RHODE ISLAND GOVERNMENT REGISTER

PUBLIC NOTICE OF PROPOSED RULEMAKING

DEPARTMENT OF HEALTH

Title of Rule: General Provisions and Standards for Protection Against Radiation (216-RICR-40-20-1)

Rule Identifier: 216-RICR-40-20-1

Rulemaking Action: Proposed Amendment

Important Dates:

Date of Public Notice: January 24, 2022

Hearing Date: February 7, 2022

End of Public Comment: February 23, 2022

Rulemaking Authority:

R.I. Gen. Laws § 23-1.3-5

Summary of Rulemaking Action:

This is a technical revision to update an incorporation by reference with the most recent version.

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-40-20-1

TITLE 216 – DEPARTMENT OF HEALTH

CHAPTER 40 – PROFESSIONAL LICENSING AND FACILITY REGULATION

SUBCHAPTER 20 – RADIATION

PART 1 – General Provisions and Standards for Protection Against Radiation

1.1 Authority

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

B. This Part establishes generally applicable provisions, including standards for protection against radiation hazards. Except as otherwise specifically provided, this Part applies to persons licensed or registered by the Agency to receive, possess, use, transfer, or dispose of any source of radiation; provided, however, that nothing in this Part shall apply to any person to the extent such person is subject to regulation by the U.S. Nuclear Regulatory Commission. The limits in this Part do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, to exposure from individuals administered radioactive material and released under § 9.5.16 of this Subchapter, or to voluntary participation in medical research programs.

C. The requirements of this Part are designed to control the receipt, possession, use, transfer, and disposal of sources of radiation by any licensee or registrant in such a manner that the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in this Part. However, nothing in this Part shall be construed as limiting actions that may be necessary to protect health and safety.

1.2 Incorporated Material

A. Except as provided in this Part, the requirements of 10 C.F.R. Part 20 (~~2018~~ 2021) are incorporated by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with this Part.

B. Notwithstanding the provisions of § 1.2(A) of this Part, §§ 20.1001, 20.1002, 20.1006, 20.1007, 20.1008, 20.1009, 20.1205, 20.1401, 20.1406(b), 20.1905(g), 20.2109, 20.2202, 20.2203(c), 20.2206(a)(1), (3), (4) and (5), 20.2205, 20.2206, 20.2301, 20.2302, 20.2401, 20.2402, Appendix D to Part 20 and Appendix F to 10 C.F.R. Part 20 are not incorporated by reference.

C. Effect of incorporation of 10 C.F.R. Part 20. To reconcile differences between this Part and the incorporated sections of 10 C.F.R. Part 20, the following words and phrases shall be substituted for the language in 10 C.F.R. Part 20 as follows:

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

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

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

4. Any notifications, reports or correspondence referenced in the incorporated sections of 10 C.F.R. Part 20 shall be directed to the Agency using contact information specified in § 1.4 of this Part.

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

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

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

8. Any requirement to utilize NRC Form 4 may also be satisfied by use of Agency Form RCA-2.

9. Any requirement to utilize NRC Form 5 may also be satisfied by use of Agency Form RCA-3.

10. 10 C.F.R. Part 20 notwithstanding, exposures involving the use of X-rays may be weighted, in a manner specified by the Agency, so that, with Agency approval, the effective dose equivalent may be substituted for the deep dose equivalent in determining compliance with occupational exposure limits for specified groups of individuals.

1.3 Definitions

A. In addition to the definitions contained in 10 C.F.R. § 20.1003, 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. “Annual” means an interval not to exceed twelve (12) months.

4. "NARM" means any naturally occurring or accelerator-produced radioactive material. It does not include byproduct, source, or special nuclear material.

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

6. "Registrant" means any person who is registered with the Agency and is legally obligated to register with the Agency pursuant to this Subchapter and the Act.

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

1.4 Communications

A. All communications and reports concerning this Subchapter, and applications filed thereunder, should be addressed to the Agency at its office located at:

Rhode Island Department of Health

Center for Health Facilities Regulation

Radiation Control Program

Three Capitol Hill – Room 305

Providence, RI 02908-5097

B. During normal business hours, the Agency may be contacted at (401) 222-2566. At other times, this number will allow you to leave a message on the answering machine. In case of an emergency when it is necessary to immediately contact the Agency, utilize the Rhode Island Department of Health's twenty-four (24) hour number (401) 276-8046 and indicate the nature of your emergency. FAX communications may be sent twenty-four (24) hours a day to (401) 222-3999. For non-emergency situations, any required report or other routine correspondence may also be submitted via e-mail to doh.radhealth@health.ri.gov.

1.5 General Provisions

1.5.1 Implementation

A. Any existing license or registration condition that is more restrictive than this Part remains in force until there is an amendment or renewal of the license or registration.

B. If a license or registration condition exempts a licensee or registrant from a provision of this Part in effect on or before January 1, 1994, it also exempts the licensee or registrant from the corresponding provision of this Part.

C. If a license or registration condition cites provisions of this Part in effect prior to January 1, 1994, which do not correspond to any provisions of this Part, the license or registration condition remains in force until there is an amendment or renewal of the license or registration that modifies or removes this condition.

1.5.2 Exemptions and Additional Requirements

A. The Agency may, upon application by a licensee or registrant or upon its own initiative, grant an exemption from the requirements of this Subchapter if it determines the exemption is authorized by law and would not result in undue hazard to life or property.

B. The Agency may, by Rule, Regulation, or order, impose requirements on a licensee or registrant, in addition to those established in this Subchapter, as it deems appropriate or necessary to protect health or to minimize danger to life or property.

1.5.3 Inspections

A. Each licensee and registrant shall afford the Agency at all reasonable times the opportunity to inspect sources of radiation and the premises and facilities wherein such sources of radiation are used or stored, and the cooperation and assistance of the registrant or licensee, or his staff, if needed.

B. Each licensee and registrant shall make available to the Agency for inspection, upon reasonable notice, records maintained pursuant to this Subchapter.

1.5.4 Tests

A. Each licensee and registrant shall perform upon instructions from the Agency, or shall permit the Agency to perform such reasonable tests as the Agency deems appropriate or necessary including, but not limited to, tests of:

1. Sources of radiation;

2. Facilities wherein sources of radiation are used or stored;

3. Radiation detection and monitoring instruments; and

4. Other equipment and devices used in connection with utilization or storage of licensed or registered sources of radiation.

1.5.5 Violations

An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any Regulation or order issued thereunder. Any person who willfully violates any provision of the Act or any Regulation or order issued thereunder may be guilty of a misdemeanor and upon conviction, may be punished by fine or imprisonment or both, as provided by law.

1.5.6 Units of Radiation Dose

For the purpose of this Part, the units of radiation dose are defined by 10 C.F.R. § 20.1004.

1.5.7 Units of Radioactivity

For the purpose of this Part, the units of radioactivity are defined by 10 C.F.R. § 20.1005.

1.5.8 Deliberate Misconduct

A. Any licensee, certificate of registration holder, applicant for a license or certificate of registration, employee of a licensee, certificate of registration holder or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any licensee or certificate of registration holder or applicant for a license or certificate of registration, who knowingly provides to any licensee, applicant, certificate holder, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's, certificate holder's or applicant's activities in this Part, may not:

1. Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, certificate of registration holder, or applicant to be in violation of any Rule, Regulation, or order; or any term, condition, or limitation of any license issued by the Agency; or

2. Deliberately submit to the Agency, a licensee, certificate of registration holder, an applicant, or a licensee's, certificate holder's or applicant's, contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the Agency.

B. A person who violates §§ 1.5.8(A)(1) or (2) of this Part may be subject to enforcement action in accordance with the procedures in § 2.11 of this Subchapter.

C. For the purposes of § 1.5.8(A)(1) of this Part, deliberate misconduct by a person means an intentional act or omission that the person knows:

1. Would cause a licensee, certificate of registration holder or applicant to be in violation of any Rule, Regulation, or order; or any term, condition, or limitation, of any license issued by the Agency; or

2. Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, certificate of registration holder, applicant, contractor, or subcontractor.

1.6 Radiation Protection Programs

For the purpose of this Part, the required radiation protection program is defined by 10 C.F.R. § 20.1101.

1.7 Occupational Dose Limits

1.7.1 Occupational Dose Limits for Adults

A. For the purpose of this Part, the occupational dose limits for adults are defined by 10 C.F.R. § 20.1201.

B. For sources of radiation other than radioactive material, when a protective apron is worn and monitoring is conducted as specified in § 1.10.3(B) of this Part, the effective dose equivalent for external radiation shall be determined as follows:

1. When only one individual monitoring device is used and it is located at the neck outside the protective apron, and the reported dose exceeds twenty-five percent (25%) of the limit specified in § 1.7.1(A) of this Part, the reported deep dose equivalent value multiplied by three tenths (0.3) shall be the effective dose equivalent for external radiation; or

2. When individual monitoring devices are worn, both under the protective apron at the waist and outside the protective apron at the neck, the effective dose equivalent for external radiation shall be assigned the value of the sum of the deep dose equivalent reported for the individual monitoring device located at the waist under the protective apron multiplied by one and one half (1.5) and the deep dose equivalent reported for the individual monitoring device located at the neck outside the protective apron multiplied by four one hundredths (0.04).

1.7.2 Compliance with Requirements for Summation of External and Internal Doses

For the purpose of this Part, compliance with requirements for summation of external and internal doses is defined by 10 C.F.R. § 20.1202.

1.7.3 Determination of External Dose from Airborne Radioactive Material

For the purpose of this Part, determination of external dose from airborne radioactive material is defined by 10 C.F.R. § 20.1203.

1.7.4 Determination of Internal Exposure

For the purpose of this Part, determination of internal exposure is defined by 10 C.F.R. § 20.1204.

1.7.5 Determination of Prior Occupational Dose

A. For the purpose of this Part, determination of prior occupational dose is defined by 10 C.F.R. § 20.2104.

B. The licensee or registrant shall retain the records of prior occupational dose and exposure history as specified in § 1.7.5(A) of this Part on Agency Form RCA-2 or equivalent until the Agency terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing Agency Form RCA-2 or equivalent for three (3) years after the record is made.

C. Upon termination of the license or registration, the licensee or registrant shall make arrangements, satisfactory to the Agency, for permanent storage of records contained on Agency Form RCA-2 or equivalent.

1.7.6 Planned Special Exposures

For the purpose of this Part, planned special exposures are defined by 10 C.F.R. § 20.1206.

1.7.7 Occupational Dose Limits for Minors

For the purpose of this Part, occupational dose limits for minors are defined by 10 C.F.R. § 20.1207.

1.7.8 Dose Equivalent to an Embryo/Fetus

For the purpose of this Part, dose equivalent to an embryo/fetus is defined by 10 C.F.R. § 20.1208.

1.8 Radiation Dose Limits for Individual Members of the Public

1.8.1 Dose Limits for Individual Members of the Public

A. For the purpose of this Part, dose limits for individual members of the public are defined by 10 C.F.R. § 20.1301.

B. Each registrant shall conduct operations so that the total effective dose equivalent to individual members of the public does not exceed the original

design criteria of five (5) mSv (one half (0.5) rem) in a year at locations within registered facilities where only radiation machines were installed prior to January 1, 1994 and which continue to meet the original design criteria (e.g. workload, type and use of radiation machine, room configuration, etc.) on or after January 1, 1994.

1.8.2 Compliance with Dose Limits for Individual Members of the Public

For the purpose of this Part, compliance with dose limits for individual members of the public is defined by 10 C.F.R. § 20.1302.

1.9 Radiological Criteria for License Termination

1.9.1 General Provisions and Scope

A. Applicability. The criteria in §§ 1.9.1 through 1.9.6 of this Part apply to the decommissioning of facilities licensed under Parts 7, 9, 10 and 11 of this Subchapter, as well as other facilities subject to the Agency's jurisdiction.

B. After a site has been decommissioned and the license terminated in accordance with the criteria in §§ 1.9.1 through 1.9.6 of this Part, the Agency will require additional cleanup only if, based on new information, it determines that the criteria in §§ 1.9.1 through 1.9.6 of this Part were not met and residual radioactivity remaining at the site could result in significant threat to public health and safety.

C. When calculating TEDE to the average member of the critical group the licensee shall determine the peak annual TEDE dose expected within the first one thousand (1,000) years after decommissioning.

1.9.2 Radiological Criteria for Unrestricted Use

For the purpose of this Part, compliance with radiological criteria for unrestricted use is defined by 10 C.F.R. § 20.1402.

1.9.3 Criteria for License Termination Under Restricted Conditions

For the purpose of this Part, criteria for license termination under restricted conditions is defined by 10 C.F.R. § 20.1403.

1.9.4 Alternate Criteria for License Termination

For the purpose of this Part, alternate criteria for license termination is defined by 10 C.F.R. § 20.1404.

1.9.5 Public Notification and Public Participation

For the purpose of this Part, requirements for public notification and public participation are defined by 10 C.F.R. § 20.1405.

1.9.6 Minimization of Contamination

For the purpose of this Part, requirements for minimization of contamination are defined by 10 C.F.R. § 20.1406, excluding 10 C.F.R. § 20.1406(b).

1.10 Surveys and Monitoring

1.10.1 Testing for Leakage or Contamination of Sealed Sources

A. The licensee in possession of any sealed source shall assure that:

1. Each sealed source, except as specified in § 1.10.1(B) of this Part, is tested for leakage or contamination and the test results are received before the sealed source is put into use unless the licensee has a certificate from the transferor indicating that the sealed source was tested within six (6) months before transfer to the licensee.

2. Each sealed source that is not designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed six (6) months or at alternative intervals approved by the Agency, after evaluation of information specified by § 7.6.17 of this Subchapter, another Agreement State or the U.S. Nuclear Regulatory Commission.

3. Each sealed source that is designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed three (3) months or at alternative intervals approved by the Agency, after evaluation of information specified by § 7.6.17 of this Subchapter, another Agreement State or the U.S. Nuclear Regulatory Commission.

4. For each sealed source that is required to be tested for leakage or contamination, at any other time there is reason to suspect that the sealed source might have been damaged or might be leaking, the licensee shall assure that the sealed source is tested for leakage or contamination before further use.

5. Tests for leakage for all sealed sources, except brachytherapy sources manufactured to contain radium, shall be capable of detecting the presence of one hundred eighty-five (185) Bq (five one thousandths (0.005) µCi) of radioactive material on a test sample. Test samples shall be taken from the sealed source or from the surfaces of the container in which the sealed source is stored or mounted on which one might expect contamination to accumulate. For a sealed source contained in a device, test samples are obtained when the source is in the "off" position.

6. The test for leakage for brachytherapy sources manufactured to contain radium shall be capable of detecting an absolute leakage rate of thirty-seven (37) Bq (one one thousandth (0.001) µCi) of radon-222 in a twenty-four (24) hour period when the collection efficiency for radon-222 and its daughters has been determined with respect to collection method, volume and time.

7. Tests for contamination from radium daughters shall be taken on the interior surface of brachytherapy source storage containers and shall be capable of detecting the presence of one hundred eighty-five (185) Bq (five one thousandths (0.005) µCi) of a radium daughter which has a half-life greater than four (4) days.

B. A licensee need not perform test for leakage or contamination on the following sealed sources:

1. Sealed sources containing only radioactive material with a half-life of less than thirty (30) days;

2. Sealed sources containing only radioactive material as a gas;

3. Sealed sources containing three and seven tenths (3.7) MBq (one hundred (100) µCi) or less of beta or photon-emitting material or three hundred seventy (370) kBq (ten (10) µCi) or less of alpha-emitting material;

4. Sealed sources containing only hydrogen-3;

5. Seeds of iridium-192 encased in nylon ribbon; and

6. Sealed sources, except teletherapy and brachytherapy sources, which are stored, not being used and identified as in storage. The licensee shall, however, test each such sealed source for leakage or contamination and receive the test results before any use or transfer unless it has been tested for leakage or contamination within six (6) months before the date of use or transfer. No sealed source shall be stored for a period of more than ten (10) years without being tested for leakage and/or contamination.

C. Tests for leakage or contamination from sealed sources shall be performed by persons specifically authorized by the Agency, another Agreement State or the U.S. Nuclear Regulatory Commission to perform such services.

D. Records of tests for leakage or contamination of sealed sources required by § 1.10.1 of this Part shall be kept in units of becquerel or microcurie and maintained for inspection by the Agency for five (5) years after the records are made.

E. The following shall be considered evidence that a sealed source is leaking:

1. The presence of one hundred eighty-five (185) Bq (five one thousandths (0.005) µCi) or more of removable contamination on any test sample; or

2. Leakage of thirty-seven (37) Bq (one one thousandth (0.001) µCi) of radon-222 per twenty-four (24) hours for brachytherapy sources manufactured to contain radium.

F. The licensee shall immediately withdraw a leaking sealed source from use and shall take action to prevent the spread of contamination. The leaking sealed source shall be repaired or disposed of in accordance with this Part.

G. The licensee shall file a report within five (5) working days with the Agency if the test for leakage or contamination indicates a sealed source is leaking or contaminated. The report shall include the equipment involved, the test results and the corrective action taken.

1.10.2 General Survey and Monitoring Requirements

A. For the purpose of this Part, general survey and monitoring requirements are defined by 10 C.F.R. § 20.1501.

B. Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

1.10.3 Conditions Requiring Individual Monitoring of External and Internal Occupational Dose

A. For the purpose of this Part, conditions requiring individual monitoring of external and internal occupational dose are defined by 10 C.F.R. § 20.1502.

B. Individuals wearing a protective apron, when personnel monitoring is otherwise required by this Subchapter, shall position their individual monitoring devices as follows:

1. An individual monitoring device used for the dose to an embryo/fetus of a declared pregnant woman, pursuant to § 1.7.8 of this Part, shall be located under the protective apron at the waist.

a. It is recognized that, in the specific work environment of medical fluoroscopic equipment, the dose to the embryo/fetus is overestimated by the individual monitoring device because of the overlying tissue of the pregnant individual. A medical physicist who is registered with the Agency pursuant to § 3.6 of this Subchapter as a Provider of Diagnostic X-Ray Physics Services should be consulted to determine the dose to the embryo/fetus for the rare occasion in which this individual monitoring device has a monthly reported dose equivalent value in excess of five tenths (0.5) mSv (fifty (50) mrem). Therefore, for purposes of this Part, the value to

be used for determining the dose to an embryo/fetus pursuant to § 1.7.8 of this Part for occupational exposure to radiation from medical fluoroscopic equipment may be the value reported by the individual monitoring device worn at the waist underneath the protective apron which has been corrected for the particular individual and her work environment by the above referenced medical physicist.

2. An individual monitoring device used for eye dose equivalent shall be located at the neck, or an unshielded location closer to the eye, outside the protective apron.

3. When only one individual monitoring device is used to determine the effective dose equivalent for external radiation pursuant to § 1.7.1(B) of this Part, it shall be located at the neck outside the protective apron. When a second individual monitoring device is used, for the same purpose, it shall be located under the protective apron at the waist. The second individual monitoring device is required for a declared pregnant woman.

C. An individual monitoring device used for monitoring the dose to the extremities, to demonstrate compliance with § 1.7.1(A) of this Part, shall be worn on the extremity likely to receive the highest exposure. Each individual monitoring device shall be oriented to measure the highest dose to the extremity being monitored.

1.11 Control of Exposure from External Sources in Restricted Areas

1.11.1 Control of Access to High Radiation Areas

A. For the purpose of this Part, control of access to high radiation areas is defined by 10 C.F.R. § 20.1601.

B. The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a high radiation area as described in § 1.11.1(A) of this Part if the registrant has met all the specific requirements for access and control specified in other applicable Parts of this Subchapter.

1.11.2 Control of Access to Very High Radiation Areas

A. For the purpose of this Part, control of access to very high radiation areas is defined by 10 C.F.R. § 20.1602.

B. The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a very high radiation area as described in § 1.11.2(A) of this Part if the registrant has met all the specific requirements for access and control specified in other applicable Parts of this Subchapter.

1.12 Respiratory Protection and Controls to Restrict Internal Exposure in Restricted Areas

1.12.1 Use of Process or Other Engineering Controls

For the purpose of this Part, use of process or other engineering controls is defined by 10 C.F.R. § 20.1701.

1.12.2 Use of Other Controls

For the purpose of this Part, use of other controls is defined by 10 C.F.R. § 20.1702.

1.12.3 Use of Individual Respiratory Protection Equipment

A. For the purpose of this Part, use of individual respiratory protection equipment is defined by 10 C.F.R. § 20.1703.

B. For the purpose of this Part, further restrictions on the use of respiratory protection equipment are defined by 10 C.F.R. § 20.1704.

C. For the purpose of this Part, authorization for use of higher assigned protection factors is required by 10 C.F.R. § 20.1705.

1.13 Storage and Control of Licensed Material

1.13.1 Security of Stored Material

For the purpose of this Part, security of stored material is defined by 10 C.F.R. § 20.1801.

1.13.2 Control of Material Not in Storage

A. For the purpose of this Part, control of material not in storage is defined by 10 C.F.R. § 20.1802.

B. The registrant shall maintain control of radiation machines that are in an unrestricted area and that are not in storage.

1.14 Precautionary Procedures

1.14.1 Caution Signs

For the purpose of this Part, caution signs are defined by 10 C.F.R. § 20.1901.

1.14.2 Posting Requirements

For the purpose of this Part, posting requirements are defined by 10 C.F.R. § 20.1902.

1.14.3 Exceptions to Posting Requirements

A. For the purpose of this Part, exceptions to posting requirements are defined by 10 C.F.R. § 20.1903.

B. A room or area is not required to be posted with a caution sign because of the presence of radiation machines used solely for diagnosis in the healing arts.

1.14.4 Labeling Containers and Radiation Machines

A. For the purpose of this Part, labeling of containers is defined by 10 C.F.R. § 20.1904.

B. Each registrant shall ensure that each radiation machine is labeled in a conspicuous manner which cautions individuals that radiation is produced when it is energized.

1.14.5 Exemptions to Labeling Requirements

For the purpose of this Part, exemptions to labeling requirements are defined by 10 C.F.R. § 20.1905, excluding 10 C.F.R. § 20.1905(g).

1.14.6 Procedures for Receiving and Opening Packages

For the purpose of this Part, procedures for receiving and opening packages are defined by 10 C.F.R. § 20.1906.

1.15 Waste Disposal

1.15.1 General Requirements for Waste Disposal

For the purpose of this Part, general requirements for waste disposal are defined by 10 C.F.R. § 20.2001.

1.15.2 Method for Obtaining Approval of Proposed Disposal Procedures

For the purpose of this Part, the method for obtaining approval of proposed disposal procedures is defined by 10 C.F.R. § 20.2002.

1.15.3 Disposal by Release into Sanitary Sewerage

For the purpose of this Part, disposal by release into sanitary sewerage is defined by 10 C.F.R. § 20.2003.

1.15.4 Treatment or Disposal by Incineration

For the purpose of this Part, treatment or disposal by incineration is defined by 10 C.F.R. § 20.2004.

1.15.5 Disposal of Specific Wastes

For the purpose of this Part, disposal of specific wastes is defined by 10 C.F.R. § 20.2005.

1.15.6 Transfer for Disposal and Manifests

For the purpose of this Part, transfer for disposal and manifests are defined by 10 C.F.R. § 20.2006.

1.15.7 Compliance with Environmental and Health Protection Regulations

For the purpose of this Part, compliance with environmental and health protection regulations is defined by 10 C.F.R. § 20.2007.

1.15.8 Disposal of 11e(3) and 11e(4) Byproduct Material

For the purpose of this Part, disposal of 11e(3) and 11e(4) Byproduct Material is defined by 10 C.F.R. § 20.2008.

1.16 Records

1.16.1 General Provisions

A. For the purpose of this Part, general recordkeeping provisions are defined by 10 C.F.R. § 20.2101.

B. Each licensee and registrant shall maintain records showing the receipt, transfer, and disposal of all sources of radiation. All records required by this Subchapter shall be maintained indefinitely unless otherwise specified in this Subchapter.

1.16.2 Records of Radiation Protection Programs

For the purpose of this Part, requirements for maintenance of records of radiation protection programs are defined by 10 C.F.R. § 20.2102.

1.16.3 Records of Surveys

For the purpose of this Part, requirements for maintenance of records of surveys are defined by 10 C.F.R. § 20.2103.

1.16.4 Records of Tests for Leakage or Contamination of Sealed Sources

Records of tests for leakage or contamination of sealed sources required by § 1.10.1(A) of this Part shall be kept in units of becquerel or microcurie and

maintained for inspection by the Agency for five (5) years after the records are made.

1.16.5 Records of Planned Special Exposures

For the purpose of this Part, requirements for maintenance of records of planned special exposures are defined by 10 C.F.R. § 20.2105.

1.16.6 Records of Individual Monitoring Results

For the purpose of this Part, requirements for maintenance of records of individual monitoring results are defined by 10 C.F.R. § 20.2106.

1.16.7 Records of Dose to Individual Members of the Public

For the purpose of this Part, requirements for maintenance of records of dose to individual members of the public are defined by 10 C.F.R. § 20.2107.

1.16.8 Records of Waste Disposal

For the purpose of this Part, requirements for maintenance of records of waste disposal are defined by 10 C.F.R. § 20.2108.

1.16.9 Form of Records

For the purpose of this Part, requirements regarding the form of records are defined by 10 C.F.R. § 20.2110.

1.17 Reports

1.17.1 Reports of Theft or Loss of Licensed Material

For the purpose of this Part, requirements regarding reports of theft or loss of licensed material are defined by 10 C.F.R. § 20.2201.

1.17.2 Notification of Incidents

A. Immediate Notification. Notwithstanding other requirements for notification, each licensee or registrant shall immediately report each event involving a source of radiation possessed by the licensee or registrant that may have caused or threatens to cause any of the following conditions:

1. Immediately notify the Agency of each event involving a source of radiation possessed by the licensee or registrant that may have caused or threatens to cause any of the following conditions:

    a. An individual to receive:

(1) A total effective dose equivalent of twenty-five one hundredths (0.25) Sv (twenty-five (25) rem) or more; or

(2) A lens dose equivalent of seventy-five one hundredths (0.75) Sv (seventy-five (75) rem) or more; or

(3) A shallow dose equivalent to the skin or extremities or a total organ dose equivalent of two and one half (2.5) Gy (two hundred fifty (250) rad) or more; or

b. The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for twenty-four (24) hours, the individual could have received an intake five (5) times the occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

2. Immediately notify the Agency as soon as possible, but not later than four (4) hours after the discovery, of an event (e.g., fire, explosion, toxic gas release, etc.) that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits.

B. Twenty-Four Hour Notification. Each licensee or registrant shall, within twenty-four (24) hours of discovery of the event, report to the Agency each event involving loss of control of a licensed or registered source of radiation possessed by the licensee or registrant that may have caused, or threatens to cause, any of the following conditions:

1. An individual to receive, in a period of twenty-four (24) hours:

a. A total effective dose equivalent exceeding five one hundredths (0.05) Sv (five (5) rem); or

b. A lens dose equivalent exceeding fifteen one hundredths (0.15) Sv (fifteen (15) rem); or

c. A shallow dose equivalent to the skin or extremities or a total organ dose equivalent exceeding one half (0.5) Sv (fifty (50) rem); or

2. The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for twenty-four (24) hours, the individual could have received an intake in excess of one (1) occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

3. An unplanned contamination event that:

   a. Requires access to the contaminated area, by workers or the public, to be restricted for more than twenty-four (24) hours by imposing additional radiological controls or by prohibiting entry into the area; and

   b. Involves a quantity of material greater than five (5) times the lowest annual limit on intake specified for the material in § 1.19 of this Part; and

   c. Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than twenty-four (24) hours to decay prior to decontamination.

4. An event in which equipment is disabled or fails to function as designed when:

   a. The equipment is required by regulation or license/registration condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and/or radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident; and

   b. The equipment is required to be available and operable when it is disabled or fails to function; and

   c. No redundant equipment is available and operable to perform the required safety function.

5. An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.

6. An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:

   a. The quantity of material involved is greater than five (5) times the lowest annual limit on intake specified for the material in § 1.19 of this Part; and

   b. The damage affects the integrity of the licensed material or its container.

C. The licensee or registrant shall prepare each report filed with the Agency pursuant to § 1.17.2 of this Part so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.

D. Licensees or registrants shall make the reports required by §§ 1.17.2(A) and (B) of this Part to the Agency by telephone, telegram, mailgram, or facsimile to the Agency. To the extent that the information is available at the time of notification, the information provided in these reports shall include:

1. The name of the person making the report and their call-back telephone number;

2. A description of the event, including time and date;

3. The exact location of the event;

4. The levels of radiation and the isotopes, quantities, and chemical and physical form of the licensed material involved; and

5. Any personnel radiation exposure data available.

E. The provisions of § 1.17.2 of this Part do not apply to doses that result from planned special exposures, provided such doses are within the limits for planned special exposures and are reported pursuant to § 1.17.4 of this Part.

1.17.3 Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Constraints or Limits

For the purpose of this Part, requirements regarding reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits are defined by 10 C.F.R. § 20.2203, excluding 10 C.F.R. § 20.2203(c).

1.17.4 Reports of Planned Special Exposures

For the purpose of this Part, requirements regarding reports of planned special exposures are defined by 10 C.F.R. § 20.2204.

1.17.5 Notifications and Reports to Individuals

When a licensee or registrant is required pursuant to §§ 1.17.3 or 1.17.4 of this Part to report to the Agency any exposure of an individual to radiation or radioactive material, the licensee or registrant shall also notify the individual. Such notice shall be transmitted at a time not later than the transmittal to the Agency.

1.17.6 Reports of Transactions Involving Nationally Tracked Sources

For the purpose of this Part, requirements regarding reports of transactions involving nationally tracked sources are defined by 10 C.F.R. § 20.2207.

1.17.7 Vacating Premises

Each specific licensee shall, no less than thirty (30) days before vacating or relinquishing possession or control of premises which may have been contaminated with radioactive material as a result of his or her activities, notify the Agency in writing of intent to vacate. When deemed necessary by the Agency, the licensee shall decontaminate the premises in such a manner as the Agency may specify.

1.18 Assigned Protection Factors for Respirators

For the purpose of this Part, assigned protection factors for respirators are defined in Appendix A to 10 C.F.R. Part 20.

1.19 Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage

For the purpose of this Part, Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of radionuclides for occupational exposure; effluent concentrations; and concentrations for release to sewerage are defined in Appendix B to 10 C.F.R. Part 20.

1.20 Quantities of Licensed Material Requiring Labeling

For the purpose of this Part, quantities of licensed material requiring labeling are defined in Appendix C to 10 C.F.R. Part 20.

1.21 Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and Manifests

For the purpose of this Part, requirements for transfers of low-level radioactive waste intended for disposal at licensed land disposal facilities and manifests are defined in Appendix G to 10 C.F.R. Part 20.

1.22 Nationally Tracked Source Thresholds

For the purpose of this Part, requirements for nationally tracked source thresholds are defined in Appendix E to 10 C.F.R. Part 20.