

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 the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health [Part 10-05-2 of this Title].

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 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 3I.

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 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 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.
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 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.