RHODE ISLAND GOVERNMENT REGISTER

PUBLIC NOTICE OF PROPOSED RULEMAKING

DEPARTMENT OF HEALTH

Title of Rule: Licensing of Radioactive Material (216-RICR-40-20-7)

Rule Identifier: 216-RICR-40-20-7

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 references and citations; add an incorporation by reference; clarifies require when a license amendment is needed.

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: 9:30 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-40-20-7

TITLE 216 – DEPARTMENT OF HEALTH

CHAPTER 40 – PROFESSIONAL LICENSING AND FACILITY REGULATION

SUBCHAPTER 20 – RADIATION

PART 7 – Licensing of Radioactive Material

7.1 Authority

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

B. This Part provides for the licensing of radioactive material. No person shall receive, possess, use, transfer, own or acquire radioactive material except as authorized in a specific or general license issued pursuant to this Part or as otherwise provided in this Part.

C. This Part establishes general licenses for the possession and use of radioactive material and a general license for ownership of radioactive material. The general licenses provided in this Part are subject to the provisions of §§ 7.4.3, 7.6.2, 7.6.3, 7.6.9 and 7.8.5 ~~and 7.12.1~~ of this Part, and Parts 1 and 2 of this Subchapter unless indicated otherwise in the specific provision of the general license.

D. This Part prescribes requirements for the issuance of specific licenses to persons who manufacture or initially transfer items containing radioactive material for sale or distribution to:

1. Persons generally licensed under this Part, 10 C.F.R. Part 31 or equivalent regulations of another Agreement State (as defined by 10 C.F.R. § 40.4).

2. Persons licensed under Part 9 of this Subchapter.

E. This Part prescribes requirements for the issuance of specific licenses to persons who introduce radioactive material into a product or material owned by or in the possession of a licensee or another, and Regulations governing holders of such licenses.

F. This Part prescribes requirements for the issuance of specific licenses of broad scope for radioactive material (“broad licenses”).

G. This Part prescribes certain requirements governing holders of licenses to manufacture or distribute items containing radioactive material.

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

1. All licensees are subject to the requirements of Parts 1 and 2 of this Subchapter.

2. Licensees engaged in use of radionuclides in the healing arts are subject to the requirements of Part 9 of this Subchapter.

3. Licensees engaged in industrial radiographic operations are subject to the requirements of Part 10 of this Subchapter.

4. Licensees engaged in wireline and/or subsurface tracer studies are subject to the requirements of Part 11 of this Subchapter.

I. In any conflict between the requirements in this Part and a specific requirement in another Part of the Regulations in this Subchapter, the specific requirement governs.

7.2 Incorporated Material

7.2.1 General Provisions for Radioactive Material

A. Except as provided in this Part, the requirements of 10 C.F.R. Part 30 (~~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 § 7.2.1(A) of this Part, 10 C.F.R. §§ 30.1, 30.2, 30.3, 30.4 (paragraph 2 of the definition of "Commencement of Construction" and paragraph 9ii of the definition of "Construction" only), 30.5, 30.6, 30.8, 30.9, 30.12, 30.21(c), 30.31, 30.32(e), 30.34(d), (e)(1) and (3), 30.37, 30.39, 30.41(b)(6), 30.52, 30.53, 30.55, 30.61, 30.63 and 30.64 are not incorporated by reference.

7.2.2 General Licenses for Radioactive Material

A. Except as provided in this Part, the requirements of 10 C.F.R. Part 31 (~~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 § 7.2.2(A) of this Part, 10 C.F.R. §§ 31.1, 31.2, 31.4, 31.9, 31.13, 31.14, 31.15, 31.16, 31.17, 31.18, 31.19, 31.21, 31.22 and 31.23 are not incorporated by reference.

7.2.3 Specific Licenses to Manufacture or Transfer Certain Items Containing Radioactive Material

A. Except as provided in this Part, the requirements of 10 C.F.R. Part 32 (~~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 § 7.2.3(A) of this Part, 10 C.F.R. §§ 32.1, 32.8, 32.11, 32.12, 32.14, 32.15, 32.16, 32.18, 32.19, 32.20, ~~32.21(a)~~, 32.21, 32.21a, 32.21(a), 32.22, 32.23, 32.25, 32.26, 32.27, 32.28, 32.29, 32.30, 32.31, 32.32, 32.40, 32.201, 32.210, 32.211, 32.301 and 32.303 are not incorporated by reference.

7.2.4 Specific Domestic Licenses of Broad Scope for Radioactive Material

A. Except as provided in this Part, the requirements of 10 C.F.R. Part 33 (~~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 § 7.2.4(A) of this Part, 10 C.F.R. §§ 33.1, 33.8, 33.12, 33.16, 33.21 and 33.23 are not incorporated by reference.

7.2.5 Licensing of Source Material

A. Except as provided in this Part, the requirements of 10 C.F.R. Part 40 (~~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 § 7.2.5(A) of this Part, 10 C.F.R. §§ 40.1, 40.2, 40.4 (definition of "Reconciliation", paragraph 2 in the definition of Commencement of Construction and paragraph 9ii in the definition of Construction and definition of "Foreign obligations only), 40.5, 40.6, 40.7, 40.8, 40.9, 40.10, 40.11, 40.12, ~~40.12(c)(5)(iv)~~ 40.13(c)(5)(iv), 40.14, 40.20, 40.21, 40.23, 40.26, 40.27, 40.28, 40.31, 40.32(d), (e), and (g), 40.33, 40.36(c), (e), (f), and (g), 40.38, 40.41(d), (e)(1) and (3)(g) and (h), 40.43, 40.45, 40.51(b)(6), 40.52, 40.53, 40.56, 40.60, 40.62, 40.63, 40.64, 40.65, 40.66, 40.67, 40.71, 40.81 and 40.82 are not incorporated by reference.

7.2.6 Licensing of Special Nuclear Material

A. Except as provided in this Part, the requirements of 10 C.F.R. Part 70 (~~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 § 7.2.6(A) of this Part, 10 C.F.R. §§ 70.1, 70.2, 70.3, 70.4 (paragraph 2 in the definition of Commencement of Construction and paragraph 9ii in the definition of Construction only), 70.5, 70.6, 70.7, 70.8, 70.9,

70.10, 70.13, 70.14, 70.17, 70.18, 70.20, 70.20a, 70.20b, 70.21, 70.22, 70.23(a)(1), (a)(5) through (a)(12) and (b), 70.24, 70.25(a)(1), (c), (d), and (f), 70.31(c), (d) and (e), 70.32(a)(1), (4), (5), (6) and (7) and (b)(1), (3) and (4) and (c), (d), (e), (f), (g), (h), (i), (j) and (k), 70.33, 70.35, 70.37, 70.40, 70.42(b)(6), 70.44, 70.51(c), (d) and (e), 70.52, 70.53, 70.54, 70.55, 70.56, 70.57, 70.58, 70.59, 70.60, 70.61, 70.62, 70.64, 70.65, 70.66, 70.72, 70.73, 70.74, 70.76, 70.81 and 70.82, 70.91, 70.92 and Appendix A are not incorporated by reference.

C. Except as provided in this Part, the requirements of 10 C.F.R. § 150.11(b) (2019) 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.

7.2.7 Effect of incorporation of 10 C.F.R. Parts 30, 31, 32, 33, 40 and 70

A. To reconcile differences between this Part and the incorporated sections of 10 C.F.R. Parts 30, 31, 32, 33, 40 and 70 the following words and phrases shall be substituted for the language in 10 C.F.R. Parts 30, 31, 32, 33, 40 and 70 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 reference to special nuclear material shall be deemed to be a reference to special nuclear material in quantities not sufficient to form a critical mass.

5. Any reference to “NRC Form 313, Application for Material License" shall be deemed to be a reference to Agency Form MAT-1, Application for Material License.

6. Any reference to “NRC Form 244, Registration Certificate - Use of Depleted Uranium Under General License" shall be deemed to be a reference to Agency Form GEN-1 "Registration Certificate - Use of Depleted Uranium Under General License."

7. Any reference to “NRC Form 483, Registration Certificate - In Vitro Testing with Byproduct Material Under General License" shall be deemed to be a reference to Agency Form GEN-3, Certificate - *In-Vitro* Testing with Radioactive Material Under General License.

8. Any notifications, reports or correspondence referenced in the incorporated sections of 10 C.F.R. Parts 30, 31, 32, 33, 40 and 70 shall be directed to the Agency using Agency contact information specified in § 1.4 of this Subchapter.

7.3 Definitions

A. In addition to the definitions contained in 10 C.F.R. §§ 30.4, 32.2, 40.4 and § 70.4, 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. "NARM" means any naturally occurring or accelerator-produced radioactive material. It does not include byproduct, source, or special nuclear material.

4. "Offshore waters" means that area of land and water, beyond Rhode Island's Submerged Lands Act jurisdiction, on or above the U.S. Outer Continental Shelf.

5. "Radioactive material" means any material (solid, liquid, or gas) which emits radiation spontaneously.

6. "Special nuclear material in quantities not sufficient to form a critical mass" means uranium enriched in the isotope U-235 in quantities not exceeding three hundred fifty (350) grams of contained U-235; uranium-233 in quantities not exceeding two hundred (200) grams; plutonium in quantities not exceeding two hundred (200) grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination shall not exceed "1" (i.e., unity). For example, the following quantities in combination would not exceed the limitation and are within the formula: (175 (grams contained U-235)/350) + (50 (grams U-233)/200) + (50 (grams Pu)/200) = 1.

7.4 Exemptions

7.4.1 Persons Using Sources of Radiation Under Certain Department of Energy and Nuclear Regulatory Commission Contracts

A. Any prime contractor or subcontractor of the U.S. Department of Energy (DOE) or the U.S. Nuclear Regulatory Commission (NRC) operating within the State of Rhode Island is exempt from the requirements for a license set forth in this Subchapter to the extent that such prime contractor or subcontractor under his contract manufactures, produces, transfers, receives, acquires, owns, possesses, or uses sources of radiation:

1. The performance of work for the DOE at a United States Government-owned or controlled site, including the transportation of sources of radiation to or from such site and the performance of contract services during temporary interruptions of such transportation;

2. Research in, or development, manufacture, storage, testing or transportation of, atomic weapons or components thereof; or

3. The use or operation of nuclear reactors or other nuclear devices in a United States Government-owned vehicle or vessel.

B. In addition to the foregoing exemptions, any prime contractor or subcontractor of the DOE or the NRC is exempt from the requirements for a license set forth in this Subchapter to the extent that such prime contractor or subcontractor manufacturers, produces, transfers, receives, acquires, owns, possesses, or uses sources of radiation under his prime contract or subcontract when the State of Rhode Island and the NRC jointly determine that:

1. The exemption of the prime contractor or subcontractor is authorized by law; and

2. Under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.

7.4.2 Carriers

Common and contract carriers, freight forwarders, warehousemen, and the U.S. Postal Service are exempt from the requirements in this Part to the extent that they transport or store radioactive material in the regular course of carriage for another or storage incident thereto.

7.4.3 Exempt Concentrations

For the purpose of this Part, exempt concentrations are defined by 10 C.F.R. §§ 30.14 and § 30.70, Schedule A [§ 7.9.1 of this Part].

7.4.4 Exempt Quantities

For the purpose of this Part, exempt quantities are defined by 10 C.F.R. §§ 30.18 and § 30.71, Schedule B [§ 7.9.2 of this Part].

7.4.5 Certain Items Containing Radioactive Material

For the purpose of this Part, exemptions for certain items containing radioactive material are defined by 10 C.F.R. § 30.15.

7.4.6 Self-luminous Products Containing Tritium, Krypton-85, or Promethium-147

For the purpose of this Part, exemptions for self-luminous products containing tritium, Krypton-85, or Promethium-147 are defined by 10 C.F.R. § 30.19.

7.4.7 Gas and Aerosol Detectors Containing Radioactive Material

For the purpose of this Part, exemptions for gas and aerosol detectors containing radioactive material are defined by 10 C.F.R. § 30.20.

7.4.8 Radioactive Drug: Capsules Containing C-14 Urea for "in vivo" Diagnostic Use for Humans

For the purpose of this Part, exemptions for capsules containing C-14 urea for "in vivo" diagnostic use for humans are defined by 10 C.F.R. § 30.21, excluding 10 C.F.R. § 30.21(c).

7.4.9 Certain Industrial Devices

For the purpose of this Part, exemptions for certain industrial devices are defined by 10 C.F.R. § 30.22.

7.4.10 Unimportant Quantities of Source Material

For the purpose of this Part, unimportant quantities of source material are defined by 10 C.F.R. § 40.13, ~~excluding~~ with the exception of § 40.13(c)(5)(iv).

7.5 Licenses

A. Licenses for radioactive materials are of two (2) types: general and specific.

1. The Agency issues a specific license to a named person who has filed an application for the license under the provisions of this Subchapter.

2. A general license is provided by regulation, grants authority to a person for certain activities involving radioactive material, and is effective without the filing of an application with the Agency or the issuance of a licensing document to a particular person. However, registration with the Agency may be required by the particular general license.

B. Types of specific licenses of broad scope:

1. A "Type A specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any

chemical or physical form of the radioactive material specified in the license, but not exceeding quantities specified in the license, for any authorized purpose. The quantities specified are usually in the multicurie range.

2. A "Type B specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in the table referenced in § 7.9.6 of this Part, for any authorized purpose. The possession limit for a Type B broad license, if only one (1) radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Column I of the table referenced in § 7.9.6 of this Part. If two (2) or more radionuclides are possessed thereunder, the possession limit for each is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Column I of the table referenced in § 7.9.6 of this Part, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

3. A "Type C specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in the table referenced in § 7.9.6 of this Part, for any authorized purpose. The possession limit for a Type C broad license, if only one (1) radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Column II of the table referenced in § 7.9.6 of this Part. If two (2) or more radionuclides are possessed thereunder, the possession limit is determined for each as follows: For each radionuclide determine the ratio of the quantity possessed to the applicable quantity specified in Column II of the table referenced in § 7.9.6 of this Part, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

7.6 Specific Licenses

7.6.1 Application for Specific Licenses

A. Applications for specific licenses shall be filed in duplicate on a form prescribed by the Agency, and shall include a designated e-mail address for receipt of official Agency correspondence in electronic format.

B. The Agency may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the Agency to determine whether the application should be granted or denied or whether a license should be modified or revoked.

C. Each application shall be signed by the applicant or licensee or a person duly authorized to act on their behalf.

D. An application for a license may include a request for a license authorizing one (1) or more activities.

E. In the application, the applicant shall submit the required information to the Agency without reference to previously submitted documents unless permission has been obtained from the Agency, in advance, to incorporate by reference information contained in previous applications, statements, or reports filed with the Agency. All references shall be clear and specific and shall contain all of the information needed for a particular item on the application.

F. Applications and documents submitted to the Agency may be made available for public inspection except that the Agency may withhold any document or part thereof from public inspection if disclosure of its content is not required in the public interest and would adversely affect the interest of a person concerned.

G. Specific License to Use Radioactive Material in the Form of a Sealed Source or in a Device That Contains the Sealed Source. For the purposes of this Part, requirements for a specific license to use radioactive material in the form of a sealed source or in a device that contains the sealed source are defined by 10 C.F.R. § 30.32(g).

H. Consideration of the Need for an Emergency Plan for Responding to a Release of Radioactive Materials. For the purpose of this Part, requirements for consideration of the need for an emergency plan for responding to a release of radioactive materials are defined by 10 C.F.R. § 30.32(i).

I. Production of PET Radioactive Drugs for Noncommercial Transfer. An application from a medical facility or educational institution to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use under Part 9 of this Subchapter shall include:

1. A request for authorization for the production of PET radionuclides or evidence of an existing license issued under this Part, or equivalent Regulations of the U.S. Nuclear Regulatory Commission or another Agreement State, for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

2. Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one (1) of the criteria in § 7.6.16(B) of this Part.

3. Identification of individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an Authorized Nuclear Pharmacist as specified in 10 C.F.R. § 32.72(b)(2) and § 7.6.16(C) of this Part.

4. Information identified in 10 C.F.R. § 32.72(a)(3) on the PET drugs to be noncommercially transferred to members of its consortium.

7.6.2 General Requirements for Issuance of Specific Licenses

A. For the purposes of this Part, general requirements for issuance of specific licenses are defined by 10 C.F.R. §§ 30.33, 40.32 and 70.31.

B. Use of Radioactive Material at Property Not Owned by Applicant. In addition to the requirements set forth in § 7.6.2(A) of this Part and/or Part 9 of this Subchapter, a specific license for use of radioactive material where the proposed location of use is not owned by the applicant will be issued under the following conditions:

1. Each initial application shall include a letter signed by the property owner (or authorized representative) that permits the use of licensed radioactive material at the proposed location of use.

2. Each amendment request for an additional location of use shall include a letter signed by the property owner (or authorized representative) that permits the use of licensed radioactive material at the proposed location of use.

7.6.3 Terms and Conditions of Licenses

For the purpose of this Part, terms and conditions of licenses are defined by 10 C.F.R. §§ 30.34 [excluding §§ 30.34(d), (e)(1), & (e)(3)], 40.41 [excluding §§ 40.41(d), (e)(1) and (3) and (g)] and 10 C.F.R. § 70.32 [excluding §§ 70.32(a)(1), (4), (5), (6) and (7) and (b)(1), (3) and (4) and (c), (d), (e), (f), (g), (h), (i), (j) and (k)].

7.6.4 Financial Assurance and Recordkeeping for Decommissioning

A. For the purpose of this Part, requirements for financial assurance and recordkeeping for decommissioning for a specific license authorizing the possession and use of unsealed radioactive material are defined by 10 C.F.R. § 30.35.

B. For the purpose of this Part, requirements for financial assurance and recordkeeping for decommissioning for licenses authorizing the receipt, possession and use of source material are defined by 10 C.F.R. §§ 40.36 (a), (b), (d) and (f).

C. For the purpose of this Part, requirements for financial assurance and recordkeeping for decommissioning for licenses authorizing the receipt, possession and use of special nuclear material in quantities not sufficient to form a critical mass are defined by 10 C.F.R. §§ 70.25(a)(2), (b), (e) and (g).

7.6.5 Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas

For the purpose of this Part, requirements for expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas are defined by 10 C.F.R. §§ 30.36, 40.42 and 70.38.

7.6.6 Renewal of Specific Licenses

A. Applications for renewal of specific licenses shall be filed in accordance with § ~~7.5.2~~ 7.6.1 of this Part.

B. In any case in which a licensee, not less than thirty (30) days prior to expiration of his existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until the application has been finally determined by the Agency.

7.6.7 Amendment of Licenses

A. For the purpose of this Part, requirements for amendment of licenses are defined by 10 C.F.R. §§ 30.38, 40.44 and 70.34.

B. A licensee shall notify the Agency by letter no later than thirty (30) days after:

1. An Authorized User or Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or

2. The licensee's mailing address changes; or

3. The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in § 7.6.3 of this Part; or

4. The licensee has added to or changed the areas of use identified in the application or on the license where radioactive material is used.

7.6.8 Agency Action on Applications to Renew or Amend

In considering an application to renew or amend a license, the Agency will apply the criteria set forth in §§ ~~7.6.2,~~ 7.5 or 7.6 of this Part as applicable.

7.6.9 Transfer of Radioactive Material

For the purpose of this Part, requirements for transfer of radioactive material are defined by 10 C.F.R. §§ 30.41 [excluding § 30.41(b)(6)], 40.51 [excluding § 40.51(b)(6)] and 70.42 [excluding § 70.42(b)(6)].

7.6.10 Requirements for a Specific License of Broad Scope

A. A person may file an application for specific license of broad scope in accordance with the provisions of § 7.6.1 of this Part.

B. For the purpose of this Part, requirements for the issuance of a Type A specific license of broad scope are defined by 10 C.F.R. § 32.13.

C. For the purpose of this Part, requirements for the issuance of a Type B specific license of broad scope are defined by 10 C.F.R. § 32.14.

D. For the purpose of this Part, requirements for the issuance of a Type C specific license of broad scope are defined by 10 C.F.R. § 32.15.

E. An application filed pursuant to this Part for a specific license other than one of broad scope will be considered by the Agency as an application for a specific license of broad scope under this Part if the requirements of the applicable sections of this Part are satisfied.

7.6.11 Requirements for License to Manufacture or Initially Transfer Devices to Persons Generally Licensed Under § 7.7.1

A. For the purpose of this Part, requirements for a license to manufacture or initially transfer devices to persons generally licensed under § 7.7.1 of this Part are defined by 10 C.F.R. § 32.51.

B. For the purpose of this Part, license conditions for a person licensed under § 7.6.11(A) of this Part are defined by 10 C.F.R. § 32.51(a).

C. For the purpose of this Part, requirements for material transfer reports and records for a person licensed under § 7.6.11(A) of this Part are defined by 10 C.F.R. § 32.52.

7.6.12 Requirements for License to Manufacture, Assemble, Repair or Initially Transfer Luminous Safety Devices for Use in Aircraft

A. For the purpose of this Part, requirements for a license to manufacture, assemble, repair or initially transfer luminous safety devices for use in aircraft are defined by 10 C.F.R. § 32.53.

B. For the purpose of this Part, requirements for labeling of devices licensed under § 7.6.12(A) of this Part are defined by 10 C.F.R. § 32.54.

C. For the purpose of this Part, requirements for quality assurance and prohibition of transfer of devices licensed under § 7.6.12(A) of this Part are defined by 10 C.F.R. § 32.55.

D. For the purpose of this Part, requirements for material transfer reports for persons licensed under § 7.6.12(A) of this Part are defined by 10 C.F.R. § 32.56.

7.6.13 Requirements for License to Manufacture or Initially Transfer Calibration or Reference Sources Containing Americium-241, Plutonium or Radium-226

A. For the purpose of this Part, requirements for a license to manufacture or initially transfer calibration or reference sources containing Americium-241 or Radium-226 are defined by 10 C.F.R. § 32.57.

~~1~~ B. For the purpose of this Part, requirements for labeling of devices licensed under § 7.6.13(A) of this Part are defined by 10 C.F.R. § 32.58.

~~2~~ C. For the purpose of this Part, requirements for leak testing of each source licensed under § 7.6.13(A) of this Part are defined by 10 C.F.R. § 32.59.

~~B~~ D. For the purpose of this Part, requirements for a license to manufacture or initially transfer calibration or reference sources containing plutonium are defined by 10 C.F.R. § 70.39.

7.6.14 Requirements for License to Manufacture or Initially Transfer Ice Detection Devices Containing Strontium-90

A. For the purpose of this Part, requirements for a license to manufacture or initially transfer ice detection devices containing Strontium-90 are defined by 10 C.F.R. § 32.61.

B. For the purpose of this Part, requirements for quality assurance and prohibition of transfer of devices licensed under § 7.6.14(A) of this Part are defined by 10 C.F.R. § 32.62.

7.6.15 Requirements for License to Manufacture and Distribute Radioactive Material for Certain *in-vitro* Clinical or Laboratory Testing Under General License

For the purpose of this Part, requirements for a license to manufacture and distribute radioactive material for certain *in-vitro* clinical or laboratory testing under general license are defined by 10 C.F.R. § 32.71.

7.6.16 Requirements for License to Manufacture, Prepare, or Transfer for Commercial Distribution of Radioactive Drugs Containing Radioactive Material for Medical Use Under Part 9

A. For the purpose of this Part, requirements for a license to manufacture, prepare, or transfer for commercial distribution of radioactive drugs containing radioactive material for medical use under Part 9 of this Subchapter are defined by 10 C.F.R. § 32.72.

B. In addition to the requirements in § 7.6.16(A) of this Part, the applicant shall submit evidence that the applicant is at least one (1) of the following:

1. Registered with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 C.F.R. § 207.20(a);

2. Licensed as a drug manufacturer and/or pharmacy in accordance with Subchapter 15 Part 1 of this Chapter, Pharmacists, Pharmacies and Manufacturers, Wholesalers and Distributors; or

3. Licensed as a positron emission tomography (PET) drug production facility pursuant to this Part.

C. In addition to the provisions of 10 C.F.R. § 32.72(b)(4), an individual may function as an authorized nuclear pharmacist only if they are licensed as a pharmacist in accordance with Subchapter 15 Part 1 of this Chapter, Pharmacists, Pharmacies and Manufacturers, Wholesalers and Distributors.

7.6.17 Requirements for License to Manufacture and Distribute Sources or Devices Containing Radioactive Material for Medical Use

For the purpose of this Part, requirements for a license to manufacture and distribute sources or devices containing radioactive material for medical use are defined by 10 C.F.R. § 32.74.

7.6.18 Requirements for License to Manufacture and Distribute Industrial Products Containing Depleted Uranium for Mass-Volume Applications

A. For the purpose of this Part, requirements for a license to manufacture and distribute industrial products containing depleted uranium for mass-volume applications are defined by 10 C.F.R. § 40.34.

B. For the purpose of this Part, conditions of specific licenses issued pursuant to § 7.6.18(A) of this Part are defined by 10 C.F.R. § 40.35.

7.6.19 Requirements for License to Initially Transfer Source Material for Use Under The 'Small Quantities of Source Material' General License

A. For the purpose of this Part, requirements for a license to initially transfer source material for use under the “small quantities of source material” general license are defined by 10 C.F.R. § 40.54.

B. For the purpose of this Part, requirements for quality control, labeling, safety instructions, and records and reports for licenses issued pursuant to § 7.6.19(A) of this Part are defined by 10 C.F.R. § 40.56.

7.7 General Licenses

7.7.1 General License for Certain Detecting, Measuring, Gauging, or Controlling Devices and Certain Devices for Producing Light or an Ionized Atmosphere

For the purpose of this Part, requirements for a general license for certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere are defined by 10 C.F.R. § 31.5.

7.7.2 General License to Install Devices Generally Licensed in § ~~7.5.11~~ 7.7.1

For the purpose of this Part, requirements for a general license to install devices generally licensed in § ~~7.5.11~~ 7.7.1 of this Part are defined by 10 C.F.R. § 31.6.

7.7.3 General License for Luminous Safety Devices for Use in Aircraft

For the purpose of this Part, requirements for a general license for luminous safety devices for use in aircraft are defined by 10 C.F.R. § 31.7.

7.7.4 General License for Calibration or Reference Sources

A. For the purpose of this Part, requirements for a general license for Americium-241 and Radium-226 in the form of calibration or reference sources are defined by 10 C.F.R. § 31.8.

B. For the purpose of this Part, requirements for a general license for plutonium in the form of calibration or reference sources are defined by 10 C.F.R. § 70.19.

7.7.5 General License to Own Radioactive Material

A. A general license is hereby issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of this Part, a general licensee not authorized to manufacture, produce, transfer, receive, possess, use, import, or export radioactive material except as authorized by a specific license.

B. A general license is hereby issued to own special nuclear material in quantities not sufficient to form a critical mass. Notwithstanding any other provisions of this Part, a general licensee under this section is not authorized to acquire, deliver, receive, possess, use or transfer special nuclear material in quantities not sufficient to form a critical mass, except as authorized in a specific license.

7.7.6 General License for Strontium 90 in Ice Detection Devices

For the purpose of this Part, requirements for a general license for Strontium 90 in ice detection devices are defined by 10 C.F.R. § 31.10.

7.7.7 General License for Use of Radioactive Material for Certain *in vitro* Clinical or Laboratory Testing

For the purpose of this Part, requirements for a general license for use of radioactive material for certain *in vitro* clinical or laboratory testing are defined by 10 C.F.R. § 31.11.

7.7.8 General License for Use of Radioactive Material for Certain *in vitro* Clinical or Laboratory Testing

For the purpose of this Part, requirements for a general license for certain items and self-luminous products containing Radium-226 are defined by 10 C.F.R. § 31.12.

7.7.9 General License for Small Quantities of Source Material

For the purpose of this Part, requirements for a general license for small quantities of source material are defined by 10 C.F.R. § 40.22.

7.7.10 General License for Use of Certain Industrial Products or Devices

For the purpose of this Part, requirements for a general license for use of certain industrial products or devices are defined by 10 C.F.R. § 40.25.

7.8 Serialization of Nationally Tracked Sources, Sealed Source & Device Registry, Records and Reports

7.8.1 Records

A. For the purpose of this Part, recordkeeping requirements are defined by 10 C.F.R. §§ 30.51, 40.61 and 70.51 [excluding 10 C.F.R. §§ 70.51(c), (d) and (e)].

B. Each record required by this Part must be legible throughout the retention period specified by each Agency Regulation. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, specifications, must include all pertinent information such as letters, stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

7.8.2 Right to Cause the Withholding or Recall of Radioactive Material

For the purpose of this Part, the right to cause the withholding or recall of radioactive material defined by 10 C.F.R. § 30.62.

7.8.3 Serialization of Nationally Tracked Sources

Each licensee who manufactures a nationally tracked source after February 6, 2007 shall assign a unique serial number to each nationally tracked source. Serial numbers shall be composed only of alpha-numeric characters.

7.8.4 Sealed Source and Device Registry

A. Registration of Product Information. The Agency does not currently administer a sealed source and device registration program. Any manufacturer or initial distributor of a sealed source or device containing a sealed source who is subject to this Part shall submit a request for evaluation of radiation safety information about its product and for its registration to the Nuclear Regulatory Commission pursuant to 10 C.F.R. § 32.210.

B. Inactivation of Certificates of Registration of Sealed Sources and Devices

1. A certificate holder who no longer manufactures or initially transfers any of the sealed source(s) or device(s) covered by a particular certificate issued by the Agency shall request inactivation of the registration certificate. Such a request must be made to the Agency and must normally be made no later than two (2) years after initial distribution of all of the source(s) or device(s) covered by the certificate has ceased. However, if the certificate holder determines that an initial transfer was in fact the last initial transfer more than two (2) years after that transfer, the certificate holder shall request inactivation of the certificate within ninety (90) days of this determination and briefly describe the circumstances of the delay.

2. If a distribution license is to be terminated in accordance with this Part, the licensee shall request inactivation of its registration certificates associated with that distribution license before the Agency will terminate the license. Such a request for inactivation of certificate(s) must indicate that the license is being terminated and include the associated specific license number.

3. A specific license to manufacture or initially transfer a source or device covered only by an inactivated certificate no longer authorizes the licensee to initially transfer such sources or devices for use. Servicing of devices must be in accordance with any conditions in the certificate, including in the case of an inactive certificate.

7.8.5 Modification, Revocation, and Termination of Licenses

A. The terms and conditions of all licenses shall be subject to amendment, revision, or modification or the license may be suspended or revoked by reason of amendments to the Act, or by reason of Rules, Regulations, and orders issued by the Agency.

B. Any license may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or any statement of fact required under

provisions of the Act, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means which would warrant the Agency to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of the Act, or of the license, or of any Rule, Regulation, or order of the Agency.

C. Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefor, facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

D. The Agency may terminate a specific license upon request submitted by the licensee to the Agency in writing.

E. Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than one hundred twenty (120) days, in an unsealed form, shall forward the following records to the Agency:

1. Records of disposal of licensed material made under §§ 1.15.2, 1.15.3, 1.15.4 and 1.15.5 of this Subchapter; and

2. Records required by § 1.16.3 of this Subchapter.

F. If licensed activities are transferred or assigned in accordance with § 7.6.3 of this Part, each licensee authorized to possess radioactive material, with a half-life greater than one hundred twenty (120) days, in an unsealed form, shall forward the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

1. Records of disposal of licensed material made under §§ 1.15.2, 1.15.3, 1.15.4 and 1.15.5 of this Subchapter; and

2. Records required by § 1.16.3 of this Subchapter.

G. Prior to license termination, each licensee shall forward the records required by § 7.6.4 of this Part to the Agency.

7.9 Schedules

7.9.1 Exempt Concentrations

For the purpose of this Part, the schedule of exempt concentrations is defined by 10 C.F.R. § 30.70, Schedule A.

7.9.2 Exempt Quantities

For the purpose of this Part, the schedule of exempt quantities is defined by 10 C.F.R. § 30.71, Schedule B.

7.9.3 Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release

For the purpose of this Part, quantities of radioactive materials requiring consideration of the need for an emergency plan for responding to a release are defined by 10 C.F.R. § 30.72.

7.9.4 Schedule C: Quantities of Licensed Material Requiring Labeling

For the purpose of this Part, quantities of licensed material requiring labeling are defined by Appendix B to 10 C.F.R. Part 30.

7.9.5 Decommissioning Funding Criteria

A. For the purpose of this Part, criteria relating to use of financial tests and parent company guarantees for providing reasonable assurance of funds for decommissioning are defined by Appendix A to 10 C.F.R. Part 30.

B. For the purpose of this Part, criteria relating to use of financial tests and self guarantees for providing reasonable assurance of funds for decommissioning are defined by Appendix C to 10 C.F.R. Part 30.

C. For the purpose of this Part, criteria relating to use of financial tests and self-guarantee for providing reasonable assurance of funds for decommissioning by commercial companies that have no outstanding rated bonds are defined by Appendix D to 10 C.F.R. Part 30.

D. For the purpose of this Part, criteria relating to use of financial tests and self-guarantee for providing reasonable assurance of funds for decommissioning by nonprofit colleges, universities, and hospitals are defined by Appendix E to 10 C.F.R. Part 30.

7.9.6 Limits for a Specific License of Broad Scope

A. For the purpose of this Part, limits for a specific license of broad scope are defined by 10 C.F.R. § 33.100, Schedule C.

B. In addition to the values referenced in § 7.9.6(A) of this Part, the following table of limits for a specific license of broad scope is also applicable to this Part:

Radioactive Material	Col. I curies	Col. II curies
Beryllium-7	10	0.1

Cobalt-57	10	0.1
Radium-226	0.01	0.0001
Scandium-46	1	0.01
Sodium-22	0.1	0.001

7.10 Reciprocal Recognition of Licenses

7.10.1 Specific Radioactive Material Licenses

A. Subject to this Subchapter, and the limitations contained in § 7.10.1(D) of this Part, any person who holds a specific license from the U.S. Nuclear Regulatory Commission or any Agreement State, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within Rhode Island, except for areas under exclusive federal jurisdiction, for a period not in excess of one hundred eighty (180) days in any calendar year provided that:

1. The licensing document does not limit the activity authorized by such document to specified installations or locations;

2. The out-of-State licensee submits Agency Form MAT-9i, a copy of the pertinent licensing document, and the appropriate fee as prescribed in § 15.5.4 of this Subchapter to the Agency at least three (3) days prior to engaging in such activity for the first time in a calendar year. If a submittal cannot be filed three (3) days before engaging in activities under reciprocity, because of an emergency or other reason, the Agency may waive the three (3) day time requirement provided the licensee:

   a. Informs the Agency by telephone, facsimile, an Agency Form MAT-9N, or a letter of initial activities or revisions to the information submitted on the initial Agency Form MAT-9i;

   b. Receives oral or written authorization for the activity from the Agency; and

   c. Within three (3) days after the notification, files an Agency Form MAT-9N, a copy of the pertinent licensing document, and the appropriate fee as prescribed in § 15.5.4 of this Subchapter.

3. The out-of-State licensee complies with all applicable Regulations of the Agency and with all the terms and conditions of his licensing document, except any such terms and conditions which may be inconsistent with applicable Regulations of the Agency;

4. The out-of-State licensee supplies such other information as the Agency may request; and

5. The out-of-State licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in § 7.10.1(A) of this Part except by transfer to a person specifically licensed by the Agency, another Agreement State or by the U.S. Nuclear Regulatory Commission to receive such material.

6. The out-of-State licensee files an amended Agency Form MAT-9N with the Agency to request approval for changes in work locations, radioactive material, or work activities different from the information contained on the initial MAT-9N.

B. Notwithstanding the provisions of § 7.10.1(A) of this Part, any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement State authorizing the holder to manufacture, transfer, install, or service a device described in § 7.7.1 of this Part within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate or service such a device in Rhode Island, except for areas under exclusive federal jurisdiction, provided that:

1. Such person shall file a report with the Agency within thirty (30) days after the end of each calendar quarter in which any device is transferred to or installed in Rhode Island. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;

2. The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the U.S. Nuclear Regulatory Commission or an Agreement State;

3. Such person shall assure that any labels required to be affixed to the device under Regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited;" and

4. The holder of the specific license shall furnish to each general licensee to whom he transfers such device or on whose premises he installs such device a copy of the general license contained in § 7.7.1 of this Part.

C. The Agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by another agency, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

D. The Agency will not accept any applications for reciprocity under this Part with respect to activities authorized pursuant to regulations that are equivalent to Part 9 of this Subchapter entitled "Medical Use of Radioactive Material." These activities will only be authorized under the provision of a specific license issued by the Agency.

7.10.2 Generally Licensed Devices

A. Reciprocity requests involving generally licensed devices registered pursuant to § 7.7.1 of this Part or the equivalent Regulations of the U.S. Nuclear Regulatory Commission or another Agreement State shall be handled in accordance with the procedures contained in § 7.10.1 of this Part. Applicants for reciprocity shall submit evidence of current registration pursuant to § 7.7.1 of this Part (or the equivalent regulations of the U.S. Nuclear Regulatory Commission or another Agreement State) in lieu of a specific radioactive materials license.

B. Reciprocity requests involving other generally licensed devices shall also be handled in accordance with the procedures contained in § 7.10.1 of this Part. In lieu of a specific radioactive materials license, applicants for reciprocity shall submit a copy of the general license authorization for the device and documentation that they are authorized to possess the device under a general license pursuant to the regulations of the U.S. Nuclear Regulatory Commission or another Agreement State that are applicable to the jurisdiction where the reciprocity request originated.