

1 **216-RICR-40-20-7**

2 **TITLE 216 – DEPARTMENT OF HEALTH**

3 **CHAPTER 40 – PROFESSIONAL LICENSING & FACILITIES REGULATION**

4 **SUBCHAPTER 20 - RADIATION**

5 **PART 7 – LICENSING OF RADIOACTIVE MATERIAL**

6 **7.1 Authority**

7 A. This Part is promulgated pursuant to the authority conferred under R.I. Gen.  
8 Laws § [23-1.3-5\(f\)](#), as amended.

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

13 C. This Part establishes general licenses for the possession and use of radioactive  
14 material and a general license for ownership of radioactive material. The general  
15 licenses provided in this Part are subject to the provisions of §§ 7.4.3, 7.6.2,  
16 7.6.3, 7.6.9, 7.8.5 and 12.1 of this Part, and Parts 1 and 2 of this Subchapter  
17 unless indicated otherwise in the specific provision of the general license.

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

21 1. Persons generally licensed under this Part, 10 CFR Part 31 or equivalent  
22 regulations of another Agreement State.

23 2. Persons licensed under Part 9 of this Subchapter.

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

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

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

- 1 H. The requirements of this Part are in addition to, and not in substitution for, other  
2 applicable requirements of this Subchapter.
- 3 1. All licensees are subject to the requirements of Parts 1 and 2 of this  
4 Subchapter.
- 5 2. Licensees engaged in use of radionuclides in the healing arts are subject  
6 to the requirements of Part 9 of this Subchapter.
- 7 3. Licensees engaged in industrial radiographic operations are subject to the  
8 requirements of Part 10 of this Subchapter.
- 9 4. Licensees engaged in wireline and/or subsurface tracer studies are  
10 subject to the requirements of Part 11 of this Subchapter.
- 11 I. In any conflict between the requirements in this Part and a specific requirement  
12 in another Part of the regulations in this Subchapter, the specific requirement  
13 governs.

## 14 **7.2 Incorporated Material**

### 15 **7.2.1 General Provisions for Radioactive Material**

- 16 A. Except as provided in this Part, the requirements of 10 CFR Part 30 (2018)  
17 <https://www.nrc.gov/reading-rm/doc-collections/cfr/part030/> are incorporated by  
18 reference, not including any further editions or amendments thereof and only to  
19 the extent that the provisions therein are not inconsistent with this Part.
- 20 B. Notwithstanding the provisions of § 7.2.1(A) of this Part, §§ 30.1, 30.2, 30.3,  
21 30.5, 30.6, 30.8, 30.9, 30.12, 30.21(c), 30.31, 30.32(e), 30.34(d), (e)(1) and  
22 (3), 30.37, 30.39, 30.41(a)(6), 30.52, 30.53, 30.55, 30.61, 30.63 and 30.64 are  
23 not incorporated by reference.

### 24 **7.2.2 General Licenses for Radioactive Material**

- 25 A. Except as provided in this Part, the requirements of 10 CFR Part 31 (2018)  
26 <https://www.nrc.gov/reading-rm/doc-collections/cfr/part031/> are incorporated by  
27 reference, not including any further editions or amendments thereof and only to  
28 the extent that the provisions therein are not inconsistent with this Part.
- 29 B. Notwithstanding the provisions of § 7.2.2(A) of this Part, §§ 31.1, 31.2, 31.4,  
30 31.9, 31.13, 31.14, 31.15, 31.16, 31.17, 31.18, 31.19, 31.21, 31.22 and 31.23 are  
31 not incorporated by reference.

1 **7.2.3 Specific Licenses to Manufacture or Transfer Certain Items Containing**  
2 **Radioactive Material**

- 3 A. Except as provided in this Part, the requirements of 10 CFR Part 32 (2018)  
4 <https://www.nrc.gov/reading-rm/doc-collections/cfr/part032/> are incorporated by  
5 reference, not including any further editions or amendments thereof and only to  
6 the extent that the provisions therein are not inconsistent with this Part.
- 7 B. Notwithstanding the provisions of § 7.2.3(A) of this Part, §§ 32.1, 32.2, 32.8,  
8 32.11, 32.12, 32.13, 32.14, 32.15, 32.16, 32.18, 32.19, 32.20, 32.21, 32.22,  
9 32.23, 32.24, 32.25, 32.26, 32.27, 32.28, 32.29, 32.40, 32.201, 32.210, 32.211,  
10 32.301 and 32.303 are not incorporated by reference.

11 **7.2.4 Specific Domestic Licenses of Broad Scope for Radioactive Material**

- 12 A. Except as provided in this Part, the requirements of 10 CFR Part 33 (2018)  
13 <https://www.nrc.gov/reading-rm/doc-collections/cfr/part033/> are incorporated by  
14 reference, not including any further editions or amendments thereof and only to  
15 the extent that the provisions therein are not inconsistent with this Part.
- 16 B. Notwithstanding the provisions of § 7.2.4(A) of this Part, §§ 33.1, 33.8, 33.12,  
17 33.16, 33.21 and 33.23 are not incorporated by reference.

18 **7.2.5 Licensing of Source Material**

- 19 A. Except as provided in this Part, the requirements of 10 CFR Part 40 (2018)  
20 <https://www.nrc.gov/reading-rm/doc-collections/cfr/part040/> are incorporated by  
21 reference, not including any further editions or amendments thereof and only to  
22 the extent that the provisions therein are not inconsistent with this Part.
- 23 B. Notwithstanding the provisions of § 7.2.5(A) of this Part, §§ 40.1, 40.2, 40.5,  
24 40.6, 40.7, 40.8, 40.9, 40.10, 40.11, 40.12, 40.14, 40.20, 40.21, 40.23, 40.26,  
25 40.27, 40.28, 40.31, 40.32(e) and (g), 40.33, 40.36, 40.38, 40.41(d), (e)(1) and  
26 (3) and (g), 40.43, 40.45, 40.46, 40.51(b)(6), 40.52, 40.53, 40.56, 40.60, 40.62,  
27 40.63, 40.64, 40.65, 40.66, 40.67, 40.71, 40.81 and 40.82 are not incorporated  
28 by reference.

29 **7.2.6 Licensing of Special Nuclear Material**

- 30 A. Except as provided in this Part, the requirements of 10 CFR Part 70 (2018)  
31 <https://www.nrc.gov/reading-rm/doc-collections/cfr/part070/> are incorporated by  
32 reference, not including any further editions or amendments thereof and only to  
33 the extent that the provisions therein are not inconsistent with this Part.
- 34 B. Notwithstanding the provisions of § 7.2.6(A) of this Part, §§ 70.1, 70.2, 70.3,  
35 70.5, 70.6, 70.7, 70.8, 70.9, 70.10, 70.13, 70.14, 70.17, 70.18, 70.20, 70.20a,  
36 70.20b, 70.21, 70.22, 70.23, 70.23a, 70.24, 70.25, 70.31(c), (d) and (e),  
37 70.32(a)(1), (4), (5), (6) and (7) and (b)(1), (3) and (4) and (c), (d), (e), (f), (g), (h),

1 (i), (j) and (k), 70.33, 70.35, 70.36, 70.37, 70.40, 70.41, 70.42(b)(6), 70.44,  
2 70.51(c), (d) and (e), 70.52, 70.53, 70.54, 70.55, 70.56, 70.57, 70.58, 70.59,  
3 70.60, 70.61, 70.62, 70.64, 70.65, 70.66, 70.72, 70.73, 70.74, 70.76, 70.81 and  
4 70.82, 70.91, 70.92 and Appendix A to 10 CFR Part 70 are not incorporated by  
5 reference.

6 **7.2.7 Effect of incorporation of 10 CFR Parts 30, 31, 32, 33, 40 and 70**

7 A. To reconcile differences between this Part and the incorporated sections of 10  
8 CFR Parts 30, 31, 32, 33, 40 and 70 the following words and phrases shall be  
9 substituted for the language in 10 CFR Parts 30, 31, 32, 33, 40 and 70 as  
10 follows:

- 11 1. Any reference to NRC or Commission shall be deemed to be a reference  
12 to the Agency.
- 13 2. Any reference to NRC or agreement state shall be deemed to be a  
14 reference to the Agency, NRC or agreement state.
- 15 3. Any reference to byproduct material shall be deemed to be a reference to  
16 radioactive material.
- 17 4. Any reference to special nuclear material shall be deemed to be a  
18 reference to special nuclear material in quantities not sufficient to form a  
19 critical mass.
- 20 5. Any reference to "NRC Form 313, Application for Material License" shall  
21 be deemed to be a reference to Agency Form MAT-1, Application for  
22 Material License.
- 23 6. Any reference to "NRC Form 244, Registration Certificate - Use of  
24 Depleted Uranium Under General License" shall be deemed to be a  
25 reference to Agency Form GEN-1 "Registration Certificate - Use of  
26 Depleted Uranium Under General License".
- 27 7. Any reference to "NRC Form 483, Registration Certificate - In Vitro Testing  
28 with Byproduct Material Under General License" shall be deemed to be a  
29 reference to Agency Form GEN-3, Certificate - In-Vitro Testing with  
30 Radioactive Material Under General License.
- 31 8. Any notifications, reports or correspondence referenced in the  
32 incorporated sections of 10 CFR Parts 30, 31, 32, 33, 40 and 70 be  
33 directed to the Agency using Agency contact information specified in § 1.4  
34 of this Subchapter.

1 **7.3 Definitions**

2 A. In addition to the definitions contained in 10 CFR 30.4, 10 CFR 32.2, 10 CFR  
3 40.4 and 10 CFR 70.4, whenever used in this Part, the following terms shall be  
4 construed as follows:

5 “Act” means Title 23, Chapter 1.3 of the General Laws of the State of Rhode  
6 Island entitled "Radiation Control".

7 “Agency” means Rhode Island Radiation Control Agency (RCA), Center for  
8 Health Facilities Regulation - Radiation Control Program, Rhode Island  
9 Department of Health.

10 “NARM” means any naturally occurring or accelerator-produced radioactive  
11 material. It does not include byproduct, source, or special nuclear material.

12 “Radioactive material” means any material (solid, liquid, or gas) which emits  
13 radiation spontaneously.

14 “R.I. Gen. Laws” means the General Laws of Rhode Island, as amended.

15 “Special nuclear material in quantities not sufficient to form a critical mass”  
16 means uranium enriched in the isotope U-235 in quantities not exceeding 350  
17 grams of contained U-235; uranium-233 in quantities not exceeding 200 grams;  
18 plutonium in quantities not exceeding 200 grams; or any combination of them in  
19 accordance with the following formula: For each kind of special nuclear material,  
20 determine the ratio between the quantity of that special nuclear material and the  
21 quantity specified above for the same kind of special nuclear material. The sum  
22 of such ratios for all of the kinds of special nuclear material in combination shall  
23 not exceed "1" (i.e., unity). For example, the following quantities in combination  
24 would not exceed the limitation and are within the formula:

25 
$$\frac{175 \text{ (grams contained U-235)}}{350} + \frac{50 \text{ (grams U-233)}}{200} + \frac{50 \text{ (grams Pu)}}{200} = 1$$
  
26

27 **7.4 Exemptions**

28 **7.4.1 Persons Using Sources of Radiation Under Certain Department of Energy  
29 and Nuclear Regulatory Commission Contracts**

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

- 1           1.     The performance of work for the DOE at a United States Government-  
2                     owned or controlled site, including the transportation of sources of  
3                     radiation to or from such site and the performance of contract services  
4                     during temporary interruptions of such transportation;
- 5           2.     Research in, or development, manufacture, storage, testing or  
6                     transportation of, atomic weapons or components thereof; or
- 7           3.     The use or operation of nuclear reactors or other nuclear devices in a  
8                     United States Government-owned vehicle or vessel.

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

- 15           1.     The exemption of the prime contractor or subcontractor is authorized by  
16                     law; and
- 17           2.     Under the terms of the contract or subcontract, there is adequate  
18                     assurance that the work thereunder can be accomplished without undue  
19                     risk to the public health and safety.

20    **7.4.2 Carriers**

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

25    **7.4.3 Exempt Concentrations**

26           For the purpose of this Part, exempt concentrations are defined by 10 CFR §  
27           30.14 and 10 CFR § 30.70, Schedule A [§ 7.9.1 of this Part].

28    **7.4.4 Exempt Quantities**

29           For the purpose of this Part, exempt quantities are defined by 10 CFR § 30.18  
30           and 10 CFR § 30.71, Schedule B [§ 7.9.2 of this Part].

31    **7.4.5 Certain Items Containing Radioactive Material**

32           For the purpose of this Part, exemptions for certain items containing radioactive  
33           material are defined by 10 CFR § 30.15.

1 **7.4.6 Self-luminous Products Containing Tritium, Krypton-85, or Promethium-147**

2 For the purpose of this Part, exemptions for self-luminous products containing  
3 tritium, krypton-85, or promethium-147 are defined by 10 CFR § 30.19.

4 **7.4.7 Gas and Aerosol Detectors Containing Radioactive Material**

5 For the purpose of this Part, exemptions for gas and aerosol detectors containing  
6 radioactive material are defined by 10 CFR § 30.20.

7 **7.4.8 Radioactive Drug: Capsules Containing C-14 Urea for "in vivo" Diagnostic**  
8 **Use for Humans**

9 For the purpose of this Part, exemptions for capsules containing C-14 urea for "in  
10 vivo" diagnostic use for humans are defined by 10 CFR § 30.21.

11 **7.4.9 Certain Industrial Devices**

12 For the purpose of this Part, exemptions for certain industrial devices are defined  
13 by 10 CFR § 30.22.

14 **7.4.10 Unimportant Quantities of Source Material**

15 For the purpose of this Part, unimportant quantities of source material are  
16 defined by 10 CFR § 40.13.

17 **7.5 Licenses**

18 A. Licenses for radioactive materials are of two types: general and specific.

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

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

26 B. Types of specific licenses of broad scope:

27 1. A "Type A specific license of broad scope" is a specific license authorizing  
28 receipt, acquisition, ownership, possession, use and transfer of any  
29 chemical or physical form of the radioactive material specified in the  
30 license, but not exceeding quantities specified in the license, for any  
31 authorized purpose. The quantities specified are usually in the multicurie  
32 range.

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

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

27     **7.6    Specific Licenses**

28     **7.6.1   Application for Specific Licenses**

- 29     A.     Applications for specific licenses shall be filed in duplicate on a form prescribed  
30             by the Agency, and shall include a designated e-mail address for receipt of  
31             official Agency correspondence in electronic format.
- 32     B.     The Agency may at any time after the filing of the original application, and before  
33             the expiration of the license, require further statements in order to enable the  
34             Agency to determine whether the application should be granted or denied or  
35             whether a license should be modified or revoked.
- 36     C.     Each application shall be signed by the applicant or licensee or a person duly  
37             authorized to act on their behalf.
- 38     D.     An application for a license may include a request for a license authorizing one or  
39             more activities.



- 1 E. In the application, the applicant shall submit the required information to the  
2 Agency without reference to previously submitted documents unless permission  
3 has been obtained from the Agency, in advance, to incorporate by reference  
4 information contained in previous applications, statements, or reports filed with  
5 the Agency. All references shall be clear and specific and shall contain all of the  
6 information needed for a particular item on the application.
- 7 F. Applications and documents submitted to the Agency may be made available for  
8 public inspection except that the Agency may withhold any document or part  
9 thereof from public inspection if disclosure of its content is not required in the  
10 public interest and would adversely affect the interest of a person concerned.
- 11 G. Specific License to Use Radioactive Material in the Form of a Sealed Source or  
12 in a Device That Contains the Sealed Source
- 13 For the purpose of this Part, requirements for a specific license to use radioactive  
14 material in the form of a sealed source or in a device that contains the sealed  
15 source are defined by 10 CFR § 30.32(g).
- 16 H. Consideration of the Need for an Emergency Plan for Responding to a Release  
17 of Radioactive Materials
- 18 For the purpose of this Part, requirements for consideration of the need for an  
19 emergency plan for responding to a release of radioactive materials are defined  
20 by 10 CFR § 30.32(i).
- 21 I. Production of PET Radioactive Drugs for Noncommercial Transfer. An  
22 application from a medical facility or educational institution to produce Positron  
23 Emission Tomography (PET) radioactive drugs for noncommercial transfer to  
24 licensees in its consortium authorized for medical use under Part 9 of this  
25 Subchapter shall include:
- 26 1. A request for authorization for the production of PET radionuclides or  
27 evidence of an existing license issued under this Part, or equivalent  
28 regulations of the U.S. Nuclear Regulatory Commission or another  
29 Agreement State, for a PET radionuclide production facility within its  
30 consortium from which it receives PET radionuclides.
- 31 2. Evidence that the applicant is qualified to produce radioactive drugs for  
32 medical use by meeting one of the criteria in § 7.6.16(B) of this Part.
- 33 3. Identification of individual(s) authorized to prepare the PET radioactive  
34 drugs if the applicant is a pharmacy, and documentation that each  
35 individual meets the requirements of an Authorized Nuclear Pharmacist as  
36 specified in 10 CFR 32.72(b)(2) and § 7.6.16(C) of this Part.
- 37 4. Information identified in 10 CFR 32.72(a)(3) on the PET drugs to be  
38 noncommercially transferred to members of its consortium.

1 **7.6.2 General Requirements for Issuance of Specific Licenses**

2 A. For the purpose of this Part, general requirements for issuance of specific  
3 licenses are defined by 10 CFR § 30.33, 10 CFR § 40.32 and 10 CFR § 70.31.

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

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

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

16 **7.6.3 Terms and Conditions of Licenses**

17 For the purpose of this Part, terms and conditions of licenses are defined by 10  
18 CFR § 30.34, 10 CFR § 40.41 [excluding §§ 40.41(d), (e)(1) and (3) and (g)] and  
19 10 CFR § 70.32 [excluding §§ 70.32(a)(1), (4), (5), (6) and (7) and (b)(1), (3) and  
20 (4) and (c), (d), (e), (f), (g), (h), (i), (j) and (k)].

21 **7.6.4 Financial Assurance and Recordkeeping for Decommissioning**

22 For the purpose of this Part, requirements for financial assurance and  
23 recordkeeping for decommissioning are defined by 10 CFR § 30.35.

24 **7.6.5 Expiration and Termination of Licenses and Decommissioning of Sites and  
25 Separate Buildings or Outdoor Areas**

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

29 **7.6.6 Renewal of Specific Licenses**

30 A. Applications for renewal of specific licenses shall be filed in accordance with §  
31 7.5.2 of this Part.

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

1 **7.6.7 Amendment of Licenses**

2 For the purpose of this Part, requirements for amendment of licenses are defined  
3 by 10 CFR § 30.38, 10 CFR § 40.44 and 10 CFR § 70.34.

4 **7.6.8 Agency Action on Applications to Renew or Amend**

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

7 **7.6.9 Transfer of Radioactive Material**

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

11 **7.6.10 Requirements for License to Manufacture, Process, Produce, or Initially**  
12 **Transfer Certain Industrial Devices Containing Radioactive Material**

13 A. For the purpose of this Part, requirements for a license to manufacture, process,  
14 produce, or initially transfer certain industrial devices containing radioactive  
15 material are defined by 10 CFR § 32.30.

16 B. For the purpose of this Part, safety criteria for certain industrial devices  
17 containing radioactive material are defined by 10 CFR § 32.31.

18 C. For the purpose of this Part, requirements for quality control, labeling, and  
19 reports of transfer for certain industrial devices issued under § 7.6.10(A) of this  
20 Part are defined by 10 CFR § 32.32.

21 **7.6.11 Requirements for License to Manufacture or Initially Transfer Devices to**  
22 **Persons Generally Licensed Under § 7.7.1**

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

26 B. For the purpose of this Part, license conditions for person licensed under §  
27 7.6.11(A) of this Part are defined by 10 CFR § 32.51(a).

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

1 **7.6.12 Requirements for License to Manufacture, Assemble, Repair or Initially**  
2 **Transfer Luminous Safety Devices for Use in Aircraft**

- 3 A. For the purpose of this Part, requirements for a license to manufacture,  
4 assemble, repair or initially transfer luminous safety devices for use in aircraft are  
5 defined by 10 CFR § 32.53.
- 6 B. For the purpose of this Part, requirements for labeling of devices licensed under  
7 § 7.6.12(A) of this Part are defined by 10 CFR § 32.54.
- 8 C. For the purpose of this Part, requirements for quality assurance and prohibition of  
9 transfer of devices licensed under § 7.6.12(A) of this Part are defined by 10 CFR  
10 § 32.55.
- 11 D. For the purpose of this Part, requirements for material transfer reports for  
12 persons licensed under § 7.6.12(A) of this Part are defined by 10 CFR § 32.56.

13 **7.6.13 Requirements for License to Manufacture or Initially Transfer Calibration or**  
14 **Reference Sources Containing Americium-241, Plutonium or Radium-226**

- 15 A. For the purpose of this Part, requirements for a license to manufacture or initially  
16 transfer calibration or reference sources containing americium-241 or radium-226  
17 are defined by 10 CFR § 32.57.
- 18 1. For the purpose of this Part, requirements for labeling of devices licensed  
19 under § 7.6.13(A) of this Part are defined by 10 CFR § 32.58.
- 20 2. For the purpose of this Part, requirements for leak testing of each source  
21 licensed under § 7.6.13(A) of this Part are defined by 10 CFR § 32.59.
- 22 B. For the purpose of this Part, requirements for a license to manufacture or initially  
23 transfer calibration or reference sources containing plutonium are defined by 10  
24 CFR § 70.39.

25 **7.6.14 Requirements for License to Manufacture or Initially Transfer Ice Detection**  
26 **Devices Containing Strontium-90**

- 27 A. For the purpose of this Part, requirements for a license to manufacture or initially  
28 transfer ice detection devices containing strontium-90 are defined by 10 CFR §  
29 32.61.
- 30 B. For the purpose of this Part, requirements for quality assurance and prohibition of  
31 transfer of devices licensed under § 7.6.14(A) of this Part are defined by 10 CFR  
32 § 32.62.

1 **7.6.15 Requirements for License to Manufacture and Distribute Radioactive**  
2 **Material for Certain in-vitro Clinical or Laboratory Testing Under General**  
3 **License**

- 4 A. For the purpose of this Part, requirements for a license to manufacture and  
5 distribute radioactive material for certain in-vitro clinical or laboratory testing  
6 under general license are defined by 10 CFR § 32.61.

7 **7.6.16 Requirements for License to Manufacture, Prepare, or Transfer for**  
8 **Commercial Distribution of Radioactive Drugs Containing Radioactive**  
9 **Material for Medical Use Under Part 9**

- 10 A. For the purpose of this Part, requirements for a license to manufacture, prepare,  
11 or transfer for commercial distribution of radioactive drugs containing radioactive  
12 material for medical use under Part 9 of this Subchapter are defined by 10 CFR §  
13 32.72.

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

- 16 1. Registered with the U.S. Food and Drug Administration (FDA) as the  
17 owner or operator of a drug establishment that engages in the  
18 manufacture, preparation, propagation, compounding, or processing of a  
19 drug under 21 CFR 207.20(a);
- 20 2. Licensed as a drug manufacturer in accordance with Pharmacists,  
21 Pharmacies and Manufacturers, Wholesalers and Distributors [216-RICR-  
22 40-15-1];
- 23 3. Licensed as a pharmacy in accordance with Pharmacists, Pharmacies and  
24 Manufacturers, Wholesalers and Distributors [216-RICR-40-15-1]; or
- 25 4. Licensed as a positron emission tomography (PET) drug production facility  
26 pursuant to this Part.

- 27 C. In addition to the provisions of 10 CFR § 32.72(b)(4), an individual may function  
28 as an authorized nuclear pharmacist only if they are licensed as a pharmacist in  
29 accordance with Pharmacists, Pharmacies and Manufacturers, Wholesalers and  
30 Distributors [216-RICR-40-15-1].

31 **7.6.17 Requirements for License to Manufacture and Distribute Sources or**  
32 **Devices Containing Radioactive Material for Medical Use**

- 33 For the purpose of this Part, requirements for a license to manufacture and  
34 distribute sources or devices containing radioactive material for medical use are  
35 defined by 10 CFR § 32.74.

1 **7.6.18 Requirements for License to Manufacture and Distribute Industrial**  
2 **Products Containing Depleted Uranium for Mass-Volume Applications**

- 3 A. For the purpose of this Part, requirements for a license to manufacture and  
4 distribute industrial products containing depleted uranium for mass-volume  
5 applications are defined by 10 CFR § 40.34.
- 6 B. For the purpose of this Part, conditions of specific licenses issued pursuant to §  
7 7.6.18(A) of this Part are defined by 10 CFR § 40.35.

8 **7.6.19 Requirements for License to initially transfer source material for use under**  
9 **the 'small quantities of source material' general license**

- 10 A. For the purpose of this Part, requirements for a license to initially transfer source  
11 material for use under the “small quantities of source material” general license  
12 are defined by 10 CFR § 40.54.
- 13 B. For the purpose of this Part, requirements for quality control, labeling, safety  
14 instructions, and records and reports for licenses issued pursuant to § 7.6.19(A)  
15 of this Part are defined by 10 CFR § 40.56.

16 **7.6.20 Requirements for a Specific License of Broad Scope**

- 17 A. A person may file an application for specific license of broad scope in  
18 accordance with the provisions of § 7.6.1 of this Part.
- 19 B. For the purpose of this Part, requirements for the issuance of a Type A specific  
20 license of broad scope are defined by 10 CFR § 33.13.
- 21 C. For the purpose of this Part, requirements for the issuance of a Type B specific  
22 license of broad scope are defined by 10 CFR § 33.14.
- 23 D. For the purpose of this Part, requirements for the issuance of a Type C specific  
24 license of broad scope are defined by 10 CFR § 33.15.
- 25 E. An application filed pursuant to this Part for a specific license other than one of  
26 broad scope will be considered by the Agency as an application for a specific  
27 license of broad scope under this Part if the requirements of the applicable  
28 sections of this Part are satisfied.
- 29 F. For the purpose of this Part, conditions for specific licenses of broad scope are  
30 defined by 10 CFR § 33.17.

1 **7.7 General Licenses**

2 **7.7.1 General License for Certain Detecting, Measuring, Gauging, or Controlling**  
3 **Devices and Certain Devices for Producing Light or an Ionized Atmosphere**

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

7 **7.7.2 General License to Install Devices Generally Licensed in § 7.5.11**

8 For the purpose of this Part, requirements for a general license to install devices  
9 generally licensed in § 7.5.11 of this Part are defined by 10 CFR § 31.6.

10 **7.7.3 General License for Luminous Safety Devices for Use in Aircraft**

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

13 **7.7.4 General License for Calibration or Reference Sources**

14 A. For the purpose of this Part, requirements for a general license for americium-  
15 241 and radium-226 in the form of calibration or reference sources are defined by  
16 10 CFR § 31.8.

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

19 **7.7.5 General License to Own Radioactive Material**

20 A. A general license is hereby issued to own radioactive material without regard to  
21 quantity. Notwithstanding any other provisions of this Part, this general license  
22 does not authorize the manufacture, production, transfer, receipt, possession or  
23 use of radioactive material.

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

29 **7.7.6 General License for Strontium 90 in Ice Detection Devices**

30 For the purpose of this Part, requirements for a general license for strontium 90  
31 in ice detection devices are defined by 10 CFR § 31.10.

1 **7.7.7 General License for Use of Radioactive Material for Certain in vitro Clinical**  
2 **or Laboratory Testing**

3 For the purpose of this Part, requirements for a general license for use of  
4 radioactive material for certain in vitro clinical or laboratory testing are defined by  
5 10 CFR § 31.11.

6 **7.7.8 General License for Use of Radioactive Material for Certain in vitro Clinical**  
7 **or Laboratory Testing**

8 For the purpose of this Part, requirements for a general license for certain items  
9 and self-luminous products containing radium-226 are defined by 10 CFR §  
10 31.12.

11 **7.7.9 General License for Small Quantities of Source Material**

12 For the purpose of this Part, requirements for a general license for small  
13 quantities of source material are defined by 10 CFR § 40.23.

14 **7.7.10 General License for Use of Certain Industrial Products or Devices**

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

17 **7.8 Serialization of Nationally Tracked Sources, Sealed Source &**  
18 **Device Registry, Records and Reports**

19 **7.8.1 Records**

20 A. For the purpose of this Part, recordkeeping requirements are defined by 10 CFR  
21 § 30.51, 10 CFR § 40.61 and 10 CFR § 70.51 [excluding 10 CFR §§ 70.51(c), (d)  
22 and (e)].

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

33 **7.8.2 Right to Cause the Withholding or Recall of Radioactive Material**

34 For the purpose of this Part, the right to cause the withholding or recall of  
35 radioactive material defined by 10 CFR § 30.62.



1 **7.8.3 Serialization of Nationally Tracked Sources**

2 Each licensee who manufactures a nationally tracked source after 6 February  
3 2007 shall assign a unique serial number to each nationally tracked source.  
4 Serial numbers shall be composed only of alpha-numeric characters.

5 **7.8.4 Sealed Source and Device Registry**

6 A. Registration of Product Information. The Agency does not currently administer a  
7 sealed source and device registration program. Any manufacturer or initial  
8 distributor of a sealed source or device containing a sealed source who is subject  
9 to these Regulations shall submit a request for evaluation of radiation safety  
10 information about its product and for its registration to the Nuclear Regulatory  
11 Commission pursuant to 10 CFR 32.210.

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

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

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

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

34 **7.8.5 Modification, Revocation, and Termination of Licenses**

35 A. The terms and conditions of all licenses shall be subject to amendment, revision,  
36 or modification or the license may be suspended or revoked by reason of  
37 amendments to the Act, or by reason of rules, regulations, and orders issued by  
38 the Agency.

- 1 B. Any license may be revoked, suspended, or modified, in whole or in part, for any  
2 material false statement in the application or any statement of fact required under  
3 provisions of the Act, or because of conditions revealed by such application or  
4 statement of fact or any report, record, or inspection or other means which would  
5 warrant the Agency to refuse to grant a license on an original application, or for  
6 violation of, or failure to observe any of the terms and conditions of the Act, or of  
7 the license, or of any rule, regulation, or order of the Agency.
- 8 C. Except in cases of willfulness or those in which the public health, interest or  
9 safety requires otherwise, no license shall be modified, suspended, or revoked  
10 unless, prior to the institution of proceedings therefor, facts or conduct which may  
11 warrant such action shall have been called to the attention of the licensee in  
12 writing and the licensee shall have been accorded an opportunity to demonstrate  
13 or achieve compliance with all lawful requirements.
- 14 D. The Agency may terminate a specific license upon request submitted by the  
15 licensee to the Agency in writing.
- 16 E. Prior to license termination, each licensee authorized to possess radioactive  
17 material with a half-life greater than one hundred and twenty (120) days, in an  
18 unsealed form, shall forward the following records to the Agency:
- 19 1. Records of disposal of licensed material made under §§ 1.15.2, 1.15.3,  
20 1.15.4 and 1.15.5 of this Subchapter; and
- 21 2. Records required by § 1.16.3 of this Subchapter.
- 22 F. If licensed activities are transferred or assigned in accordance with § 7.6.3 of this  
23 Part, each licensee authorized to possess radioactive material, with a half-life  
24 greater than one hundred and twenty (120) days, in an unsealed form, shall  
25 forward the following records to the new licensee and the new licensee will be  
26 responsible for maintaining these records until the license is terminated:
- 27 1. Records of disposal of licensed material made under §§ 1.15.2, 1.15.3,  
28 1.15.4 and 1.15.5 of this Subchapter; and
- 29 2. Records required by § 1.16.3 of this Subchapter.
- 30 G. Prior to license termination, each licensee shall forward the records required by §  
31 7.6.4 of this Part to the Agency.

## 32 **7.9 Schedules**

### 33 **7.9.1 Exempt Concentrations**

- 34 A. For the purpose of this Part, the schedule of exempt concentrations is defined by  
35 10 CFR § 30.70, Schedule A.

- 1 B. In addition to the values referenced in § 7.9.1(A) of this Part, the following table  
 2 of exempt concentrations is also applicable to this Part:

Element (atomic number)	Isotope	Column I Gas concentration μCi/ml	Column II Liquid and solid concentration μCi/ml
Actinium (89)	Ac-228		9E-04
Cesium (55)	Cs-129		3E-03
Europium (63)	Eu-154		2E-04
Gallium (31)	Ga-67		2E-03
Germanium (32)	Ge-68		9E-03
Gold (79)	Au-195		1E-02
Indium (49)	In-111		1E-03
Iodine (53)	I-123		3E-04
	I-124		4E-06
	I-125		2E-06
Lead (82)	Pb-212		2E-04
Phosphorus (15)	P-33		3E-04
Potassium (19)	K-43		2E-04
Protactinium (91)	Pa-230		2E-03
Radium (88)	Ra-223		7E-06
	Ra-224		2E-05
	Ra-228		3E-07
Radon (86)	Rn-220	1E-07	
	Rn-222	3E-08	
Sodium (11)	Na-22		4E-04
Technetium (43)	Tc-97m		4E-03
Xenon (54)	Xe-127	4E-06	
Yttrium (39)	Y-88		8E-04

3 Note: The Table values are presented in the computer “E” notation. In this notation, a  
 4 value of 6E-02 represents a value of 6 x 10<sup>-2</sup> or 0.06, 6E+2 represents 6 x 10<sup>2</sup> or 600  
 5 and 6E+0 represents 6 x 10<sup>0</sup> or 6

6 **7.9.2 Exempt Quantities**

- 7 A. For the purpose of this Part, the schedule of exempt quantities is defined by 10  
 8 CFR § 30.71, Schedule B.

- 9 B. In addition to the values referenced in § 7.9.2(A) of this Part, the following table  
 10 of exempt quantities is also applicable to this Part:

Radioactive Material	Microcuries	Radioactive Material	Microcuries
Actinium-228 (Ac 228)	1	Protactinium-230 (Pa 230)	10
Beryllium-7 (Be 7)	10	Protactinium-231 (Pa 231)	0.1
Bismuth-207 (Bi 207)	10	Radium-223 (Ra 223)	1
Cesium-129 (Cs 129)	100	Radium-224 (Ra 224)	1
Cobalt-57 (Co 57)	100	Radium-226 (Ra 226)	0.1
Gallium-67 (Ga 67)	100	Radium-228 (Ra 228)	0.1
Germanium-68	10	Radon-220 (Rn 220)	1
Gold-195 (Au 195)	10	Radon-222 (Rn 222)	1
Gold-196 (Au 196)	1	Rhenium-183 (Re 183)	100
Indium-111 (In 111)	100	Rhenium-187 (Re 187)	100
Iodine-123 (I 123)	100	Rubidium-81 (Rb 81)	10

Radioactive Material	Microcuries	Radioactive Material	Microcuries
Iodine-124 (I 124)	1	Scandium-46 (Sc 46)	10
Iridium-190 (Ir 190)	100	Sodium-22 (Na 22)	10
Lead-203 (Pb 203)	100	Technetium-96m (Tc 96m)	100
Lead-210 (Pb 210)	0.1	Xenon-127 (Xe 127)	1,000
Lead-212 (Pb 212)	10	Yttrium-87 (Y 87)	10
Phosphorus-33 (P 33)	10	Yttrium-88 (Y 88)	10
Potassium-43 (K 43)	10		

1 **7.9.3 Quantities of Radioactive Materials Requiring Consideration of the Need for**  
 2 **an Emergency Plan for Responding to a Release**

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

6 **7.9.4 Schedule C: Quantities of Licensed Material Requiring Labeling**

7 For the purpose of this Part, quantities of licensed material requiring labeling are  
 8 defined by Appendix B to 10 CFR 30.

9 **7.9.5 Decommissioning Funding Criteria**

- 10 A. For the purpose of this Part, criteria relating to use of financial tests and parent  
 11 company guarantees for providing reasonable assurance of funds for  
 12 decommissioning are defined by Appendix A to 10 CFR Part 30.
- 13 B. For the purpose of this Part, criteria relating to use of financial tests and self  
 14 guarantees for providing reasonable assurance of funds for decommissioning are  
 15 defined by Appendix C to 10 CFR Part 30.
- 16 C. For the purpose of this Part, criteria relating to use of financial tests and self-  
 17 guarantee for providing reasonable assurance of funds for decommissioning by  
 18 commercial companies that have no outstanding rated bonds are defined by  
 19 Appendix D to 10 CFR Part 30.
- 20 D. For the purpose of this Part, criteria relating to use of financial tests and self-  
 21 guarantee for providing reasonable assurance of funds for decommissioning by  
 22 nonprofit colleges, universities, and hospitals are defined by Appendix E to 10  
 23 CFR Part 30.

24 **7.9.6 Limits for a Specific License of Broad Scope**

- 25 A. For the purpose of this Part, limits for a specific license of broad scope are  
 26 defined by 10 CFR § 33.100, Schedule C.
- 27 B. In addition to the values referenced in § 7.9.6(A) of this Part, the following table  
 28 of limits for a specific license of broad scope is also applicable to this Part:

Radioactive Material	Col. I curies	Col. II curies
Beryllium-7	10	0.1
Cobalt-57	10	0.1
Radium-226	0.01	0.0001
Scandium-46	1	0.01
Sodium-22	0.1	0.001

1 **7.10 Reciprocal Recognition of Licenses**

2 **7.10.1 Specific Radioactive Material Licenses**

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

- 12 1. The licensing document does not limit the activity authorized by such  
13 document to specified installations or locations;
- 14 2. The out-of-state licensee submits Agency Form MAT-9i, a copy of the  
15 pertinent licensing document, and the appropriate fee as prescribed in §  
16 15.5.4 of this Subchapter to the Agency at least three (3) days prior to  
17 engaging in such activity for the first time in a calendar year. If a submittal  
18 cannot be filed three (3) days before engaging in activities under  
19 reciprocity, because of an emergency or other reason, the Agency may  
20 waive the three (3) day time requirement provided the licensee:
  - 21 a. Informs the Agency by telephone, facsimile, an Agency Form MAT-  
22 9N, or a letter of initial activities or revisions to the information  
23 submitted on the initial Agency Form MAT-9i;
  - 24 b. Receives oral or written authorization for the activity from the  
25 Agency; and
  - 26 c. Within three (3) days after the notification, files an Agency Form  
27 MAT-9N, a copy of the pertinent licensing document, and the  
28 appropriate fee as prescribed in § 15.5.4 of this Subchapter.
- 29 3. The out-of-state licensee complies with all applicable regulations of the  
30 Agency and with all the terms and conditions of his licensing document,  
31 except any such terms and conditions which may be inconsistent with  
32 applicable regulations of the Agency;

- 1           4.     The out-of-state licensee supplies such other information as the Agency  
2                   may request; and
- 3           5.     The out-of-state licensee shall not transfer or dispose of radioactive  
4                   material possessed or used under the general license provided in §  
5                   7.10.1(A) of this Part except by transfer to a person specifically licensed  
6                   by the Agency, another Agreement State or by the U.S. Nuclear  
7                   Regulatory Commission to receive such material
- 8           6.     The out-of-state licensee files an amended Agency Form MAT-9N with the  
9                   Agency to request approval for changes in work locations, radioactive  
10                  material, or work activities different from the information contained on the  
11                  initial MAT-9N.
- 12    B.     Notwithstanding the provisions of § 7.10.1(A) of this Part, any person who holds  
13                  a specific license issued by the U.S. Nuclear Regulatory Commission or an  
14                  Agreement State authorizing the holder to manufacture, transfer, install, or  
15                  service a device described in § 7.7.1 of this Part within areas subject to the  
16                  jurisdiction of the licensing body is hereby granted a general license to install,  
17                  transfer, demonstrate or service such a device in Rhode Island, except for areas  
18                  under exclusive federal jurisdiction, provided that:
  - 19                  1.     such person shall file a report with the Agency within thirty (30) days after  
20                          the end of each calendar quarter in which any device is transferred to or  
21                          installed in Rhode Island. Each such report shall identify each general  
22                          licensee to whom such device is transferred by name and address, the  
23                          type of device transferred, and the quantity and type of radioactive  
24                          material contained in the device;
  - 25                  2.     the device has been manufactured, labeled, installed, and serviced in  
26                          accordance with applicable provisions of the specific license issued to  
27                          such person by the U.S. Nuclear Regulatory Commission or an  
28                          Agreement State;
  - 29                  3.     such person shall assure that any labels required to be affixed to the  
30                          device under regulations of the authority which licensed manufacture of  
31                          the device bear a statement that "Removal of this label is prohibited;" and
  - 32                  4.     the holder of the specific license shall furnish to each general licensee to  
33                          whom he transfers such device or on whose premises he installs such  
34                          device a copy of the general license contained in § 7.7.1 of this Part.
- 35    C.     The Agency may withdraw, limit, or qualify its acceptance of any specific license  
36                  or equivalent licensing document issued by another agency, or any product  
37                  distributed pursuant to such licensing document, upon determining that such  
38                  action is necessary in order to prevent undue hazard to public health and safety  
39                  or property.

- 1 D. The Agency will not accept any applications for reciprocity under this Part with  
2 respect to activities authorized pursuant to regulations that are equivalent to Part  
3 9 of this Subchapter ["Medical Use of Radioactive Material"]. These activities will  
4 only be authorized under the provision of a specific license issued by the Agency.

5 **7.10.2 Generally Licensed Devices**

- 6 A. Reciprocity requests involving generally licensed devices registered pursuant to  
7 § 7.7.1 of this Part or the equivalent regulations of the U.S. Nuclear Regulatory  
8 Commission or another Agreement State shall be handled in accordance with the  
9 procedures contained in § 7.10.1 of this Part. Applicants for reciprocity shall  
10 submit evidence of current registration pursuant to § 7.7.1 of this Part (or the  
11 equivalent regulations of the U.S. Nuclear Regulatory Commission or another  
12 Agreement State) in lieu of a specific radioactive materials license.
- 13 B. Reciprocity requests involving other generally licensed devices shall also be  
14 handled in accordance with the procedures contained in § 7.10.1 of this Part. In  
15 lieu of a specific radioactive materials license, applicants for reciprocity shall  
16 submit a copy of the general license authorization for the device and  
17 documentation that they are authorized to possess the device under a general  
18 license pursuant to the regulations of the U.S. Nuclear Regulatory Commission  
19 or another Agreement State that are applicable to the jurisdiction where the  
20 reciprocity request originated.