT OF HEALTH

Title of Rule: Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations (216-RICR-40-20-10)

Rule Identifier: 216-RICR-40-20-10

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 update an incorporation by reference with the most recent version and 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-40-20-10

TITLE 216 – DEPARTMENT OF HEALTH

CHAPTER 40 – PROFESSIONAL LICENSING AND FACILITY REGULATION

SUBCHAPTER 20 - RADIATION

PART 10 – Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations

10.1 Authority

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

B. This Part provides establishes radiation safety requirements for persons utilizing sources of radiation for industrial radiography operations.

C. Except for industrial radiation machines regulated pursuant to Part 6 of this Subchapter, the Regulations in this Part apply to all licensees or registrants who use sources of radiation for industrial radiography; provided, however, that nothing in this Part shall apply to the use of sources of radiation in the healing arts.

D. The provisions and requirements of this Part are in addition to, and not in substitution for, other requirements of this Subchapter.

10.2 Incorporated Material

A. Except as provided in this Part, the requirements of 10 C.F.R. Part 34 (~~2018~~ 2021) are incorporated by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with this Part.

B. Notwithstanding the provisions of § 10.2(A) of this Part, 10 C.F.R. §§ 34.5, 34.8, 34.11, 34.13, 34.41, 34.43, 34.63, 34.65, 34.67, 34.69, 34.71, 34.73, 34.75, 34.81, 34.89, 34.101, 34.111, 34.121 and 34.123 are not incorporated by reference.

C. Effect of incorporation of 10 C.F.R. Part 34. To reconcile differences between this Part and the incorporated sections of 10 C.F.R. Part 34, the following words and phrases shall be substituted for the language in 10 C.F.R. Part 34 as follows:

1. Any reference to NRC or Commission shall be deemed to be a reference to the Agency.

2. Any reference to NRC or Agreement State shall be deemed to be a reference to the Agency, NRC or Agreement State.

3. Any reference to byproduct material shall be deemed to be a reference to radioactive material.

4. Any notifications, reports or correspondence referenced in the incorporated sections of 10 C.F.R. Part 34 shall be directed to the Agency using contact information specified in § 1.4 of this Subchapter.

5. Any reference to licensee shall be deemed to include registrant.

6. Any reference to license shall be deemed to include registration.

7. Any reference to licensed shall be deemed to include registered.

10.3 Definitions

A. In addition to the definitions contained in 10 C.F.R. § 34.3, 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. "Radioactive material" means any material (solid, liquid, or gas) which emits radiation spontaneously.

4. "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.

5. "Registration" means registration with the Agency pursuant to this Subchapter and the Act.

10.4 Specific Licensing Provisions

A. In addition to the requirements set forth in § 7.6.2 of this Subchapter, a specific license for use of sealed sources in industrial radiography will be issued if:

1. The applicant submits an adequate program for training radiographers and radiographer's assistants that meets the requirements of § 10.6.3 of this Part.

2. The applicant submits procedures for verifying and documenting the certification status of radiographers and for ensuring that the certification of individuals acting as radiographers remains valid.

3. The applicant submits written operating and emergency procedures as described in § 10.6.4 of this Part.

4. The applicant submits a description of a program for inspections of the job performance of each radiographer and radiographer's assistant at intervals not to exceed six (6) months as described in § 10.6.3(E) of this Part.

5. The applicant submits a description of the applicant's overall organizational structure as it applies to the radiation safety responsibilities in industrial radiography, including specified delegations of authority and responsibility.

6. The applicant identifies and lists the qualifications of the individual(s) designated as the RSO pursuant to § 10.6.2 of this Part, and potential designees responsible for ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures.

7. If an applicant intends to perform leak testing of sealed sources or exposure devices containing depleted uranium (DU) shielding, the applicant must describe the procedures for performing the test and the qualifications of the person(s) authorized to do the leak testing. If the applicant intends to analyze its own wipe samples, the application must include a description of the procedures to be followed. The description must include the:

    a. Instruments to be used;

    b. Method(s) of performing the analysis; and

    c. Pertinent experience of the person who will analyze the wipe samples.

8. If the applicant intends to perform "in-house" calibrations of survey instruments the applicant must describe methods to be used and the relevant experience of the person(s) who will perform the calibrations. All calibrations must be performed according to the procedures described and at the intervals prescribed in § 10.5.4(A) of this Part.

9. The applicant identifies and describes the location(s) of all field stations and permanent radiographic installations.

10. The applicant identifies the location(s) where all records required by this Part and other Parts of this Subchapter will be maintained.

10.5 Equipment

10.5.1 Performance Requirements for Industrial Radiography Equipment

For the purpose of this Part, performance requirements for industrial radiography equipment are defined by 10 C.F.R. § 34.20.

10.5.2 Limits on External Radiation Levels from Storage Containers and Source Changers

For the purpose of this Part, limits on external radiation levels from storage containers and source changers are defined by 10 C.F.R. § 34.21.

10.5.3 Locking of Radiographic Exposure Devices, Storage Containers, and Source Changers

For the purpose of this Part, requirements for locking of radiographic exposure devices, storage containers, and source changers are defined by 10 C.F.R. § 34.23.

10.5.4 Radiation Survey Instruments

For the purpose of this Part, requirements for radiation survey instruments are defined by 10 C.F.R. § 34.25.

10.5.5 Leak Testing and Replacement of Sealed Sources

For the purpose of this Part, requirements for leak testing and replacement of sealed sources are defined by 10 C.F.R. § 34.27.

10.5.6 Quarterly Inventory

For the purpose of this Part, requirements for quarterly inventory are defined by 10 C.F.R. § 34.29.

10.5.7 Inspection and Maintenance of Radiographic Exposure Devices, Transport And Storage Containers, Associated Equipment, Source Changers, and Survey Instruments

For the purpose of this Part, requirements for inspection and maintenance of radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments are defined by 10 C.F.R. § 34.31.

10.5.8 Permanent Radiographic Installations

For the purpose of this Part, requirements for permanent radiographic installations are defined by 10 C.F.R. § 34.33.

10.5.9 Labeling, Storage, and Transportation

For the purpose of this Part, requirements for labeling, storage, and transportation are defined by 10 C.F.R. § 34.35.

10.6 Radiation Safety Requirements

10.6.1 Conducting Industrial Radiographic Operations

A. Whenever radiography is performed at a location other than a permanent radiographic installation, the radiographer must be accompanied by at least one (1) other qualified radiographer or an individual who has at a minimum met the requirements of § 10.6.3(C) of this Part. The additional qualified individual shall observe the operations and be capable of providing immediate assistance to prevent unauthorized entry. Radiography may not be performed if only one (1) qualified individual is present.

B. All radiographic operations shall be conducted in a permanent radiographic installation, unless otherwise specifically authorized by the Agency.

C. Except when physically impossible, collimators shall be used in industrial radiographic operations that use radiographic exposure devices that allow the source to be moved out of the device.

D. A licensee or registrant may conduct lay-barge, offshore platform, or underwater radiography only if procedures have been approved by the Agency, the U.S. Nuclear Regulatory Commission or another Agreement State.

E. At a job site, the following shall be supplied by the licensee or registrant:

1. At least one (1) operable, calibrated survey instrument for each exposure device or radiation machine in use;

2. A current whole body personnel monitor (TLD or film badge) for each person performing radiographic operations;

3. An operable, calibrated pocket dosimeter with a range of zero (0) to two (2) millisieverts (two hundred (200) mrem) for each person performing radiographic operations;

4. An operable, calibrated, alarming ratemeter for each person performing radiographic operations using a radiographic exposure device; and

5. The appropriate barrier ropes and signs.

F. Each radiographer at a job site shall have on their person a valid certification ID card issued by a certifying entity.

G. Industrial radiographic operations shall not be performed if any of the items in §§ 10.6.1(E) and (F) of this Part are not available at the job site or are inoperable.

H. During an inspection, the Agency may terminate an operation if any of the items in §§ 10.6.1(E) and (F) of this Part are not available or operable, or if the required number of radiographic personnel are not present. Operations shall not be resumed until all required conditions are met.

10.6.2 Radiation Safety Officer for Industrial Radiography

For the purpose of this Part, requirements for Radiation Safety Officer for industrial radiography are defined by 10 C.F.R. § 34.42.

10.6.3 Training and Testing

A. The licensee or registrant shall not permit any individual to act as a radiographer until the individual:

1. Has received at least forty (40) hours of training in the subjects outlined in § 10.6.3(G) of this Part, in addition to on-the-job training consisting of hands-on experience under the supervision of a radiographer and is certified through a radiographer certification program by a certifying entity in accordance with the criteria specified in § 10.6.11 of this Part. The on-the-job training shall include a minimum of two (2) months (three hundred twenty (320) hours) of active participation in the performance of industrial radiography utilizing radioactive material and/or one (1) month (one hundred sixty (160) hours) of active participation in the performance of industrial radiography utilizing radiation machines. Individuals performing industrial radiography utilizing radioactive materials and radiation machines must complete both segments of the on the job training (three (3) months or four hundred eighty (480) hours).

B. In addition, the licensee or registrant shall not permit any individual to act as a radiographer until the individual:

1. Has received copies of and instruction in RCA regulations as contained in this Part and applicable sections of Parts 1, 2, 7 and 12 of this Subchapter, in applicable DOT regulations as referenced in 10 C.F.R. Part 71, in the license(s) and/or certificate(s) of registration under which the radiographer will perform industrial radiography, and the licensee's or registrant's operating and emergency procedures.

2. Has demonstrated understanding of the items in § 10.6.3(B)(1) of this Part by successful completion of a written or oral examination.

3. Has received training in the use of the registrant's radiation machines or the licensee's radiographic exposure devices, sealed sources, in the daily

inspection of devices and associated equipment, and in the use of radiation survey instruments; and

4. Has demonstrated understanding of the use of the equipment described in § 10.6.3(B)(3) of this Part by successful completion of a practical examination.

C. The licensee or registrant shall not permit any individual to act as a radiographer's assistant until the individual:

1. Has received copies of and instruction in RCA regulations as contained in this Part and applicable sections of Parts 1, 2, 7 and 12 of this Subchapter, in applicable DOT regulations as referenced in 10 C.F.R. Part 71, license(s) and/or certificate(s) of registration under which the radiographer's assistant will perform industrial radiography, and the licensee's or registrant's operating and emergency procedures;

2. Has demonstrated an understanding of items in ~~§ 10.6.3(B)(1)~~ § 10.6.3(C)(1) of this Part by successful completion of a written or oral examination;

3. Has received training in the use of the registrant's radiation machines, or the licensee's radiographic exposure devices, sealed sources, in the daily inspection of devices and associated equipment, and in the use of radiation survey instruments;

4. Has demonstrated understanding of the use of the equipment described in ~~§ 10.6.3(B)(3)~~ § 10.6.3(C)(3) of this Part by successful completion of a practical examination.

D. The licensee or registrant shall provide annual refresher safety training for each radiographer and radiographer's assistant at intervals not to exceed twelve (12) months.

E. Except as provided in § 10.6.3(E)(4) of this Part, the RSO or designee shall conduct an inspection program of the job performance of each radiographer and radiographer's assistant to ensure that the Agency's regulations, license and/or certificate of registration requirements, and the applicant's operating and emergency procedures are followed. The inspection program shall:

1. Include observation of the performance of each radiographer and radiographer's assistant during an actual industrial radiographic operation, at intervals not to exceed six (6) months; and

2. Provide that, if a radiographer or a radiographer's assistant has not participated in an industrial radiographic operation for more than six (6) months since the last inspection, the radiographer must demonstrate knowledge of the training requirements of § 10.6.3(B)(3) of this Part and

the radiographer's assistant must re-demonstrate knowledge of the training requirements of § 10.6.3(C)(2) of this Part by a practical examination before these individuals can next participate in a radiographic operation.

3. The Agency may consider alternatives in those situations where the individual serves as both radiographer and RSO.

4. In those operations where a single individual serves as both radiographer and RSO, and performs all radiography operations, an inspection program is not required.

F. The licensee or registrant shall maintain records of the above training to include certification documents, written and practical examinations, refresher safety training and inspections of job performance in accordance with § 10.7.5 of this Part.

G. The licensee or registrant shall include the following subjects required in § 10.6.3(A) of this Part:

1. Fundamentals of radiation safety including:

a. Characteristics of gamma and X-radiation;

b. Units of radiation dose and quantity of radioactivity;

c. Hazards of exposure to radiation;

d. Levels of radiation from sources of radiation; and

e. Methods of controlling radiation dose (time, distance, and shielding);

2. Radiation detection instruments including:

a. Use, operation, calibration, and limitations of radiation survey instruments;

b. Survey techniques; and

c. Use of personnel monitoring equipment.

3. Equipment to be used including:

a. Operation and control of radiographic exposure equipment, remote handling equipment, and storage containers, including pictures or models of source assemblies (pigtails);

b. Operation and control of radiation machines;

c. Storage, control, and disposal of sources of radiation; and

d. Inspection and maintenance of equipment.

4. The requirements of pertinent Agency and Federal Regulations; and

5. Case histories of accidents in radiography.

H. Records of radiographer certification maintained in accordance with ~~§ 10.7.5(A)~~ § 10.7.5 of this Part provide appropriate affirmation of certification requirements specified in § 10.6.3(A) of this Part.

10.6.4 Operating and Emergency Procedures

For the purpose of this Part, requirements for operating and emergency procedures are defined by 10 C.F.R. § 34.45.

10.6.5 Supervision of Radiographers' Assistants

For the purpose of this Part, requirements for supervision of radiographers' assistants are defined by 10 C.F.R. § 34.46.

10.6.6 Personnel Monitoring

For the purpose of this Part, requirements for personnel monitoring are defined by 10 C.F.R. § 34.47.

10.6.7 Radiation Surveys

For the purpose of this Part, requirements for radiation surveys are defined by 10 C.F.R. § 34.49.

10.6.8 Surveillance

For the purpose of this Part, surveillance requirements are defined by 10 C.F.R. § 34.51.

10.6.9 Posting

For the purpose of this Part, posting requirements are defined by 10 C.F.R. § 34.53.

10.6.10 Reporting Requirements

A. In addition to the reporting requirements specified under other sections of this Subchapter, each licensee shall provide a written report to the Agency within thirty (30) days of the occurrence of any of the following incidents involving radiographic equipment:

1. Unintentional disconnection of the source assembly from the control cable;

2. Inability to retract the source assembly to its fully shielded position and secure it in this position;

3. Failure of any component (critical to safe operation of the device) to properly perform its intended function; or

4. An indicator on a radiation machine fails to show that radiation is being produced, an exposure switch fails to terminate production of radiation when turned to the off position, or a safety interlock fails to terminate X-ray production.

B. The licensee or registrant shall include the following information in each report submitted under § 10.6.10(A) of this Part:

1. A description of the equipment problem;

2. Cause of each incident, if known;

3. Name of the manufacturer and model number of equipment involved in the incident;

4. Place, time and date of the incident;

5. Actions taken to establish normal operations;

6. Corrective actions taken or planned to prevent recurrence; and

7. Names and qualifications of personnel involved in the incident.

C. Reports of overexposure submitted under § 1.17.3 of this Subchapter which involve failure of safety components of radiography equipment must also include the information specified in § 10.6.10(B) of this Part.

D. Any licensee or registrant conducting radiographic operations or storing sources of radiation material at any location not listed on the license and/or certificate of registration for a period in excess of one hundred eighty (180) days in a calendar year, shall notify the Agency prior to exceeding the one hundred eighty (180) days.

10.6.11 Radiographer Certification

For the purpose of this Part, requirements for radiographer certification are defined by Appendix A to 10 C.F.R. Part 34.

10.7 Recordkeeping Requirements

10.7.1 Records Required at Temporary Jobsites

A. Each licensee or registrant shall maintain current copies of the following documents and records sufficient to demonstrate compliance at each applicable field station and each temporary jobsite:

1. Appropriate license, certificate of registration or equivalent document authorizing the use of sources of radiation.

2. Operating and emergency procedures required by § 10.7.6 of this Part.

3. A copy of this Subchapter.

4. Survey records as required by § 10.7.8 of this Part, for the period of operation at the site.

5. Records of dosimeter readings as required by § 10.7.7 of this Part.

6. Utilization log for each source of radiation dispatched from that location as required by § 10.7.4 of this Part.

7. Records of equipment problems identified in daily checks of equipment as required by ~~§§ 10.5.7(B) and (C)~~ § 10.5.7 of this Part;

8. Records of alarm system and entrance control checks required by ~~§ 10.5.8(B)~~ § 10.5.8 of this Part, if applicable;

9. Evidence of the latest calibration of the radiation survey instruments in use at the site, as required by ~~§ 10.5.4(B)~~ § 10.5.4 of this Part;

10. Evidence of the latest calibrations of alarm ratemeters and operability checks of dosimeters as required by § 10.7.7 of this Part;

11. The shipping papers for the transportation of radioactive materials required by 10 C.F.R. § 71.5; and

12. When operating under reciprocity pursuant to § 7.10 of this Subchapter, a copy of the applicable State license or certificate of registration, or U.S. Nuclear Regulatory Commission license authorizing the use of sources of radiation.

10.7.2 Records of the Specific License for Industrial Radiography

For the purpose of this Part, requirements for records of the specific license for industrial radiography are defined by 10 C.F.R. § 34.61.

10.7.3 Records of the Receipt and Transfer of Sealed Sources

For the purpose of this Part, requirements for records of the receipt and transfer of sealed sources are defined by 10 C.F.R. § 34.63.

10.7.4 Utilization Logs

A. Each licensee or registrant shall maintain utilization logs showing for each source of radiation the following information:

1. A description, including the make, model and serial number of the radiation machine or the radiographic exposure device, transport or storage container in which the sealed source is located;

2. The identity and signature of the radiographer to whom assigned;

3. Locations where used and dates of use, including the dates removed and returned to storage; and

4. For permanent radiographic installations, the dates each radiation machine is energized.

B. The licensee or registrant shall retain the logs required by § 10.7.4(A) of this Part for three (3) years after the log is made.

10.7.5 Records of Training and Certification

For the purpose of this Part, requirements for records of training and certification are defined by 10 C.F.R. § 34.79.

10.7.6 Copies of Operating and Emergency Procedures

Each licensee or registrant shall maintain a copy of current operating and emergency procedures until the Agency terminates the license and/or certificate of registration. Superseded material must be retained for three (3) years after the change is made.

10.7.7 Records of Personnel Monitoring Procedures

For the purpose of this Part, requirements for records of personnel monitoring procedures are defined by 10 C.F.R. § 34.83.

10.7.8 Records of Radiation Surveys

For the purpose of this Part, requirements for records of radiation surveys are defined by 10 C.F.R. § 34.85.

10.7.9 Form of Records

For the purpose of this Part, requirements for form of records are defined by 10 C.F.R. § 34.87.

10.7.10 Location of Documents and Records

A. Each licensee or registrant shall maintain copies of records required by this Part and other applicable parts of this Subchapter at the location specified in ~~§ 10.4(A)~~ § 10.4(A)(10) of this Part.

B. Records shall also be maintained at each applicable field station and each temporary jobsite, as specified by § 10.7.1 of this Part.