RHODE ISLAND GOVERNMENT REGISTER

PUBLIC NOTICE OF PROPOSED RULEMAKING

DEPARTMENT OF HEALTH

Title of Rule: X-Ray and Radioactive Materials Fees (216-RICR-40-20-15)

Rule Identifier: 216-RICR-40-20-15

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 clarify that Category 3K includes all other use of unsealed radioactive material not authorized for commercial distribution.

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-40-20-15

TITLE 216 – DEPARTMENT OF HEALTH

CHAPTER 40 – PROFESSIONAL LICENSING AND FACILITY REGULATION

SUBCHAPTER 20 – RADIATION

PART 15 – X-Ray and Radioactive Materials Fees

15.1 Authority

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

B. Persons and individuals who are subject to licensure and/or registration with the Agency pursuant to the Act and this Subchapter shall be assessed fees, established in the Department fee schedule, and in accordance with § 15.4 of this Part for X-ray registrants and/or § 15.5 of this Part for radioactive materials licensees.

15.2 Definitions

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

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

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

3. "Department fee schedule" means Part 10-05-2 of this Title, Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health.

15.3 General Provisions

A. Fee Exempt: Notwithstanding the requirement of § 15.1(B) of this Part, no fees shall be required for radioactive materials licenses authorizing the use of source material as shielding only in devices and containers, provided, however, that all other licensed radioactive material in the device or container will be subject to the fees required by § 15.5 of this Part.

B. Payment of Fees: All fees specified in the Department fee schedule shall be submitted to the Agency.

C. Inquiries: Any inquiry regarding Agency fees should be addressed to the Agency as specified in § 1.4 of this Subchapter.

15.4 X-Ray Fees

15.4.1 Submission of Initial Fee

A. Each initial application for a Registration Certificate in a category for which a fee has been established in the Department fee schedule shall be accompanied by a fee in the amount of the Annual Fee specified for that registration category. A registration application shall not be considered prior to payment of the full amount specified. Registration applications for which no remittance is received shall be returned to the applicant.

B. Initial applications, accompanied by the appropriate registration fee and which are received by the Agency during the period July 1 through August 31 of a calendar year shall also constitute a renewal application for the period ending August 31 of the following calendar year, without payment of an additional annual registration fee.

15.4.2 Nonstandard Facilities and Services Fee

Facilities and services which are approved by the Agency for registration, but which do not fit the descriptions of the categories in § 15.4.6 of this Part shall be assessed at a rate which coincides with an appropriate category, as determined by the Agency.

15.4.3 Fee Rebates Not Authorized

Rebates shall not be made for existing registrants who terminate operations prior to the expiration of their Registration Certificates.

15.4.4 Late Fees

Failure of any registered facility or service to submit the indicated annual registration fee for renewal of registration prior to the expiration date of current Registration Certificate shall be assessed a late fee established in the Department fee schedule in addition to the required registration fee.

15.4.5 Annual Fees

The Agency shall issue an annual fee invoice to each registrant, based on the applicable annual fee established in the Department fee schedule. Fees shall be payable prior to the expiration date of the registrant's current Registration Certificate.

15.4.6 X-Ray Registration Categories

A. Healing Arts Registration Categories

1. Dental X-ray Facility [DEF]. Facilities performing diagnostic radiography limited to intra-oral dental procedures and/or extra-oral dental procedures, including panoramic procedures and cephalometric procedures.

2. Hospital Radiology Facility [HRF]. Facilities performing general purpose diagnostic radiographic procedures (including fluoroscopy) in an institution licensed by the State of Rhode Island as a hospital.

3. Radiology Facility [RAD]. Facilities performing general purpose diagnostic radiographic procedures (including fluoroscopy) outside of an institution licensed by the State of Rhode Island as a hospital.

4. Radiation Therapy Facility [RTF]. Facilities utilizing one (1) or more therapeutic radiation machines, including dedicated therapy simulator(s).

5. Specific Radiology Facility (Single Category) [SRF]

   a. Facilities performing diagnostic radiography (excluding fluoroscopy) limited to a single category of specific radiographic procedures, as specified on the facility's application. The category shall also include facilities performing only chiropractic or podiatric procedures.

   b. Facilities utilizing X-ray system(s) solely for human subjects research in accordance with Institutional Review Board (IRB) approval.

6. Specific Radiology Facility (Multiple Categories) [SRM]. Facilities performing two (2) or more categories of specific diagnostic radiography procedures (excluding fluoroscopy), as specified on the facility's application.

7. Veterinary X-ray Facility [VEF]. Facilities performing diagnostic radiography limited to veterinary procedures.

B. Non-Healing Arts Registration Categories

1. Industrial Radiography Facility [IRF]. Facilities utilizing X-ray equipment to perform industrial radiographic procedures.

2. Industrial Radiation Machine (Type A) Facility [IRA]. Facilities utilizing a Category A industrial radiation machines as defined in Part 6 of this Subchapter.

3. Industrial Radiation Machine (Type B) Facility [IRB]. Facilities utilizing a Category B industrial radiation machines as defined in Part 6 of this Subchapter.

4. Other Non-Healing Arts Facility [OTH]. Facilities utilizing X-ray equipment for non-healing arts applications not otherwise defined in this Subchapter.

5. Particle Accelerator Facility [PAF]. Facilities utilizing particle accelerators not authorized for human use.

C. Services Registration Categories.

1. Provider of X-ray Services [PXS].

a. Individuals or facilities providing installation and/or servicing of X-ray equipment and associated components for Agency registrants.

b. Individuals or facilities providing NVLAP certified personnel dosimetry services for Agency registrants and/or radioactive materials licensees.

2. Radiation Physics Services [RPS]

a. Calibration of health physics instrumentation for Agency registrants and/or radioactive materials licensees

b. General radiation physics services for Agency registrants and/or radioactive materials licensees

c. Diagnostic X-ray Physics services for Agency registrants [Calibration and surveys of diagnostic X-ray equipment]

d. Diagnostic X-ray Physics services for Agency registrants [Calibration and surveys of computed tomography (CT) X-ray systems]

e. Radiotherapy Physics services for Agency registrants [Calibration and surveys of therapeutic radiation machines]

f. Radiotherapy Physics services for Agency materials licensees [Calibration and surveys of remote afterloader units, teletherapy units, and/or gamma stereotactic radiosurgery units]

3. Storage X-ray Facility [STO]. Facilities limited to storage of X-ray equipment, excluding X-ray equipment exempt from registration under this Subchapter

15.5 Radioactive Materials Fees

15.5.1 Application Fee

Each initial application for a license in a category for which a fee has been established in the Department fee schedule shall be accompanied by a non-refundable fee in the amount of the Annual Fee specified for that license category. A license application shall not be considered prior to payment of the full amount specified. License applications for which no fee is received shall be returned to the applicant.

15.5.2 Annual Fees

A. Assessment of Fees: The Agency shall issue an annual fee invoice to each licensee, based on the applicable annual fee established in the Department fee schedule. Fees shall be payable within thirty (30) days after receipt of a fee invoice.

B. Eligibility for Waiver of Annual Fee: Any broad-scope (academic or medical) licensee, or any licensee which is a governmental agency of the State of Rhode Island, that provides in-kind services to the Agency and/or performs services pursuant to an accepted written agreement with the Agency, and which are valued at an amount equal to or greater than their annual license fee, may submit a written request for a waiver from payment of the annual license fee. Upon approval by the Agency, this waiver shall only remain in effect for that annual licensing period. A new waiver request must be submitted for each subsequent annual licensing period.

1. For the purposes of this Part, “governmental agency” shall be construed to include any department, office, commission or similar public entity established by Executive Order or pursuant to the Rhode Island General Laws.

C. Revocation of Annual Fee Waiver: Upon written notice of noncompliance to the licensee, the Agency may revoke any waiver, approved pursuant to § 15.5.2(B) of this Part, for failure to provide or perform all services pursuant to the accepted written agreement. The Agency may also invoice the licensee for any difference between the originally waived annual fee and the value of services already performed during that annual licensing period.

15.5.3 Amendment Fees

A. Assessment of Fees: A licensee shall notify the Agency prior to submitting an amendment so that the appropriate amendment fee can be determined. Amendment fees are established in the Department fee schedule and shall be assessed in accordance with written criteria established by the Agency. The written criteria shall be based on the Agency's estimate of the typical time and

effort required to complete action on that general category of amendment request.

B. Nonstandard Amendment Fees: A nonstandard amendment request which is not addressed by the Agency's written criteria shall be assessed an amendment fee which most closely approximates the time and effort necessary to complete action on the amendment request, as determined by the Agency.

C. Submission of Amendment Fees: The appropriate amendment fee shall accompany the amendment request when it is submitted to the Agency. If the time and effort required to complete Agency action on the amendment request is significantly different than the basis for assessing the amendment fee, the Agency shall refund any overcharges or bill the licensee for an additional amendment fee up to a total maximum fee established in the Department fee schedule.

15.5.4 Reciprocity Fees

A. Each annual application to operate in Rhode Island under reciprocity shall be accompanied by a non-refundable fee equal to the amount established in the Department fee schedule for the specified category of activity. There will be no pro-rating of reciprocity fees.

1. Category 1: Activities equivalent to those authorized by Categories 3D, 3K (broad-scope only) or 4B in § 15.5.7 of this Part.

2. Category 2: Activities equivalent to those authorized by Categories 1B, 2C, 3I, 3K (other than broad-scope), 4C or 5A in § 15.5.7 of this Part.

3. Category 3: Activities equivalent to those authorized by Categories 1A, 3L or 8A in § 15.5.7 of this Part.

4. Any activity which is not specifically identified in §§ 15.5.4(A)(1), (2) or (3) of this Part shall be assessed a fee which coincides with the appropriate Category, as determined by the Agency.

B. Notwithstanding the provisions of § 15.5.4(A) of this Part, a reciprocity application based on a radioactive materials license which authorizes activities comparable to § 15.5.7 of this Part - Category 3I, but which only requests authorization to perform “electronic checks” or other activities which do not involve disassembly of shielding or actual manipulation of sealed sources, shall be accompanied by a non-refundable fee established in the Department fee schedule.

C. A reciprocity application shall not be considered prior to payment of the full amount specified. Reciprocity applications for which no remittance is received shall be returned to the applicant.

D. No additional reciprocity fees shall be required for the same category of activity during the remainder of that calendar year. All reciprocity authorizations shall expire on December 31 of the year in which the application was submitted. Any additional reciprocity activity beyond December 31 of that year shall require a renewal application.

15.5.5 Registration of General Licenses Pursuant to § 7.7.1 [GEN-4]

A. Each initial application for registration of a generally licensed device pursuant to § 7.7.1 of this Subchapter [GEN-4] shall be accompanied by a fee established in the Department fee schedule for each address or location of use and/or storage, as defined in § 7.7.1 of this Subchapter. There will be no pro-rating of registration fees.

B. No additional fees shall be required for:

1. Registration of additional generally licensed devices at the same address or location of use and/or storage.

2. Annual renewal of registrations pursuant to § 7.7.1 of this Subchapter.

C. All registrations issued pursuant to § 7.7.1 of this Subchapter [GEN-4] shall expire on December 31 of the year for which the registration information was submitted.

15.5.6 Non-Routine Inspection Fees

A non-routine inspection is only conducted in response to a significant regulatory event including, but not limited to, a reportable incident or overexposure, loss of radioactive material or unresolved non-compliance with license conditions or regulatory requirements. The Agency shall issue a non-routine inspection fee invoice to each licensee whenever the Agency conducts an inspection of the licensee's activities at an interval more frequent than currently established for that category of licensee. The fee shall be based on fifty percent (50%) of the applicable annual fee established in the Department fee schedule. Fees shall be payable within thirty (30) days after receipt of a fee invoice.

15.5.7 Radioactive Materials License Categories

A. Category 1 – Special Nuclear Material

1. Category 1A: Licenses for possession and use of special nuclear material of less than a critical mass, as defined in 10 C.F.R. § 70.4, in sealed sources contained in devices used in industrial measuring systems including X-ray fluorescence analyzers. Licenses that cover both radioactive and special nuclear material in sealed sources for use in gauging devices will only be subject to the fee for Category 3l.

2. Category 1B – All other licenses for possession and use of special nuclear material in unsealed form and in quantities not sufficient to form a critical mass.

B. Category 2 – Source Material

1. Category 2A – Licenses for possession and use of source material in recovery operations such as milling, in-situ leaching, heap leaching, refining uranium mill concentrates to uranium hexafluoride, ore buying stations, ion exchange facilities, and in processing of ores containing source material for extraction of metals other than uranium or thorium, including licenses authorizing the possession of radioactive waste material (tailings) from source material recovery operations, as well as licenses authorizing the possession and maintenance of a facility in a standby mode.

2. Category 2B – Licenses for possession and use of source material for shielding. Licensees paying fees under Category 3B or 7B are not subject to fees under Category 2B for possession and shielding authorized on the same license.

3. Category 2C – All other source material licenses.

C. Category 3 – Radioactive Material Other Than Source Material and Special Nuclear Material

1. Category 3A

a. Licenses of broad scope for possession and use of radioactive material for processing or manufacturing of items containing radioactive material for commercial distribution.

b. Other (limited) licenses for possession and use of radioactive material for processing or manufacturing of items containing radioactive material for commercial distribution.

2. Category 3B

a. Licenses authorizing the processing or manufacturing and distribution or redistribution of radiopharmaceuticals, generators, reagent kits and/or sources and devices containing radioactive material.

b. Licenses and approvals authorizing the distribution or redistribution of radiopharmaceuticals, generators, reagent kits and/or sources and devices not involving processing of radioactive material.

3. Category 3C – This license category is not currently utilized in Rhode Island.

4. Category 3D – Licenses for possession and use of radioactive material for industrial radiography operations.

5. Category 3E – Licenses for possession and use of radioactive material in sealed sources for irradiation of materials in which the source is not removed from its shield (self-shielded units).

6. Category 3F

    a. Licenses for possession and use of less than ten thousand (10,000) curies of radioactive material in sealed sources for irradiation of materials where the source is exposed for irradiation purposes.

    b. Licenses for possession and use of ten thousand (10,000) curies or more of radioactive material in sealed sources for irradiation of materials where the source is exposed for irradiation purposes.

7. Category 3G

    a. Licenses to distribute items containing radioactive material that require sealed source and/or device review to persons generally licensed, except specific licenses authorizing redistribution of items that have been authorized for distribution to generally licensed persons.

    b. Licenses to distribute items containing radioactive material that do not require sealed source and/or device review to persons generally licensed, except specific licenses authorizing redistribution of items that have been authorized for distribution to generally licensed persons.

8. Category 3H – This license category is not currently utilized in Rhode Island.

9. Category 3I – Licenses that authorize service for other licensees, except:

    a. Licenses that authorize leak testing and/or calibration services only are subject to the fees specified in Category 3L; and

    b. Licenses that authorize waste disposal services are subject to fees specified in Categories 4A, 4B and 4C.

10. Category 3J – This license category is not currently utilized in Rhode Island.

11. Category 3K

    a. Licenses of broad scope for possession and use of radioactive material for research and development that do not authorize commercial distribution.

    b. Other (limited) licenses for possession and use of radioactive material for research and development that do not authorize commercial distribution.

    c. Any other use of unsealed radioactive material that does not authorize commercial distribution.

12. Category 3L – All other specific radioactive materials, except those in Categories 4A through 8A. Licenses that cover both radioactive and special nuclear material in sealed sources for use in gauging devices will only be subject to the fee for Category 3L.

D. Category 4 – Waste Disposal

1. Category 4A – Licenses specifically authorizing the receipt of waste radioactive material from other persons for the purpose of commercial disposal by land burial by the licensee; or licenses for treatment or disposal by incineration, packaging of residues resulting from incineration and transfer of packages to another person authorized to dispose of waste material.

2. Category 4B – Licenses specifically authorizing the receipt of waste radioactive material from other persons for the purpose of packaging or repackaging the material. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material.

3. Category 4C – Licenses specifically authorizing the receipt of prepackaged waste radioactive material from other persons. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material.

E. Category 5 – Well Logging

1. Category 5A – Licenses specifically authorizing use of radioactive material for well logging, well surveys and tracer studies other than field flooding tracer studies.

2. Category 5B – Licenses for possession and use of radioactive material for field flooding tracer studies.

F. Category 6 – Nuclear Laundries

1. Category 6A – Licenses for commercial collection and laundry of items contaminated with radioactive material.

G. Category 7 – Human Use of Radioactive Material

1. Category 7A – Licenses for human use of radioactive material in sealed sources contained in gamma stereotactic radiosurgery units, teletherapy devices, or similar beam therapy devices.

2. Category 7B – Licenses issued for human use of radioactive material, except radioactive material in sealed sources contained in gamma stereotactic radiosurgery units, teletherapy devices, or similar beam therapy devices.

3. Category 7C – This license category is not currently utilized in Rhode Island.

4. Category 7D – Licenses of broad scope issued to medical institutions or two (2) or more physicians authorizing research and development, including human use of radioactive material, except radioactive material in sealed sources contained in gamma stereotactic radiosurgery units, teletherapy devices, or similar beam therapy devices.

H. Category 8 – Civil Defense

1. Category 8A – Licenses for possession and use of radioactive material for civil defense activities.

I. Category 9 – Device, Product or Sealed Source Safety Evaluation

1. Category 9A – This license category is not currently utilized in Rhode Island.

2. Category 9B – This license category is not currently utilized in Rhode Island.

3. Category 9C – This license category is not currently utilized in Rhode Island.

4. Category 9D – This license category is not currently utilized in Rhode Island.

J. Category 10 – Other Licenses and Authorizations

1. Category 10A – Radioactive materials licenses and other approvals authorizing decommissioning, decontamination, reclamation or site restoration activities in accordance with this Subchapter.