RHODE ISLAND GOVERNMENT REGISTER

PUBLIC NOTICE OF PROPOSED RULEMAKING

DEPARTMENT OF HEALTH

Title of Rule: Registration of X-Ray Equipment Facilities and Radiation Physics Services (216-RICR-40-20-3)

Rule Identifier: 216-RICR-40-20-3

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 revise a reference to a newly named and numbered form and to correct several internal cross references.

Additional Information and Public Comments:

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

Paula Pullano

Department of Health

3 Capitol Hill

Room 410

Providence, RI 02908

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-40-20-3

TITLE 216 – DEPARTMENT OF HEALTH

CHAPTER 40 – PROFESSIONAL LICENSING AND FACILITY REGULATION

SUBCHAPTER 20 – RADIATION

PART 3 – Registration of X-Ray Equipment Facilities and Radiation Physics Services

3.1 Authority

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

B. This Part requires the registration of X-ray equipment facilities and the registration of persons providing installation and/or servicing of X-ray equipment to Agency registrants or radiation physics services to Agency registrants or licensees. For purposes of this Part, particle accelerator facilities, whether used primarily for X-ray production or other purposes, shall be considered X-ray equipment facilities.

C. In addition to the requirements of this Part, all registrants are subject to the applicable provisions of other Parts of this Subchapter.

D. Any notifications, reports or correspondence referenced in this Part shall be directed to the Agency using contact information specified in § 1.4 of this Subchapter.

3.2 Incorporation by Reference

A. This Part hereby adopts and incorporates the National Council on Radiation Protection and Measurements' (NCRP) Report 144 "Radiation Protection for Particle Accelerator Facilities" (2003) 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. This Part hereby adopts and incorporates the National Council on Radiation Protection and Measurements' (NCRP) Report 145, "Radiation Protection in Dentistry" (2003) 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.

C. This Part hereby adopts and incorporates the National Council on Radiation Protection and Measurements' (NCRP) Report 147, "Structural Shielding Design for Medical X-ray Imaging Facilities" (2004) 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.

D. This Part hereby adopts and incorporates the National Council on Radiation Protection and Measurements' (NCRP) Report 148, "Radiation Protection in Veterinary Medicine" (2004) 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.

3.3 Prohibitions and Exemptions

A. Prohibitions. All registrants shall prohibit any person from furnishing X-ray equipment servicing or radiation physics services as described in § 3.6 of this Part to their X-ray equipment facility until such person provides evidence that they are registered with the Agency as a provider of services in accordance with § 3.6 of this Part.

B. Exemptions

1. Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and certification requirements of this Part, providing dose equivalent rate averaged over an area of ten square centimeters (10 cm^2) does not exceed five tenths (0.5) mrem (five (5) uSv) per hour at five (5) cm from any accessible surface of such equipment. The production, testing, or factory servicing of such equipment shall not be exempt.

2. X-ray equipment while in transit or in storage incident to transit are exempt from the requirements of this Part. This exemption does not apply to the providers of X-ray equipment for mobile services.

3. Domestic television receivers and video display terminals are exempt from the requirements of this Part.

4. Inoperable X-ray equipment is exempt from the requirements of this Part. For the purposes of this Part, an inoperable X-ray equipment means X-ray equipment that cannot be energized when connected to a power supply without repair or modification.

5. Financial institutions that take possession of operable X-ray equipment as the result of foreclosure, bankruptcy, or other default of payment are subject to the requirements in this Part. X-ray equipment which is operable for the sole purpose of selling, leasing or transferring shall be registered in the Storage category.

3.4 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. "Facility" means the location, building, vehicle, or complex under one (1) administrative control, at which one (1) or more radiation machines are installed, located and/or used.

4. “Registration” means registration with the Agency pursuant to this Subchapter and the Act.

3.5 General Regulatory Requirements

3.5.1 Shielding Plan Review

A. Except as otherwise provided in § 3.5.1(C) of this Part, all new X-ray equipment (as defined by Part 4 of this Subchapter, Diagnostic X-Rays and Associated Imaging Systems in the Healing Arts) facilities and modifications of existing X-ray equipment facilities utilizing ionizing radiation machines shall require shielding plan review by the Agency.

B. Prior to construction, the floor plans, shielding specifications, and equipment arrangement shall be submitted to the Agency for review and approval. The required information for all ionizing radiation machines, except therapeutic radiation machines, is denoted in § 3.13 of this Part. The required information for therapeutic radiation machines is contained in § 5.13 of this Subchapter.

C. The Agency may require the applicant to utilize the services of a person registered to provide General Radiation Physics Services in developing the information required by § 3.13 of this Part.

D. Shielding plan review by the Agency is not required for the following type of X-ray equipment facilities:

1. Any type of X-ray equipment which provides sufficient self-shielding to reduce the radiation levels at all external surfaces of the equipment below those levels required by §§ 1.7.1, 1.7.7 and 1.8.1 of this Subchapter.

2. Any X-ray equipment facility performing only dental intraoral and/or panoramic procedures whose estimated workload has been evaluated in accordance with NCRP Report 145 [“Radiation Protection in Dentistry” (2003)], and it has been documented that existing structural configuration will provide sufficient shielding to reduce the radiation levels to those required by §§ 1.7.1, 1.7.7 and 1.8.1 of this Subchapter.

3.5.2 Submission of Application

A. Each person who owns or possesses and administratively controls an X-ray equipment facility, unless specifically exempted in § 3.3 of this Part, shall apply for registration of such facility with the Agency prior to the operation of an X-ray equipment facility. Application for registration shall be completed on forms furnished by the Agency and shall contain all the information required by the form and accompanying instructions, including a designated e-mail address for receipt of official Agency correspondence in electronic format. The issuance of a Certificate of Registration for an X-ray equipment facility shall not preclude the Agency from subsequently reassigning the registered X-ray equipment to a more appropriate registration category and/or requiring the facility to periodically reregister all X-ray equipment at the facility. The registration category for an X-ray equipment facility will be determined in accordance with the provisions of § 15.4.6 of this Subchapter.

B. Designation of Individual Responsible for Radiation Protection. An individual to be responsible for radiation protection shall be designated on each application form. The qualifications of that individual shall be submitted to the Agency with the application. The Radiation Safety Officer (RSO) shall meet the applicable requirements of § 3.15 of this Part and carry out the responsibilities in § 3.16 of this Part.

C. Designation of Facility Supervisor

1. An individual responsible for directing the operation of the X-ray equipment facility shall be designated on each application form.

2. The designation of a licensed practitioner of the healing arts shall be required on each healing arts application.

3. The designation of an individual licensed in accordance with R.I. Gen. Laws Chapter 5-25 to engage in veterinary medicine shall be required on each veterinary medicine application.

D. Additional Requirements for Medical Research on Humans. In addition to the requirements of §§ 3.5.2(A), (B) and (C) of this Part, the applicant shall submit, as a minimum, the following information:

1. A detailed description of the proposed medical research, including a copy of the form that will be used to obtain informed consent from the human subjects and an evaluation of the potential radiation exposure to individuals participating in the medical research; and

2. The following documentation:

a. Documentation that the research is conducted, funded, supported, or regulated by a Federal Agency which has implemented the Federal Policy for the Protection of Human Subjects; or

b. Documentation of prior review and approval of the research activities by an "Institutional Review Board" as required by 45 C.F.R. Part 46 and 21 C.F.R. Part 56.

E. Additional Requirements for Mobile Service Operations. In addition to the requirements of §§ 3.5.2(A), (B) and (C) of this Part, the applicant shall submit the following information:

1. The location where the X-ray equipment, records, etc. will be maintained for inspection. This shall be a street address, not a post office box number.

2. A sketch or description of the normal configuration of each radiation machine's use, including the operator's position and any ancillary personnel's location during exposures. If a mobile van is used with a fixed unit inside, furnish the floor plan indicating protective shielding and the operator's location; and

3. A current copy of the applicant's operating and safety procedures including radiological practices for protection of patients, operators, employees, and the general public.

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

3.5.3 Shielding Evaluation Required

A. Prior to routine use, but in no case later than thirty (30) days subsequent to installation of the radiation producing equipment and/or modification of the existing facility, the shielding shall be reviewed and evaluated by a person registered with the Agency to provide General Radiation Physics Services.

B. A written report of the shielding evaluation shall be provided to the facility within ten (10) days of the evaluation. The report shall specifically address any shielding and/or radiation protection deficiencies that were discovered during the evaluation and shall include recommendations for correcting these deficiencies. Any noted deficiencies shall be adequately addressed by the facility.

C. Facilities shall provide the Agency with a copy of the shielding evaluation report within ten (10) days of receipt of said report.

D. An Agency finding that an X-ray equipment facility meets appropriate radiation protection standards shall not preclude the requirement of additional modifications, should a subsequent analysis of operating conditions and/or a radiation survey indicate that an individual is likely to receive a dose in excess of the limits prescribed in §§ 1.7.1, 1.7.7 and 1.8.1 of this Subchapter.

E. Retention of Information Used to Develop Shielding Plan. After installation of radiation producing equipment, the registrant shall maintain for inspection by the Agency:

1. The maximum rated technique factors of each machine;

2. A scale drawing of the room in which a stationary radiation machine system is located with such drawing indicating the use of areas adjacent to the room and an estimation of the extent of occupancy by an individual in such areas. In addition, the drawing shall include:

   a. The results of a survey for radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions; or

   b. The type and thickness of materials, or lead equivalency, of each protective barrier.

3. All information required by § 3.5.3(E) of this Part shall be retained until disposal is authorized by the Agency. All required information shall be retained in an active file from at least the time of generation until the next Agency inspection. Information generated prior to the last Agency inspection may be microfilmed or otherwise archived as long as a complete copy of said information can be retrieved until such time as the Agency authorizes final disposal.

3.6 Application for Registration of X-Ray Equipment Servicing and Radiation Physics Services

A. Each person who is engaged in the business of installing or offering to install X-ray radiation equipment in this State, or is engaged in the business of furnishing or offering to furnish X-ray equipment servicing to an Agency registrant, or is engaged in the business of furnishing or offering to furnish radiation physics services to an Agency registrant or licensee shall apply for registration of such installation and/or servicing or radiation physics services with the Agency prior to furnishing or offering to furnish any such servicing or services.

B. Application for Registration shall be completed on forms furnished by the Agency and shall contain all information required by the Agency as indicated on the forms and accompanying instructions, including a designated e-mail address for receipt of official Agency correspondence in electronic format.

1. An application for registration to provide X-ray equipment servicing will be accepted from either a firm or an individual.

2. An application for registration to provide radiation physics services will only be accepted from an individual. If a firm employs more than one (1)

individual to provide radiation physics services, each individual shall be required to obtain a separate registration.

C. Education and Experience Requirements for Providers of Radiation Physics Services. In addition to the other requirements contained in this section, applicants for Radiation Physics Services must include documentation of the education and experience that qualify the applicant to discharge the Radiation Physics Services being requested. The minimum acceptable education and experience requirements are contained in § 3.14 of this Part. Applicants who do not explicitly meet the requirements contained in § 3.14 of this Part, but who believe they have a combination of training and/or practical experience equivalent to these requirements, may request special consideration of their situation and/or issuance of a limited Certificate of Registration by the Agency.

D. For the purpose of this Part, X-ray equipment servicing and/or radiation physics services may include but shall not be limited to:

1. Installation and/or servicing of X-ray equipment, and associated components;

2. Calibration of X-ray equipment used by Agency registrants or radiation survey instruments used by Agency registrants or licensees;

3. Radiation protection and/or radiation physics consultations or surveys, performed for Agency registrants or licensees;

4. Personnel dosimetry services.

E. Restrictions on Provision of Services

1. Persons offering the services described in § 3.6(D) of this Part shall not provide such services to any operational X-ray equipment facility or any facility utilizing radioactive materials in this State until such facility provides evidence that it has been registered or licensed with the Agency in accordance with § 3.5 of this Part or Parts 7 or 9 of this Subchapter. Persons providing the services described in § 3.6(D) of this Part to a preoperational X-ray facility or facility intending to utilize radioactive material shall inform the facility of the registration or licensing requirements of this Subchapter.

2. An individual registered with the Agency as a provider of services in accordance with § 3.6 of this Part shall only perform services that are specifically authorized for that individual on the Certificate of Registration issued by the Agency.

3.7 Certificate of Registration

A. No person who is required to be registered under this part shall operate an X-ray equipment facility or radiation physics service without a valid Certificate of Registration.

B. The Agency may incorporate in the Certificate of Registration at the time of issuance or thereafter by appropriate Rule, Regulation, or order, such additional requirements and conditions with respect to the registrant's receipt, possession, use, and transfer of radiation equipment as it deems appropriate or necessary.

C. A current Certificate of Registration or legible copy thereof shall be posted conspicuously at each registered facility.

D. Except as provided by § 3.7(F) of this Part, each Certificate of Registration shall expire at the end of the specified day in the month and year stated therein.

E. Application for renewal of registration shall be filed in accordance with §§ 3.5 or 3.6 of this Part.

F. In any case in which a registrant not less than thirty (30) days prior to the expiration of his existing Certificate of Registration has filed an application in proper form for renewal, and has remitted the renewal fee, such existing Certificate of Registration shall not expire until the application status has been finally determined by the Agency.

3.8 Report of Changes

The registrant shall notify the Agency in writing before making any change which would render the information contained in the Application for Registration and/or the Certificate of Registration no longer accurate. In the case of disposition of an X-ray system, such notification should specify the recipient of the system. In the case of modifications involving a structural change, or the addition or relocation of an X-ray system, the Agency may require the registrant to submit the information contained in § 3.13 of this Part.

3.9 Approval Not Implied

No person, in any advertisement, shall refer to the fact that he or his facility is registered with the Agency pursuant to the provisions of §§ 3.5 or 3.6 of this Part and no person shall state or imply that any activity under such registration has been approved by the Agency.

3.10 Assembler and/or Transfer Obligation

A. Any person who sells, leases, transfers, lends, disposes, assembles, or installs X-ray equipment in this State shall notify the Agency within fifteen (15) days of:

1. The name and address of persons who have received this equipment.

2. The manufacturer, model, and serial number of each X-ray system transferred; and

3. The date of transfer of each X-ray system.

4. In the case of diagnostic X-ray systems which contain certified components, a copy of ~~the assembler's report prepared in compliance with requirements of the Federal Diagnostic X-ray Standard (21 C.F.R. § 1020.30(d))~~ RCA Form 2579 shall be submitted to the Agency within fifteen (15) days following completion of the assembly. Such report shall suffice in lieu of any other report by the assembler.

B. No person shall make, sell, lease, transfer, lend, assemble, or install X-ray systems or the supplies used in connection with such system unless such supplies and equipment when properly placed in operation and used in this State shall meet the requirements of this Subchapter.

3.11 Waiver of Registration for Temporary Use

A. Whenever any X-ray system is to be brought into the State, for any temporary use, the person proposing to bring such system into the State shall give written notice to the Agency at least two (2) working days before such machine is to be used in the State. The notice shall include:

1. The type of X-ray system;

2. The nature, duration, and scope of use;

3. The exact location(s) where the X-ray system is to be used; and

4. The State(s) in which the X-ray system is registered.

5. Upon receipt of such notification, the Agency shall determine whether a waiver of registration will be granted.

B. In addition, the out-of-State person shall:

1. Comply with all applicable Regulations of the Agency;

2. Supply the Agency with such other information as the Agency may reasonably request; and

3. Not operate within the State on a temporary basis in excess of one hundred eighty (180) calendar days per year.

3.12 Registration Fees

In accordance with authority granted to the Agency in R.I. Gen. Laws § 23-1.3-5(i), registration fees are payable to the Treasurer, State of Rhode Island by persons applying for registration. A current schedule of fees is available in Part 10-05-2 of this Title, Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health. Upon approval of the application, the Agency will notify the applicant of the correct fee which is due. A Certificate of Registration will not be issued or renewed until the correct fee has been remitted. Fees which remain unpaid beyond the expiration date of the current Certificate of Registration may result in suspension of registration.

3.13 Information on Radiation Shielding Required for Plan Reviews

A. All X-Ray Equipment Facilities must submit the following information for plan reviews:

1. Basic facility information including:

   a. Name;

   b. RPS registration number and telephone number of the individual responsible for the shielding specifications;

   c. Name and telephone number of the facility supervisor; and

   d. The street address [including room number(s)] of the facility.

   e. The plan should also indicate whether this is a new structure or a modification to existing structure(s). If the facility is currently registered, the Agency registration number must be provided.

2. All wall, floor, and ceiling areas struck by the useful beam shall have primary barriers.

3. Secondary barriers, when required, shall be provided in all wall, floor, and ceiling areas.

4. Shielding in walls of diagnostic X-ray facilities shall extend to a minimum height of seven feet (7') above the floor.

B. X-Ray Equipment Facilities Up To 150 kV

1. In addition to the requirements listed in § 3.13(A) of this Part, the plans for all X-ray equipment facilities which produce only photons with a maximum energy less than or equal to one hundred fifty (150) kV shall contain, as a minimum, the following additional information:

a. Equipment specifications including the make and model of the X-ray equipment, the maximum technique factors and the energy waveform (single phase, three phase, etc.).

b. The maximum design workload for the facility in terms of milliamp-minutes or milliamp-seconds per week. The total anticipated number of patients per week or number of exposures per week, as well as the type of examination(s) or treatment(s) which will be performed with the equipment, shall also be provided.

c. A facility blueprint/drawing indicating:

(1) Scale (one quarter inch (0.25") = one foot (1') is typical);

(2) Direction of North;

(3) Normal location of the X-ray system's radiation port(s);

(4) The port's travel and traverse limits;

(5) General direction(s) of the useful beam;

(6) Locations of any windows and doors; and

(7) The location of the X-ray control panel.

(8) If the control panel is located inside the X-ray room, the location of the operator's station shall be noted in the plan and the operator's station at the control panel shall be in compliance with § 1.7.1 of this Subchapter.

d. In X-ray facilities designed for medical use, a window (of lead equivalent at least equal to that required for the adjacent barrier), mirror or other remote viewing system shall be provided and so placed that the operator can see the patient during the exposure without having to leave the protected area.

e. The structural composition and thickness or lead/concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

f. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

g. At least one (1) example calculation which shows the methodology used to determine the amount of shielding required for each

physical condition [i.e.: primary and secondary/leakage barriers, restricted and unrestricted areas, small angle scatter, entry door(s) and maze] and shielding material in the facility. If commercial software is used to generate shielding requirements, also identify the software used and the version/revision date.

C. X-Ray Equipment Facilities Over 150 kV

1. In addition to the requirements listed in §§ 3.13(A) and (B) ~~3.12(A)~~ of this Part, the plans for all X-ray equipment/accelerator facilities which produce photons with a maximum energy in excess of one hundred fifty (150) kV and/or electrons and/or protons or other subatomic particles shall also contain the following information:

a. Equipment specifications including: manufacturer and model number of the unit; rad (or rem) per minute at the isocenter; and the energy(s) and type(s) of radiation produced [ie: photon, electron, neutron]. The source to isocenter distance must be specified.

b. Maximum design workload for the facility including total weekly radiation output [expressed in rad (or rem)/week at one (1) meter], total beam-on time per day or week.

c. Facility blueprint/drawing (including both floor plan and elevation views) indicating:

(1) Position and orientation of the X-ray/accelerator unit, scale (one quarter inch (0.25") = one foot (1') is typical);

(2) Type(s) and thickness of shielding material(s);

(3) Direction of North; and

(4) The locations and size of all penetrations through each shielding barrier (ceiling, walls and floor), as well as details of the door(s) and maze.

d. The structural composition and thickness or lead/concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

e. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

f. Description of all assumptions that were used in shielding calculations including, but not limited to:

(1) Design energy [i.e.: room may be designed for six (6) MV unit although only a four (4) MV unit is currently proposed];

(2) Presence of integral beam-stop in unit;

(3) Workload, occupancy and use(s) of adjacent areas;

(4) Fraction of time that primary beam will intercept each permanent barrier (walls, floor and ceiling); and

(5) "Allowed" radiation exposure in both restricted and unrestricted areas.

g. At least one (1) example calculation which shows the methodology used to determine the amount of shielding required for each physical condition [i.e.: primary and secondary/leakage barriers, restricted and unrestricted areas, small angle scatter, entry door(s) and maze] and shielding material in the facility. If commercial software is used to generate shielding requirements, also identify the software used and the version/revision date.

D. Neutron Shielding

1. In addition to the requirements listed in §§ ~~3.12~~ 3.13(A) and (C) of this Part, X-ray equipment/accelerator facilities which are capable of operating above ten (10) MV shall submit shielding plans which contain, as a minimum, the following additional information:

a. The structural composition, thickness, minimum density and location of all neutron shielding material.

b. Description of all assumptions that were used in neutron shielding calculations including, but not limited to, neutron spectra as a function of energy, neutron fluence rate, absorbed dose and dose equivalent (due to neutrons) in both restricted and unrestricted areas.

c. At least one (1) example calculation which shows the methodology used to determine the amount of neutron shielding required for each physical condition [i.e.: restricted and unrestricted areas, entry door(s) and maze] and neutron shielding material utilized in the facility. If commercial software is used to generate shielding requirements, also identify the software used and the version/revision date.

d. The method(s) and instrumentation which will be used to verify the adequacy of all neutron shielding installed in the facility.

3.14 Education and Experience Requirements for Radiation Physics Services

A. Radiotherapy Physics Services. Calibration and surveys of: therapeutic X-ray equipment; medical accelerators; teletherapy units, remote afterloader brachytherapy units and/or stereotactic radiosurgery units utilizing sealed radioactive sources.

1. Documentation of training sufficient to qualify as:

a. An Authorized Medical Physicist pursuant to § 9.5.11 of this Subchapter in the modality(s) for which registration is being requested; or

b. A Qualified Medical Physicist pursuant to § 5.3.4 of this Subchapter.

B. Diagnostic X-ray Physics Services. Calibration and surveys of diagnostic X-ray equipment.

1. Certification by the American Board of Radiology in:

a. Radiological physics;

b. Roentgen-ray and gamma-ray physics; or

c. X-ray and radium physics; or

d. Diagnostic radiological physics; or

e. Diagnostic medical physics; or

2. Certification by the American Board of Medical Physics in Diagnostic Imaging Physics; or

3. Hold a master's or doctor's degree in radiological physics and submit documentation of appropriate experience in the area(s) for which registration is being requested. This experience must have been obtained under the supervision of an individual qualified to provide Diagnostic X-ray Physics Services; or

4. Hold a master's or doctor's degree in health physics or other related radiation discipline and submit documentation of at least one (1) year of appropriate full time experience in the area(s) for which registration is being requested. This experience must have been obtained under the supervision of an individual qualified to provide Diagnostic X-ray Physics Services; or

5. Hold a master's or doctor's degree in a physical science and submit documentation of at least two (2) years of appropriate full time training and experience in the area(s) for which registration is being requested. This experience must have been obtained under the supervision of an individual qualified to provide Diagnostic X-ray Physics Services; or

6. Hold a bachelor's degree in health physics or other related radiation discipline and submit documentation of at least two (2) years of appropriate full time experience in the area(s) for which registration is being requested. This experience must have been obtained under the supervision of an individual qualified to provide Diagnostic X-ray Physics Services; or

7. Hold a bachelor's degree in a physical science and submit documentation of at least three (3) years of appropriate full time training and experience in the area(s) for which registration is being requested. This experience must have been obtained under the supervision of an individual qualified to provide Diagnostic X-ray Physics Services.

C. General Radiation Physics Services. All radiation physics services (except calibration of health physics instrumentation) for Agency registrants and/or radioactive materials licensees not covered in §§ ~~3.13~~ 3.14(A) and (B) of this Part including:

1. Comprehensive certification by the American Board of Health Physics; or

2. Certification by the American Board of Radiology in

   a. Radiological Physics or

   b. Roentgen-ray and gamma-ray physics; or

   c. X-ray and radium physics; or

   d. Diagnostic radiological physics; or

   e. Medical nuclear physics or nuclear medical physics; or

3. Certification by the American Board of Medical Physics in Nuclear Medicine Physics or Medical Health Physics; or

4. Hold a master's or doctor's degree in radiological physics or health physics or other related radiation discipline and submit documentation of appropriate experience in the area(s) for which registration is being requested. This experience must have been obtained under the supervision of an individual qualified to provide General Radiation Physics Services; or

5. Hold a master's or doctor's degree in a physical science and submit documentation of at least one (1) year of appropriate full time training and experience in the area(s) for which registration is being requested. This experience must have been obtained under the supervision of an individual qualified to provide General Radiation Physics Services; or

6. Hold a bachelor's degree in health physics or other related radiation discipline and submit documentation of at least one (1) year of appropriate full time experience in the area(s) for which registration is being requested. This experience must have been obtained under the supervision of an individual qualified to provide General Radiation Physics Services; or

D. Instrument Calibration Services. Calibration of health physics instrumentation for Agency registrants and/or radioactive materials licensees.

1. Compliance with the criteria required to perform any of the services contained in §§ ~~3.13~~ 3.14(A), (B) or (C) of this Part; or

2. Hold at least a bachelor's degree in physics (or a closely related field such as electrical engineering) and submit documentation of at least six (6) months of appropriate full time training and experience in the calibration of health physics instrumentation.

3.15 Radiation Safety Officer (RSO) Requirements

3.15.1 General Requirements

A. An RSO shall meet the following general requirements, as well as any applicable facility-specific requirements of § 3.15.2 of this Part.

1. Knowledge of potential radiation hazards and emergency precautions;

2. Completed educational courses related to ionizing radiation safety or a radiation safety officer course;

3. Experience in the use and familiarity of the type of equipment used.

3.15.2 Facility Specific Requirements

A. Specific RSO requirements by facility are as follows.

1. Healing arts facilities subject to Part 4 of this Subchapter shall have:

a. A licensed practitioner RSO with documentation of a current unrestricted Rhode Island license; or

b. A non-practitioner RSO who meets the following requirements:

(1) An individual who has a current unrestricted license, issued in accordance with R.I. Gen. Laws Chapter 5-68.1, as a radiologic technologist, and has at least two (2) years of supervised use for the type(s) of radiation machines covered by the registration; or

(2) An individual who has a current unrestricted license, issued in accordance with R.I. Gen. Laws Chapter 5-34, as a nurse practitioner, and has at least two (2) years of supervised use for the type(s) of radiation machines covered by the registration; or

(3) An individual who has a current unrestricted license, issued in accordance with R.I. Gen. Laws Chapter 5-54, as a physician assistant, and has at least two (2) years of supervised use for the type(s) of radiation machines covered by the registration; or

(4) An individual who has a current unrestricted license, issued in accordance with R.I. Gen. Laws Chapter 5-31.1, as a dental hygienist, and has at least two (2) years of performing radiologic procedures under a dentist's instruction and direction; or

(5) An individual who has a bachelor's (or higher) degree in a natural or physical science, health physics, radiological science, nuclear medicine, or nuclear engineering.

2. Healing Arts facilities subject to Part 5 of this Subchapter shall have an individual who meets the requirements for either an Authorized User physician or qualified medical physicist, as specified in Part 5 of this Subchapter.

3. Academic institutions and/or research and development facilities shall have an RSO who is a faculty or staff member with appropriate training in radiation protection, radiation engineering, or related disciplines. (If properly qualified, this individual may also serve as the RSO over the healing arts section of the facility.)

4. Industrial radiography facilities shall have an RSO who meets the requirements specified in § 10.6.2 of this Subchapter.

5. Other industrial facilities shall have an RSO whose training and experience is sufficient to identify and control the anticipated radiation hazards.

3.16 Duties and Responsibilities of The Radiation Safety Officer (RSO)

A. Specific duties and responsibilities of the Radiation Safety Officer (RSO) include, but are not limited to, the following:

1. Establishment and oversight of operating and safety procedures that maintain radiation exposures as low as reasonably achievable (ALARA), and periodic review to ensure that the procedures are current and conform with this Subchapter;

2. Ensure that individual monitoring devices are properly used by occupationally-exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by Part 1 of this Subchapter;

3. Investigate and report to the Agency each known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by this Subchapter and each theft or loss of source(s) of radiation, determining the cause, and taking steps to prevent its recurrence;

4. Maintain a thorough knowledge of relevant management policies and administrative procedures of the registrant and keep management informed on a periodic basis of the performance of the registrant's radiation protection program, if applicable;

5. Authority to institute corrective actions including shut-down of operations when necessary in emergency situations or unsafe conditions;

6. Maintain records as required by this Subchapter; and

7. Ensure that personnel are adequately trained and complying with this Subchapter, the conditions of the Certificate of Registration, and the operating and safety procedures of the registrant.