

# STATE OF COLORADO

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Executive Director and Chief Medical Officer

Dedicated to protecting and improving the health and environment of the people of Colorado

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Colorado Department  
of Public Health  
and Environment

April 23, 2012

James G. Luehman, Deputy Director  
Division of Materials Safety and State Agreements  
Office of Federal and State Materials and  
Environmental Management Programs  
U.S. Nuclear Regulatory Commission  
T8-E24  
Washington, D.C. 20555-0001

Dear Mr. Luehman:

Enclosed is a copy of the final revisions to the Colorado Radiological Health Rules, Colorado *Rules and Regulations Pertaining to Radiation Control*, 6 CCR 1007-1, Part 7, Use of Radionuclides in the Healing Arts. This document was approved by the Colorado Board of Health on February 15, 2012, and became effective March 30, 2012. Enclosed are the final regulation changes (provided in its entirety) with changes identified by strike-out text (deletions) and bold text (additions). Also enclosed is a "clean" non-strikeout version. We believe the final revision incorporates all comments provided to our program in NRC correspondence dated December 5, 2011 (ML112971510). Following the initial review by NRC, additional changes beyond those identified by NRC were made. These additional changes are identified as a "Note" in each line item of Attachment 1.

We believe that adoption of these revisions satisfies the compatibility and health and safety categories established in the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-200.

The regulatory changes were made primarily in response to certain NRC Regulatory Action Tracking System (RATs) changes. Other changes were made to the regulations based upon programmatic needs which resulted in some additional language being added to Part 7. Further changes were a result of formatting changes to maintain consistency within the document and other Colorado regulatory parts and to correct minor typographical errors.

James G. Luehman, Deputy Director  
U.S. Nuclear Regulatory Commission  
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Item 15 of the NRC letter dated December 5, 2011, pertains to the requirement contained in 10 CFR Part 32.72(b)(5). Colorado's Part 3 contains requirements in 10 CFR Part 32. Item 15 will therefore be addressed through a future amendment to Part 3.

With respect to item 16 of the NRC letter dated December 5, 2011 as it pertains to 10 CFR Part 32.74(a), we believe this item is addressed in Section 3.12.12.1 of Part 3 of the Colorado regulations as previously reviewed by NRC (NRC letter dated October 13, 2011). We request that NRC clarify what portion of this provision would not meet the intent of the requirements of 32.74(a).

If you have any questions, please feel free to contact me at 303/692-3423 or James Jarvis of my staff at 303/692-3454 or [james.jarvis@state.co.us](mailto:james.jarvis@state.co.us).

Sincerely,



Stephen F. Tarlton, Manager  
Radiation Program  
Hazardous Materials and Waste Management Division

Enclosures: Attachment 1

Cc: Kathleen Schneider, Senior Project Manager, Office of Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, T8-E24, Washington, D.C. 20555-0001 (via email)

RATs ID	CFR Title	State Section
	<b>ITEMS FOR RATs 2006-1</b>	
2006-1 §35.2	Definitions for: Authorized Medical Physicist (AMP); Authorized Nuclear Pharmacist (ANP); Authorized User (AU); and Radiation Safety Officer (RSO).	Section 7.2  <i>NOTE: Definitions for AMP, ANP, AU, and RSO were modified to parallel the requirements of Part 35.2 following the initial review by NRC.</i>
2006-1 §35.49	Suppliers for sealed sources or devices for medical use.	Section 7.14  <i>NOTE: Part 35.49(b) was not originally incorporated into the draft previously reviewed by NRC. This provision was incorporated into the final Part 7 based on NRC comment. [Ref: Item 2 of 12/05/11 NRC Letter]</i>
2006-1 §35.50	Training for Radiation Safety Officer.	Appendix 7A (See 7A1.2(2)(b))  <i>NOTE: This provision was modified in Part 7 based on NRC comment. [Ref: Item 3 of 12/05/11 NRC Letter]</i>
2006-1 §35.51	Training for an Authorized medical physicist.	Appendix 7B (See 7B1.1(2)(b), and 7B2.3)
2006-1 §35.59	Recentness of training.	Appendices A through M. Each appendix incorporates (repeats) a section equivalent to 35.59.
2006-1 §35.100	Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.	Section 7.30.1.2  <i>NOTE: Training references modified following initial review by NRC. [Ref: Item 6 of 12/05/11 NRC Letter]</i>
2006-1 §35.190	Training for uptake, dilution, and excretion studies.	Section 7.30.2, and Appendix 7D (7D2, 7D3.1(2), and 7D3.2), where sections equivalent to 35.190 (b), (c)(1)(ii), and (c)(2) are referenced.
2006-1 §35.200	Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.	Section 7.32.1.2, and Appendix 7E. <i>NOTE: Training references of 7.32.1.2 modified following initial review and comment by NRC. [Ref: Item 8 of 12/05/11 NRC Letter]</i>

2006-1 §35.290	Training for imaging and localization studies.	Section 7.32.2, and Appendix 7E (7E1.1(1), 7E2, 7E3.1(2), and 7E3.2), where sections equivalent to 35.290 are referenced.
2006-1 §35.300	Use of unsealed byproduct material for which a written directive is required.	Section 7.36.1.2, and 7.36.2, 7.36.3, and 7.36.4 (Also see Appendix 7F, 7G, 7H, and 7I). <b>NOTE: Training references of 7.36.1.2 modified following initial review and comment by NRC. [Ref: Item 10 of 12/05/11 NRC Letter]</b>
2006-1 §35.390	Training for use of unsealed byproduct material for which a written directive is required.	Appendix 7F, 7G, 7H, and 7I where sections equivalent to 35.390 are referenced.
2006-1 §35.392	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries).	Appendix 7G.
2006-1 §35.394	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries).	Appendix 7H.
2006-1 §35.396	Training for the parenteral administration of unsealed byproduct material requiring a written directive.	Appendix 7I.
2006-1 §35.490	Training for use of manual brachytherapy sources.	Appendix 7K.
2006-1 §35.491	Training for ophthalmic use of strontium-90.	Appendix 7L.
2006-1 §35.491	Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.	Appendix 7M.
	<b>ITEMS FOR RATS 2007-1</b>	
2007-1 §35.75(a)	Release of individuals containing unsealed byproduct material or implants containing byproduct material	Section 7.26.1. Modified language contained in footnote reference to NUREG for consistency with 35.75. <b>NOTE: Footnote language modified following initial review by NRC.</b>
2007-1 §35.92	Decay-in-storage.	Section 7.29. <b>NOTE – the phrase “...or equal to...” was omitted from the draft reviewed by NRC. The phrase was added to 7.29 following review by NRC. [Ref: Item 5 of 12/05/11 NRC Letter]</b>

2007-1 §35.190	Training for uptake, dilution, and excretion studies.	Appendix 7D. <i>NOTE - the phrase "...and experience..." was omitted from the draft reviewed by NRC. This phrase and reference corrections were incorporated into the final version of Part 7.</i> [Ref: Item 7 of 12/05/11 NRC Letter]
2007-1 §35.290	Training for imaging and localization studies.	Appendix 7E. <i>NOTE – the phrase "...of training and experience..." was omitted from the draft reviewed by NRC. This phrase and reference corrections were incorporated into the final version of Part 7.</i> [Ref: Item 9 of 12/05/11 NRC Letter]
	<b>ITEMS FOR RATS 2007-3</b>	
2007-3 §35.11	License required.	7.3.1 <i>NOTE: Language modified to correct references following initial review by NRC.</i> [Ref: Item 1 of 12/05/11 NRC Letter]
2007-3 §35.63	Determination of dosages of unsealed byproduct material for medical use.	Sections 7.18.2.2(2), and 7.18.3. <i>NOTE: Slight formatting (renumbering) of section 7.18.3 following NRC review.</i>
2007-3 §35.100 (a), and (b)	Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required	Section 7.30.1. <i>NOTE: Modifications made due to 2006-1 RATS item following NRC review.</i>
2007-3 §35.200 (a), and (b)	Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.	Section 7.32.1. <i>NOTE: Modifications made due to 2006-1 RATS item following NRC review.</i>
2007-3 §35.204 (a)	Permissible molybdenum-99 concentrations	These requirements are effectively implemented in existing Part 7, Section 7.33.1. which became effective in 2005.
2007-3 §35.300 (a) & (b)	Use of unsealed byproduct material for which a written directive is required	Section 7.36.1.2 <i>NOTE: Modifications made due to 2006-1 RATS item following NRC review.</i>
	<b>ITEMS FOR RATS 2009-1</b>	
2009-1 § 35.50	Training for Radiation Safety Officer	Appendix 7A.
2009-1 § 35.51	Training for an authorized medical physicist.	Appendix 7B

2009-1 § 35.57	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist.	Appendices A-M. <i>NOTE: Reference in Appendix 7I6.2 corrected per NRC review.</i> <i>[Ref: Item 4 of 12/05/11 NRC Letter]</i>
2009-1 § 35.190	Training for uptake, dilution, and excretion studies.	Appendix 7D (See also RATs 2007-1)
2009-1 § 35.290	Training for imaging and localization studies.	Appendix 7E (See also RATs 2007-1)
2009-1 § 35.390	Training for use of unsealed byproduct material for which a written directive is required.	Appendices 7F, 7G, 7H, and 7I <i>NOTE: Reference in Appendix 7F corrected per NRC review.</i> <i>[Ref: Item 11 of 12/05/11 NRC Letter]</i>
2009-1 § 35.392	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries).	Appendix 7G. <i>NOTE: Reference in Appendix 7G corrected per NRC review.</i> <i>[Ref: Item 12 of 12/05/11 NRC Letter]</i>
2009-1 § 35.394	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries).	Appendix 7H. <i>NOTE: Reference in Appendix 7H corrected per NRC review.</i> <i>[Ref: Item 13 of 12/05/11 NRC Letter]</i>
2009-1 § 35.396	Training for the parenteral administration of unsealed byproduct material requiring a written directive.	Appendix 7I.
2009-1 § 35.490	Training for use of manual brachytherapy sources.	Appendix 7K. <i>NOTE: Reference in Appendix 7K corrected per NRC review.</i> <i>[Ref: Item 14 of 12/05/11 NRC Letter]</i>
2009-1 § 35.690	Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.	Appendix 7M.
	<b>NON-RATS (OTHER) CHANGES</b>	
§ 35.11	License required	7.3.2 Language modified for consistency and clarification. <i>NOTE: Slight wording modifications made following initial NRC review.</i>
§ 35.13	License amendments	7.4.2.1 Language modified for consistency and clarification. <i>NOTE: Modification made following initial NRC review.</i>
§ 35.24	Radiation safety committee	7.8.1 Clarifying language added. <i>NOTE: Modification made following initial NRC review.</i>

§ 35.60(c)	Possession, use and testing of instruments...	7.16 Section modified for consistency with 35.60(c). This was previously identified on the draft submitted to NRC.
§ 35.63	Determination of dosages...	7.18.3 Numbering added to section for formatting consistency. <b>NOTE: Formatting changes made following initial review by NRC.</b>
§ 35.65(d)	Authorization for calibration, transmission, and reference sources.	7.19.3 Editorial/formatting modifications. This was previously identified in draft submitted to NRC.
§ 35.67(c)	Requirements for possession of sealed sources...	7.20 Provision added consistent with 35.67. This was previously identified in draft submitted to NRC.
§ 35.70	Surveys for contamination and ambient...	7.25.2.2, 7.25.3.2 Added SI units based on stakeholder input. <b>NOTE: SI unit changes in 7.25.2.2 and 7.25.3.2 were made following initial review by NRC.</b>
§35.490(b) (1)(ii)(E)	Authorized user training for the use of manual brachytherapy sources	Appendix 7K, Section 7K2.1(2)(e) <b>NOTE: Deleted the word "unsealed" as it is not appropriate for this section.</b>

**\*DRAFT 5 –02/16/2012\***

**DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT**

**Hazardous Materials and Waste Management Division**

**RADIATION CONTROL - USE OF RADIONUCLIDES IN THE HEALING ARTS**

**6 CCR 1007-1 Part 07**

*[Editor's Notes follow the text of the rules at the end of this CCR Document.]*

**PART 7: USE OF RADIONUCLIDES IN THE HEALING ARTS**

**USE OF RADIONUCLIDES IN THE HEALING ARTS**

**7.1 Purpose and Scope.**

7.1.1 Authority

Rules and regulations set forth herein are adopted pursuant to the provisions of sections 25-1-108, 25-1.5-101(1)(l), and 25-11-104, CRS.

7.1.2 Basis and Purpose.

A statement of basis and purpose accompanies this part and changes to this part. A copy may be obtained from the Department.

7.1.3 Scope.

This part establishes requirements and provisions for the production, preparation, compounding and use of radionuclides in the healing arts and for issuance of licenses authorizing the medical use of this material. These requirements and provisions provide for the protection of the public health and radiation safety of workers, the general public, patients, and human research subjects. The requirements and provisions of this part are in addition to, and not in substitution for, others in these regulations.

7.1.4 Applicability.

The requirements and provisions of these regulations apply to applicants and licensees subject to this part unless specifically exempted.

7.1.5 Published Material Incorporated by Reference.

Published material incorporated in Part 7 by reference is available in accord with 1.4.

**7.2 Definitions.**

As used in this part, these terms have the definitions set forth as follows:

~~"Accredited institution" means a teaching facility for nuclear medicine technology or radiation therapy technology whose standards are accepted by the United States Department of Education.~~

"Address of use" means the building(s) identified on the license where radioactive material may be produced, prepared, received, used or stored.

**Comment [JJ1]:** 8/17/11 - This term was previously used in Appendix 7N, but is no longer used in Part 7 (and was deleted in a prior revision), and is therefore deleted.

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34 "Area of use" means a portion of an address of use that has been set aside for the purpose of  
35 producing, preparing, receiving, using, or storing radioactive material.

36 "Authorized medical physicist" (AMP) means an individual who meets the requirements of  
37 Appendix 7B; **or**

38 **(1) Is identified as an authorized medical physicist or teletherapy physicist on:**

- 39 **a. A specific medical license issued by the Department, NRC, or Agreement State;**
- 40 **b. A medical use permit issued by an NRC master material license;**
- 41 **c. A permit issued by an NRC or Agreement State broad scope medical use**  
42 **licensee; or**
- 43 **d. A permit issued by an NRC master material license broad scope medical use**  
44 **license.**

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45 "Authorized nuclear pharmacist" (ANP) means a pharmacist who meets the requirements of  
46 Appendix 7C; **or**

47 **(1) Is identified as an authorized nuclear pharmacist on:**

- 48 **a. A specific license issued by the Department, NRC, or Agreement State that**  
49 **authorizes medical use or the practice of nuclear pharmacy;**
- 50 **b. A permit issued by an NRC master material license that authorizes medical use**  
51 **or the practice of nuclear pharmacy;**
- 52 **c. A permit issued by an NRC or Agreement State broad scope medical use**  
53 **licensee that authorizes medical use or the practice of nuclear pharmacy; or**
- 54 **d. A permit issued by an NRC master material license broad scope medical use**  
55 **permittee that authorizes medical use or the practice of nuclear pharmacy; or**

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56 **(2) Is identified as an authorized nuclear pharmacist by a commercial nuclear**  
57 **pharmacy that has been authorized to identify authorized nuclear pharmacists;**  
58 **or**

59 **(3) Is designated as an authorized nuclear pharmacist in accordance with Part 3.**

60 "Authorized user" (AU) means a physician, dentist, or podiatrist who meets the ~~training and~~  
61 ~~experience requirements for a use of radioactive material specified in the~~ applicable appendix  
62 ~~requirements~~ of Appendix 7D through Appendix 7M.; **or**

63 **(1) Is identified as an authorized user on:**

- 64 **a. A Department, NRC, or Agreement State license that authorizes the medical use**  
65 **of radioactive material;**
- 66 **b. A permit issued by an NRC master material license that is authorized to permit**  
67 **the medical use of radioactive material;**
- 68 **c. A permit issued by an NRC or Agreement State specific licensee of broad scope**  
69 **that is authorized to permit the medical use of radioactive material; or**

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70 | **d. A permit issued by an NRC master material license broad scope permittee that is**  
71 | **authorized to permit the medical use of radioactive material.**

72 | "Brachytherapy" means a method of radiation therapy in which plated, embedded, activated, or  
73 | sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by  
74 | surface, intracavitary, intraluminal or interstitial application.

75 | "Brachytherapy source" means a radioactive source or a manufacturer-assembled source train or  
76 | a combination of these sources that is designed to deliver a therapeutic dose within a distance of  
77 | a few centimeters.

78 | "Client" means, for mobile medical service, the person for whom, or in conjunction with whom,  
79 | medical service is provided.

80 | "Client's address" means the address of use for the purpose of providing mobile medical service  
81 | in accordance with 7.27.

82 | "Dedicated –check source" means a radioactive source that is used to assure the consistent  
83 | response of a radiation detection or measurement device over several months or years.

**Comment [JJ2]:** JJ 6/22/2011: removal of extra spaces – correction of typographical error.

84 | "Dentist" means an individual licensed by a State or Territory of the United States, the District of  
85 | Columbia or the Commonwealth of Puerto Rico to practice dentistry.

86 | "Diagnostic clinical procedures manual" means a collection of written procedures that describes  
87 | each method (and other instructions and precautions) by which the licensee performs diagnostic  
88 | clinical procedures; where each diagnostic clinical procedure has been approved by the  
89 | authorized user and includes the radiopharmaceutical, dosage, and route of administration, or in  
90 | the case of sealed sources for diagnosis, the procedure.

91 | "HDR", see high dose-rate remote afterloader.

92 | "High dose-rate remote afterloader" (HDR) means a device that remotely delivers a dose rate in  
93 | excess of 12 gray (1200 rad) per hour at the treatment site.

94 | "LDR", see low dose-rate remote afterloader.

95 | "Low dose-rate remote afterloader" (LDR) means a device that remotely delivers a dose rate of  
96 | less than or equal to 2 gray (200 rad) per hour at the treatment site (at the specified distance).

97 | "Management" means the chief executive officer, or other individual having the authority to  
98 | manage, direct, or administer the licensee's activities, or such person's' delegate(s).

99 | "Manual brachytherapy" means a type of therapy in which brachytherapy sources are manually  
100 | applied or inserted.

101 | "MDR", see medium dose-rate remote afterloader".

102 | "Medical institution" means an organization in which two or more medical disciplines are  
103 | practiced.

104 | "Medical use" means, for the purposes of Part 7, the intentional internal or external administration  
105 | of radioactive material or the radiation from radioactive material to patients or human research  
106 | subjects under the supervision of an authorized user.

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- 107 "Medium dose-rate remote afterloader" (MDR) means a device that remotely delivers a dose rate  
108 of greater than 2 gray (200 rad), but less than, or equal to, 12 gray (1200 rad) per hour at the  
109 treatment site (at the specified distance).
- 110 "Misadministration" means an event that meets the criteria in 7.21.
- 111 "Mobile medical service" means the transportation of radioactive material to, or its medical use  
112 at, the client's address and/or a temporary job site.
- 113 "Nuclear medicine technologist" (NMT) means an individual who meets the requirements of  
114 Appendix 7N and who under the supervision of an authorized user prepares or administers  
115 radioactive drugs to patients or human research subjects, or performs *in vivo* or *in vitro*  
116 measurements for medical purposes.
- 117 "Nuclear medicine technology" means the science and art of *in vivo* and *in vitro* detection and  
118 measurement of radioactivity and the administration of radioactive drugs to patients or human  
119 research subjects for diagnostic and therapeutic purposes.
- 120 "Output" means the exposure rate, dose rate, or a quantity related in a known manner to these  
121 rates, from a brachytherapy source, or a teletherapy, remote afterloader, or gamma stereotactic  
122 radiosurgery unit, for a specified set of exposure conditions.
- 123 "Patient intervention" means actions by the patient or human research subject, whether  
124 intentional or unintentional, such as dislodging or removing treatment devices or prematurely  
125 terminating the administration.
- 126 "PDR", see pulsed dose-rate remote afterloader.
- 127 "Pharmacist" means an individual licensed by a State or Territory of the United States, the District  
128 of Columbia or the Commonwealth of Puerto Rico to practice pharmacy. (See also Authorized  
129 nuclear pharmacist)
- 130 "Physician" means an individual licensed by a State or Territory of the United States, the District  
131 of Columbia or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine.
- 132 "Podiatrist" means an individual licensed by a State or Territory of the United States, the District  
133 of Columbia or the Commonwealth of Puerto Rico to practice podiatry.
- 134 "Preceptor" means an individual who provides, directs or verifies training and experience required  
135 for an individual to become ~~an~~ a radiation safety officer, an authorized user, an authorized  
136 medical physicist, an authorized nuclear pharmacist, a nuclear medicine technologist, or a  
137 radiation therapy technologist (see appendices 7A through 7O).
- 138 "Prescribed dosage" means the specified activity or range of activity of a radioactive drug as  
139 documented in:
- 140 (1) A written directive as specified in 7.11; or
- 141 (2) Accordance with the directions of the authorized user for procedures performed  
142 pursuant to 7.30, 7.32, or 7.36.
- 143 "Prescribed dose" means:
- 144 (1) For gamma stereotactic radiosurgery, the total dose as documented in the written  
145 directive;

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- 146 (2) For teletherapy, the total dose and dose per fraction as documented in the written  
147 directive;
- 148 (3) For manual brachytherapy, either the total source strength and exposure time or the  
149 total dose, as documented in the written directive; or
- 150 (4) For remote brachytherapy afterloaders, the total dose and dose per fraction as  
151 documented in the written directive.

152 "Pulsed dose-rate remote afterloader" (PDR) means a special type of remote afterloading device  
153 that uses a single source capable of delivering dose rates (at the specified distance) in the "high  
154 dose-rate" range, but:

- 155 (1) Is approximately one-tenth of the activity of typical high dose-rate remote afterloader  
156 sources; and
- 157 (2) Is used to simulate the radiobiology of a low dose rate treatment by inserting the  
158 source for a given fraction of each hour.

159 "Radiation safety officer" (RSO) means, for the purposes of Part 7, an individual who has  
160 demonstrated sufficient knowledge to apply radiation protection regulations appropriately, who in  
161 accord with 7.7 has been assigned such responsibility by the licensee, and who meets the  
162 requirements in Appendix 7A-; **or**

- 163 **(1) Is identified as a Radiation Safety Officer on:**
- 164 **a. A specific medical use license issued by the Department, NRC, or Agreement**  
165 **State; or**
- 166 **b. A medical use permit issued by an NRC master material licensee.**

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167 "Radiation therapy technologist" (RTT) means an individual who meets the requirements of  
168 Appendix 7O and is under the supervision of an authorized user to perform procedures and apply  
169 radiation emitted from sealed radioactive sources to human beings for therapeutic purposes.

170 "Radiation therapy technology" means the science and art of applying radiation emitted from  
171 sealed radioactive sources to patients or human research subjects for therapeutic purposes.

172 "Radioactive drug" means any chemical compound containing radioactive material that may be  
173 used on or administered to patients or human research subjects as an aid in the diagnosis,  
174 treatment, or prevention of disease or other abnormal condition.

175 "Sealed source" means radioactive material that is permanently bonded or fixed in a capsule or  
176 matrix designed to prevent release and dispersal of the radioactive material under the most  
177 severe conditions which are likely to be encountered in normal use and handling.

178 "Sealed Source and Device Registry" means the national registry that contains the registration  
179 certificates maintained by the Nuclear Regulatory Commission, that summarize the radiation  
180 safety information for the sealed sources and devices and describe the licensing and use  
181 conditions approved for the product.

182 "Stereotactic radiosurgery" means the use of external radiation in conjunction with a stereotactic  
183 guidance device to precisely deliver a dose to a treatment site.

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184 "Structured educational program" means an accredited educational program designed to impart  
185 particular knowledge and practical education through interrelated studies and supervised training.

186 "Teletherapy", as used in this part, means a method of radiation therapy in which collimated  
187 gamma rays are delivered at a distance from the patient or human research subject.

188 "Temporary job site", as used in Part 7, means a location where mobile medical services are  
189 confined to the mobile unit not at a licensed address of use.

190 "Therapeutic dosage" means a dosage of unsealed radioactive material that is intended to deliver  
191 a radiation dose to a patient or human research subject for palliative or curative treatment.

192 "Therapeutic dose" means a radiation dose delivered from a sealed source containing radioactive  
193 material to a patient or human research subject for palliative or curative treatment.

194 "Treatment site" means the anatomical description of the tissue intended to receive a radiation  
195 dose, as described in a written directive.

196 "Trunnion" means a support bar sometimes used as a bearing instead of a socket.

197 "Type of use" means use of radioactive material as specified under 7.30, 7.32, 7.36, 7.40, 7.42,  
198 7.48 or 7.62.

199 "Unit dosage" means a dosage that:

200 (1) Is obtained or prepared in accordance with the regulations for uses described in 7.30,  
201 7.32, or 7.36; and

202 (2) Is to be administered as a single dosage to a patient or human research subject  
203 without any further manipulation of the dosage after it is initially prepared.

204 "Written directive" means an authorized user's written order for the administration of radioactive  
205 material or radiation from radioactive material to a specific patient or human research subject, as  
206 specified in 7.11.

207 **GENERAL REGULATORY REQUIREMENTS**

208 **7.3 License Required.**

209 7.3.1 A person shall manufacture, produce, prepare, acquire, receive, possess, use, or transfer  
210 radioactive material for medical use only in accordance with a specific license issued by the  
211 Department, an Agreement State or NRC, or as allowed in 7.3.1.12 or 7.3.1.23.

212 7.3.1.1 Unless prohibited by license condition, an individual may receive, possess, use, or  
213 transfer radioactive material in accordance with the regulations in this part under the  
214 supervision of an authorized user as provided in 7.10.

215 7.3.1.2 Unless prohibited by license condition, an individual may prepare unsealed radioactive  
216 material for medical use in accordance with the regulations in this part under the  
217 supervision of an authorized nuclear pharmacist or authorized user as provided in 7.10.

218

219 7.3.2 Provisions for **the protection of Human** Research **Involving Human** Subjects.

**Comment [JJ3]:** Correction to reference to address NRC comments (Nov 2011). NRC RATS 2007-3 (Ref 35.11(a))

**Comment [O4]:** Section title changed to be consistent with 10 CFR 35.6

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220 A licensee may conduct research involving human subjects using radioactive material ~~provided~~  
221 ~~that~~**under the following conditions:**

222 7.3.2.1 ~~The~~**For** research ~~is~~ conducted, funded, supported, or regulated by a federal agency  
223 which has implemented ~~The f~~**Federal p**Policy for the ~~P~~**rotection of h**Human ~~s~~**Subjects**  
224 ~~(Federal Policy), the licensee shall:~~

225 ~~(1)~~ **Obtain prior informed consent from the human research subjects; and**

226 **(2) Obtain prior review and approval of the research activities by an "Institutional**  
227 **Review Board" in accordance with the meaning of these terms as defined and**  
228 **described in the Federal Policy; or**

229 7.3.2.2 **For research not conducted, funded, supported, or regulated by a federal agency**  
230 **which has implemented the Federal Policy, then:**

231 **(1) The licensee shall apply for and receive a specific amendment to its Department**  
232 **license before conducting such research. The amendment request shall include a**  
233 **written commitment that the licensee will, before conducting research:**

234 **a. Obtain prior informed consent from the human research subjects; and**

235 **b. Obtain prior review and approval of the research activities by an**  
236 **"Institutional Review Board" in accordance with the meaning of these**  
237 **terms as defined and described in the Federal Policy;**

238 7.3.2.3 A licensee not authorized pursuant to 3.11 shall apply for and receive approval of a  
239 specific amendment to its Department license before conducting ~~such~~ research  
240 ~~involving human subjects;~~

241 ~~7.3.2.3 At a minimum, the licensee shall obtain prior informed consent from the human subjects~~  
242 ~~and obtain prior review and approval of the research activities by an "Institutional Review~~  
243 ~~Board" in accordance with the meaning of these terms as defined and described in~~  
244 ~~federal policy for the protection of human subjects;~~

245 7.3.2.4 The research involving human subjects authorized in 7.3.2.4 shall be conducted using  
246 radioactive material authorized for medical use in the license; and

247 7.3.2.5 Nothing in 7.3.2 relieves licensees from complying with the other requirements in Part 7.

248 7.3.3 Nothing in this part relieves the licensee from complying with applicable FDA, other federal, and  
249 state requirements governing radioactive drugs or devices.

250 7.3.4 Application for License, Amendment, or Renewal.

251 7.3.4.1 An application shall be signed by the applicant's or licensee's management.

252 7.3.4.2 An application for a **new or renewal** license for medical use of radioactive material as  
253 described in 7.30, 7.32, 7.36, 7.40, 7.42, 7.48 or 7.62 must be made by:

254 (1) Filing ~~an original and one copy of a completed~~ Department Form R-12 **(7C)**, and

255 (2) Submitting procedures required by **Form R-12 (7C), and -7.12, 7.15, 7.51, 7.58,**  
256 **7.59, and 7.61,-** as applicable, **and other procedures as requested by the**  
257 **Department.**

**Comment [JJ5]:** Additional clarifying language added to this section is based on feedback of Radioactive Materials Unit staff for consistency with NRC Part 35.6 and SSR G.4.

Whether a research project does or does not involve a federal agency, the requirements are effectively the same. The current language is unclear to the requirements when a federal agency is not involved and is the basis for the proposed change.

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**Comment [JJ6]:** Paragraph reworded for clarification.

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**Comment [JJ7]:** This paragraph is deleted as it has been combined into 7.3.2.1, and 7.3.2.2 above.

**Comment [JJ8]:** A stakeholder-licensee made the recommendation that we clarify that renewal licenses also require an application and other documents. Other changes to this section are to clarify and to aid in understanding the requirements.

**Comment [JJ9]:** It is proposed that this language requiring a second copy of an application be deleted, since most often it is not needed.

**Comment [JJ10]:** Modified existing wording to provide clarity based on stakeholder comment.

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**Comment [JJ11]:** Additional language added to clarify that other documents pertinent to licensed activities are needed for new or renewal licenses.

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- 258 7.3.4.3 A request for a license amendment ~~or renewal~~ must be made by:
- 259 (1) Submitting an original **amendment request and one copy** in letter format.
- 260 (2) Submitting procedures required by 7.12, 7.15, 7.51, 7.58, 7.59, and 7.61, as
- 261 applicable, **and other procedures as requested by the Department**.
- 262 7.3.4.4 In addition to the requirements in 7.3.4.2 and 7.3.4.3, an application for a **new** license,
- 263 **renewal license**, or amendment for medical use of radioactive material as described in
- 264 7.62 must also include information regarding any radiation safety aspects of the medical
- 265 use of the material that is not addressed in 7.1 through 7.29, as well as any specific
- 266 information on:
- 267 (1) Radiation safety precautions and instructions;
- 268 (2) Training and experience of proposed users;
- 269 (3) Methodology for measurement of dosages or doses to be administered to patients or
- 270 human research subjects; and
- 271 (4) Calibration, maintenance, and repair of instruments and equipment necessary for
- 272 radiation safety.
- 273 7.3.4.5 The applicant or licensee shall also provide any other information requested by the
- 274 Department in its review of the application.
- 275 7.3.4.6 An applicant that satisfies the requirements specified in 3.11 may apply for a Type A
- 276 specific license of broad scope.
- 277 7.3.5 Mobile Medical Service Administrative Requirements.
- 278 7.3.5.1 The Department shall license mobile medical services or clients of such services. The
- 279 mobile medical service shall be licensed if the service receives, uses or possesses
- 280 radioactive material. The client of the mobile medical service shall be licensed if the client
- 281 receives or possesses radioactive material to be used by a mobile medical service.
- 282 7.3.5.2 Mobile medical service licensees shall obtain a letter signed by the management of each
- 283 location where services are rendered that authorizes use of radioactive material at the
- 284 client's address of use. This letter shall clearly delineate the authority and responsibility of
- 285 both the client and the mobile medical service. If the client is licensed, the letter shall
- 286 document procedures for notification, receipt, storage and documentation of transfer of
- 287 radioactive material delivered to the client's address for use by the mobile medical
- 288 service.
- 289 7.3.5.3 A mobile medical service shall not have radioactive material delivered directly from the
- 290 manufacturer or the distributor to the client, unless the client has a license allowing
- 291 possession of the radioactive material. Radioactive material delivered to the client shall
- 292 be received and handled in conformance with the client's license.
- 293 7.3.5.4 A mobile medical service shall inform the client's management who is on site at each
- 294 client's address of use at the time that radioactive material is being administered.
- 295 7.3.5.5 A licensee providing mobile medical services shall retain the letter required in 7.3.5.2
- 296 for 3 years after the last provision of service.

**Comment [JJ12]:** It is proposed that this language requiring a second copy of an application be deleted, since most often it is not needed.

**Comment [JJ13]:** Additional language added to clarify that other documents pertinent to licensed activities are needed for license amendments.

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- 297 7.3.5.6 A mobile medical service licensee shall, at a minimum, maintain the following documents  
298 on each mobile unit:
- 299 (1) The current operating and emergency procedures;
- 300 (2) A copy of the license;
- 301 (3) Copies of the letter required by 7.3.5.2;
- 302 (4) Current calibration records for each survey instrument and diagnostic equipment or  
303 dose delivery device in use; and
- 304 (5) Survey records covering uses associated with the mobile unit during, at a minimum,  
305 the preceding 30 calendar days.
- 306 7.3.5.7 The mobile medical service shall designate and manage each area of use in the client's  
307 facility as a restricted area while radioactive material is present. For each location where  
308 radioactive materials will be routinely used, the licensee shall provide to the Department:
- 309 (1) A diagram of the location of use, including information about the placement of  
310 required postings; and
- 311 (2) Calculation(s) or survey(s) results that demonstrate compliance with applicable dose  
312 limits in 4.14 and 4.15 at the location of use.
- 313 7.3.5.8 The mobile medical service shall ensure that:
- 314 (1) Supervision by an authorized user is in accordance with 7.10.1;
- 315 (2) Radiation exposures to the client's personnel working in the client facility are:
- 316 (a) Below the dose limits to members of the public listed in 4.14; or
- 317 (b) The client's personnel are instructed as described in 10.3 and monitored for  
318 exposure in accordance with 4.18 unless the licensee can demonstrate  
319 that 4.18 does not apply.
- 320 7.3.5.9 A mobile medical service licensee shall maintain all records required by Parts 4 and 7 of  
321 these regulations at a location within the Department's jurisdiction that is:
- 322 (1) A single address of use:
- 323 (a) Identified as the records retention location; and
- 324 (b) Staffed at all reasonable hours by individual(s) authorized to provide the  
325 Department with access for purposes of inspection; or
- 326 (2) When no address of use is identified on the license for records retention, the mobile  
327 unit:
- 328 (a) Identified in the license; and
- 329 (b) Whose current client's address of use and area of use schedule is reported  
330 to the Department.

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- 331 7.3.6 A licensee possessing a Type A specific license of broad scope for medical use is exempt from:
- 332 7.3.6.1 The provisions of 7.3.4.4 regarding the need to file an amendment to the license for  
333 medical uses of radioactive material as described in 7.62;
- 334 7.3.6.2 The provisions of 7.4.2 regarding the need to file an amendment before permitting  
335 anyone to work as an authorized user, an authorized nuclear pharmacist or an authorized  
336 medical physicist under the license;
- 337 7.3.6.3 The provisions of 7.4.5 regarding additions to or changes in the areas of use at the  
338 addresses specified in the license;
- 339 7.3.6.4 The provisions of 7.5.1 regarding notification to the Department for new authorized users,  
340 new authorized nuclear pharmacists and new authorized medical physicists;
- 341 7.3.6.5 The provisions of 7.14 regarding suppliers for sealed sources.
- 342 7.3.7 The Department may, upon application of any interested person or upon its own initiative, grant  
343 such exemptions from the regulations in Part 7 as it determines are authorized by law and will not  
344 endanger life or property or the common defense and security and are otherwise in the public  
345 interest.

346 **7.4 License Amendments.**

347 A licensee shall apply for and shall have received a license amendment before the licensee:

- 348 7.4.1 Receives, prepares, or uses radioactive material for a type of use that is permitted under this part  
349 but that is not authorized on the licensee's current license issued pursuant to this part;
- 350 7.4.2 Permits anyone to work as an authorized user, authorized medical physicist, or an authorized  
351 nuclear pharmacist under the license in accordance with the training and experience  
352 requirements specified in:
- 353 7.4.2.1 ~~The applicable appendix of~~ Appendix 7D through Appendix 7M for an authorized user for  
354 a **specific** type of use of radioactive material;
- 355 7.4.2.2 Appendix 7B for an authorized medical physicist;
- 356 7.4.2.3 Appendix 7C for an authorized nuclear pharmacist; and
- 357 7.4.3 Changes a Radiation Safety Officer, except as provided in 7.7.6;
- 358 7.4.4 Receives radioactive material in excess of the amount or in a different physical or chemical form  
359 than is authorized on the license;
- 360 7.4.5 Adds to or changes the area(s) of use or address(es) of use identified in the application or on the  
361 license, except as specified in 7.5.2.4; and
- 362 7.4.6 Changes statements, representations, and procedures which are incorporated into the license; or
- 363 7.4.7 Releases licensed facilities for unrestricted use.

364 **7.5 Notifications; Maintenance of Records.**

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365 7.5.1 A licensee shall provide to the Department required documentation of adequate radiation safety  
366 training and experience under Appendix 7B for each authorized medical physicist pursuant to  
367 7.4.2, under Appendix 7C for each authorized nuclear pharmacist, and under the applicable  
368 appendix of Appendix 7D through Appendix 7M for each individual authorized user.

369 7.5.2 A licensee shall notify the Department in writing within 30 days after:

370 7.5.2.1 An authorized user, authorized medical physicist, authorized nuclear pharmacist, or  
371 Radiation Safety Officer permanently discontinues performance of duties under the  
372 license or has a name change;

373 7.5.2.2 The licensee's mailing address changes;

374 7.5.2.3 The licensee's name changes, but the name change does not constitute a transfer of  
375 control of the license as described in 3.15.2 of these regulations; or

376 7.5.2.4 The licensee has added to or changed the areas where radioactive material is used in  
377 accordance with 7.30 and 7.32.

378 7.5.3 Maintenance of Records.

379 Each record required by this part must be legible throughout the retention period specified by  
380 each Department regulation. The record may be the original, a reproduced copy, or a microform  
381 provided that the copy or microform is authenticated by authorized personnel and the microform  
382 is capable of producing a clear copy throughout the required retention period. The record may  
383 also be stored in electronic media with the capability for producing legible, accurate, and  
384 complete records during the required retention period. Records such as letters, drawings, and  
385 specifications must include all pertinent information such as stamps, initials, and signatures. The  
386 licensee shall maintain adequate safeguards against tampering with and loss of records.

387 **7.6 License Issuance.**

388 7.6.1 The Department shall issue a license for the medical use of radioactive material if:

389 7.6.1.1 The applicant has filed Department Form R-12 in accordance with the instructions in  
390 7.3.4;

391 7.6.1.2 The applicant has paid any applicable fee;

392 7.6.1.3 The applicant meets the requirements of Part 3 of these regulations; and

393 7.6.1.4 The Department finds the applicant equipped and committed to observe the safety  
394 standards established by the Department in these regulations for the protection of the  
395 public health and safety.

396 7.6.2 The Department shall issue a license for mobile services if the applicant:

397 7.6.2.1 Meets the requirements in 7.6.1, and in particular 7.3.5; and

398 7.6.2.2 Assures that individuals to whom radioactive drugs or radiation from implants containing  
399 radioactive material will be administered may be released following treatment in  
400 accordance with 7.26.

401 **ADDITIONAL OVERALL REQUIREMENTS**

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402 **7.7 Authority and Responsibilities for the Radiation Protection Program**

403 7.7.1 In addition to the radiation protection program requirements of 4.5 of these regulations, a licensee's  
404 management must approve in writing:

405 7.7.1.1 Requests for license application, renewal, or amendments before submittal to the  
406 Department;

407 7.7.1.2 Any individual before allowing that individual to work as an authorized user, authorized  
408 nuclear pharmacist or authorized medical physicist; and

409 7.7.1.3 Radiation protection program changes that do not require a license amendment and are  
410 permitted under 7.7.

411 7.7.2 A licensee's management shall appoint a Radiation Safety Officer (RSO), who agrees in writing to  
412 be responsible for implementing the radiation safety program. The licensee, through the RSO,  
413 shall ensure that radiation safety activities are being performed in accordance with approved  
414 procedures and regulatory requirements.

415 7.7.3 A licensee shall establish in writing the authority, duties, and responsibilities of the Radiation Safety  
416 Officer, and of the Alternate RSO, if required.

417 7.7.4 A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom,  
418 time, resources, and management prerogative, to:

419 7.7.4.1 Identify radiation safety problems;

420 7.7.4.2 Initiate, recommend, or provide corrective actions;

421 7.7.4.3 Stop unsafe operations; and

422 7.7.4.4 Verify implementation of corrective actions.

423 7.7.5 A licensee shall retain a record of actions taken pursuant to 7.7.1, 7.7.2 and 7.7.3 for 5 years,  
424 including:

425 7.7.5.1 A summary of the actions taken (and a signature of licensee management) in accordance  
426 with 7.7.1;

427 7.7.5.2 A signed copy of the RSO's agreement (including the signature of the RSO and licensee  
428 management) to be responsible for implementing the radiation safety program, as  
429 required by 7.7.2; and

430 7.7.5.3 A current copy of the authorities, duties and responsibilities of the RSO as required by  
431 7.7.3.

432 7.7.6 For up to sixty days each year, a licensee may permit an authorized user or an individual qualified  
433 to be a radiation safety officer to function as a temporary Radiation Safety Officer and to perform  
434 the functions of a Radiation Safety Officer, as provided in 7.7.4, provided the licensee takes the  
435 actions required in 7.7.2, 7.7.3, 7.7.4 and 7.7.5. A licensee may simultaneously appoint more  
436 than one temporary RSO, if needed, to ensure that the licensee has a temporary RSO that  
437 satisfies the requirements to be an RSO for each of the different uses of radioactive material  
438 permitted by the license.

439 **7.8 Radiation Safety Committee.**

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440 7.8.1 Licensees that are authorized for ~~two~~one or more different types of radioactive material use under  
441 7.36, 7.42, 7.48, or 7.62 ~~or two or more types of units under 7.48~~ shall establish a Radiation  
442 Safety Committee to oversee all uses of radioactive material permitted by the license.

443 7.8.2 The Committee shall:

444 7.8.2.1 Include:

- 445 (1) An authorized user of each type of use permitted by the license;
- 446 (2) The Radiation Safety Officer
- 447 (3) A representative of the nursing service
- 448 (4) A representative of management who is neither an authorized user nor a Radiation  
449 Safety Officer; and
- 450 (5) Other members as the licensee deems appropriate.

451 7.8.2.2 Meet as necessary, but at a minimum shall meet at intervals not to exceed 6 months.

452 7.8.2.3 Maintain minutes of each meeting, including:

- 453 (1) The date of the meeting;
- 454 (2) Members present;
- 455 (3) Members absent; and
- 456 (4) Summary of deliberations and discussions.

457 **7.9 Radiation Protection Program Changes.**

458 7.9.1 A licensee may revise its radiation protection program without Department approval if:

- 459 7.9.1.1 The revision does not require an amendment under 7.4;
- 460 7.9.1.2 The revision is in compliance with the regulations and the license;
- 461 7.9.1.3 The revision has been reviewed and approved by the Radiation Safety Officer, licensee  
462 management and licensee's Radiation Safety Committee (if applicable); and
- 463 7.9.1.4 The affected individuals are instructed on the revised program before the changes are  
464 implemented.

465 7.9.2 A licensee shall retain a record of each change for 5 years, including

- 466 7.9.2.1 A copy of the old and new procedures;
- 467 7.9.2.2 The effective date of the change; and
- 468 7.9.2.2 The signature of the licensee management that reviewed and approved the change.

469 **7.10 Supervision.**

**Comment [JJ14]:** [UPDATED 01/25/2012]  
Radioactive Materials Unit staff believe that Radiation Safety Committees provide a valuable mechanism to review and share radiation safety exposure and related information and are proposing to lower the threshold at which Committee meetings are required. The proposed change is expected to impact ~31 licensees (of 91 medical licensees). This would require these 31 licensees that do not already hold RSC meetings to hold them 2x per year to review and have oversight of the radiation safety program. Under current regulation, 23 licensees are now required to form and hold RSC meetings.

This change would not impact facilities that use only diagnostic radioactive materials (e.g. cardiology only facilities, sentinel node facilities, or smaller programs performing only diagnostic procedures.)

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- 470 7.10.1 A licensee that permits the receipt, possession, use, or transfer of radioactive material by an  
471 individual under the supervision of an authorized user as allowed by 7.3.2 shall:
- 472 7.10.1.1 In addition to the requirements of 10.3 of these regulations, instruct the supervised  
473 individual in the licensee's written radiation protection procedures, written directive  
474 procedures, regulations of Part 7, and license conditions with respect to the use of  
475 radioactive material; and;
- 476 7.10.1.2 Require the supervised individual to follow the instructions of the supervising authorized  
477 user for medical uses of radioactive material, written radiation protection procedures,  
478 written directive procedures, regulations of Part 7, and license conditions with respect to  
479 the medical use of radioactive material.
- 480 7.10.2 A licensee that permits the preparation of radioactive material for medical use by an individual  
481 under the supervision of an authorized nuclear pharmacist or physician who is an authorized  
482 user, as allowed by 7.3.3, shall:
- 483 7.10.2.1 **In addition to the requirements of 10.3,** instruct the supervised individual in the  
484 preparation of radioactive material for medical use, as appropriate to that individual's use  
485 of radioactive material; and
- 486 7.10.2.2 Require the supervised individual to follow the instructions of the supervising authorized  
487 user or authorized nuclear pharmacist regarding the preparation of radioactive material  
488 for medical use, the written radiation protection procedures, the regulations of Part 7, and  
489 license conditions.
- 490 7.10.3 Unless physical presence as described in other sections of Part 7 is required, a licensee who  
491 permits supervised activities under 7.10.1 and 7.10.2 shall require an authorized user to be  
492 immediately available (by telephone within ten minutes) to communicate with the supervised  
493 individual, ~~and able to be physically present within one hour, unless~~ otherwise authorized by the  
494 Department with prior written approval. ~~and~~
- 495 7.10.4 A licensee who permits supervised activities under 7.10.1 and 7.10.2 is responsible for the acts  
496 and omissions of the supervising authorized user and supervised individual(s).
- 497 **7.11 Written Directives.**
- 498 7.11.1 A written directive must be dated and signed by an authorized user, including the signatory's  
499 printed or typed name, prior to administration of:
- 500 7.11.1.1 I-131 sodium iodide greater than 1.11 MBq (30 µCi), or
- 501 7.11.1.2 Any therapeutic dosage of radioactive material, or
- 502 7.11.1.3 Any therapeutic dose of radiation from radioactive material.
- 503 7.11.2 The written directive must contain the patient or human research subject's name and the  
504 following:
- 505 7.11.2.1 For an administration of a dosage of radioactive drug containing radioactive material,  
506 the name of the radioactive drug containing radioactive material, dosage, and route of  
507 administration;

**Comment [JJ15]:** Added language to be consistent with 10 CFR 35.27.

[This change arose as a result of NRC review of 2010 CRCPD SSR Part G.]

NRC Compatibility = H&S

**Comment [JJ16]:** This proposed change will reduce the regulatory requirements associated with the availability of an authorized user. Over time, Radioactive Materials Unit staff have determined that the current requirement for physical presence within one hour has not been significantly beneficial from a radiation safety perspective.

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- 508 7.11.2.2 For gamma stereotactic radiosurgery, the total dose, treatment site, and **values for the**  
509 ~~number of target~~ coordinate settings per treatment for each anatomically distinct  
510 treatment site;
- 511 7.11.2.3 For teletherapy, the total dose, dose per fraction, number of fractions, and treatment  
512 site;
- 513 7.11.2.4 For high dose rate remote afterloading brachytherapy, the radionuclide, treatment site,  
514 dose per fraction, number of fractions, and total dose; or
- 515 7.11.2.5 For all other brachytherapy, including LDR, MDR, and PDR:
- 516 (1) Prior to implantation: treatment site, the radionuclide, and dose; and
- 517 (2) After implantation but prior to completion of the procedure: the radioisotope,  
518 treatment site, number of sources, and total source strength and exposure time  
519 (or the total dose).
- 520 7.11.3 If, because of the emergent nature of the patient's condition, a delay in order to provide a written  
521 directive would jeopardize the patient's health, an oral directive will be acceptable, provided that  
522 the information contained in the oral directive is documented as soon as possible in writing in the  
523 patient's record and a written directive is prepared within 48 hours of the oral directive.
- 524 7.11.4 A written revision to an existing written directive may be made provided that the revision is dated  
525 and signed by an authorized user prior to the administration of the dosage of radioactive drug  
526 containing radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery  
527 dose, the teletherapy dose, or the next fractional dose.
- 528 7.11.5 If, because of the patient's condition, a delay in order to provide a written revision to an existing  
529 written directive would jeopardize the patient's health, an oral revision to an existing written  
530 directive will be acceptable, provided that the oral revision is documented as soon as possible in  
531 the patient's record and a revised written directive is signed by the authorized user within 48  
532 hours of the oral revision.
- 533 7.11.6 The licensee shall retain a copy of each written directive and/or written revision to an existing  
534 written directive for 3 years.
- 535 **7.12 Procedures for Administrations Requiring a Written Directive.**
- 536 7.12.1 For any administration requiring a written directive, the licensee shall develop, implement, and  
537 maintain written procedures to provide high confidence that:
- 538 7.12.1.1 The patient's or human research subject's identity is verified before each administration;  
539 and
- 540 7.12.1.2 Each administration is in accordance with the written directive.
- 541 7.12.2 The procedures required by 7.12.1 must, at a minimum, address the following items that are  
542 applicable for the licensee's use of radioactive material:
- 543 7.12.2.1 Verifying the identity of the patient or human research subject;
- 544 7.12.2.2 Verifying that the specific details of the administration are in accordance with the  
545 treatment plan, if applicable, and the written directive;

**Comment [JJ17]:** Language added consistent with 10 CFR 35.40(b)(3).

[This change arose as a result of NRC review and comments on 2010 CRCPD SSR Draft Part G.]

NRC Compatibility = H&S

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- 546 7.12.2.3 Checking both manual and computer-generated dose calculations; and
- 547 7.12.2.4 Verifying that any computer-generated dose calculations are correctly transferred into
- 548 the consoles of therapeutic medical units authorized by 7.48

**7.13 Duties of Authorized User and Authorized Medical Physicist.**

- 550 7.13.1 A licensee shall assure that only authorized users for the type of radioactive material used:
  - 551 7.13.1.1 Prescribe the radiopharmaceutical dosage and/or dose to be administered through the
  - 552 issuance of a written directive or reference to the diagnostic clinical procedures manual;
  - 553 and
  - 554 7.13.1.2 Direct, as specified in 7.10 and 7.12, or in license conditions, the administration of
  - 555 radioactive material for medical use to patients or human research subjects;
  - 556 7.13.1.3 Prepare and administer, or supervise the preparation and administration of radioactive
  - 557 material for medical use, in accordance with 7.3.2, 7.3.3 and 7.10;

558 ~~7.13.1.4 Perform the final interpretation of the results of tests, studies, or treatments.~~

559 7.13.2 A licensee shall assure that only authorized medical physicists perform, as applicable:

- 560 **7.13.2.1 Measurements and calculations as described in 7.41;**
- 561 7.13.2.2 Full calibration measurements as described in 7.54, 7.55, and 7.56;
- 562 7.13.2.3 Periodic spot checks as described in 7.58, 7.59 and 7.61; and
- 563 7.13.2.4 Radiation surveys as described in 7.57.

**7.14 Suppliers for Sealed Sources or Devices for Medical Use.**

565 For medical use, a licensee shall use only:

- 566 7.14.1 Sealed sources or devices ~~initially~~ manufactured, labeled, packaged, and distributed in
- 567 accordance with a license issued pursuant to **Part 3 of these regulations** or the equivalent
- 568 regulations of another Agreement State, a Licensing State or the NRC; ~~and~~
- 569 7.14.2 **Sealed source or devices non-commercially transferred from a Part 7 licensee or an**
- 570 **Agreement State medical use licensee; or**
- 571 ~~7.14.3~~ Teletherapy sources manufactured and distributed in accordance with a license issued pursuant
- 572 to **Part 3 of** these regulations, or the equivalent regulations of another Agreement State, a
- 573 Licensing State, or the NRC.

**SPECIFIC REQUIREMENTS**

**7.15 Quality Control of Diagnostic Equipment.**

- 576 **7.15.1** Each licensee shall establish written quality control procedures for all diagnostic equipment used
- 577 for radionuclide studies.
- 578 **7.15.2** As a minimum, quality control procedures and frequencies shall be:

**Comment [JJ18]:** This provision is deleted at the recommendation of Radiation Control Program Staff, as it is not consistent with 10 CFR Part 35. This proposed change will no longer require an authorized user to perform the final interpretation of scans and related procedures.

The training requirements for authorized users in the Appendices of this part do not reference interpretation of tests, studies, or treatments or require any specific training related to interpretation. It is believed that retaining this provision may cross, at least in part, into the practice of medicine which is not within the purview of the Department, nor directly radiation safety related.

**Comment [JJ19]:** This new provision was added at the request of a licensee medical physicist. This does not add any new requirement – it repeats and clarifies/re-states what is already required by 7.41.

**Comment [JJ20]:** Deleted “initially” based on NRC review and comment.

**Comment [O21]:** Typo error.

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**Comment [O22]:** Changes to 7.14 added for consistency with 10 CFR 35.49.

NRC Comments, November 2011  
[NRC RATS 2006-1, Compatibility C]

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**Comment [JJ23]:** Numbers added to this section for ease of use.

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- 579           **7.15.2.1** ~~T~~Those recommended by equipment manufacturers; or
- 580           **7.15.2.2** ~~P~~Procedures which have been approved by the Department.
- 581           **7.15.3** The licensee shall conduct quality control of diagnostic equipment in accordance with written  
582           procedures.
- 583           **7.15.4** A licensee shall retain a record of each quality control test required by the written quality  
584           control procedures for 3 years.
- 585           **7.16 Possession, Use, and Testing of Instruments to Measure the Activity of Unsealed**  
586           **Radioactive Materials.**
- 587           7.16.1 For direct measurements performed in accordance with 7.18, a licensee shall possess and use  
588           instrumentation to measure the activity of unsealed radioactive materials prior to administration to  
589           each patient or human research subject.
- 590           7.16.2 A licensee shall ~~test~~ **calibrate** the instrumentation required in 7.16.1 in accordance with nationally  
591           recognized standards or the manufacturer's instructions.
- 592           7.16.3 **In addition to the calibration** ~~The tests~~ required in 7.16.2, **the licensee** shall at a minimum  
593           **include also perform** tests for constancy, linearity, ~~accuracy~~ and geometry dependence, as  
594           appropriate to demonstrate proper operation of the ~~instrument~~.
- 595           7.16.4 A licensee shall retain a record of each instrument ~~test~~ **calibration** **and test** required by 7.16 for 3  
596           years. The record shall include the:
- 597           7.16.4.1 Model and serial number of the instrument;
- 598           7.16.4.2 Date of the calibration **and other tests**;
- 599           7.16.4.3 Results of the calibration **and other tests**; and
- 600           7.16.4.4 Name of the individual who performed the calibration **and other tests**.
- 601           **7.17 Calibration of Survey Instruments.**
- 602           7.17.1 A licensee shall ensure that the survey instruments used to show compliance with Part 4 and Part  
603           7 have been calibrated before first use, annually, and following any repair that will affect the  
604           calibration.
- 605           7.17.2 To satisfy the requirements of 7.17.1 the licensee shall:
- 606           7.17.2.1 Calibrate all required scale readings up to 10 mSv (1 rem) per hour with a radiation  
607           source;
- 608           7.17.2.2 Have each radiation survey instrument calibrated as follows, or by acceptable  
609           equivalent methods:
- 610           (1) At energies appropriate for use and at intervals not to exceed 12 months or after  
611           instrument servicing, except for battery changes;
- 612           (2) For linear scale instruments, at 2 points located approximately one-third and two-  
613           thirds of full-scale on each scale;

**Comment [JJ24]:** This is a new requirement. This new requirement is added at the suggestion of Radioactive Materials Unit staff. A requirement for performing quality control in accordance with written procedures is less meaningful and effective if there are no requirements related to recordkeeping and is the basis for this added requirement. Only the recordkeeping requirement is new. The timeframe of 3 years is consistent with other recordkeeping requirements of this Part.

**Comment [JJ25]:** This and subsequent sections changed to be consistent with 10 CFR Part 35.60(b).  
  
[Item identified in NRC comments dated April 1, 2010 SSR Part G draft.]  
(Compatibility = H&S)

**Comment [JJ26]:** Radioactive Materials Unit staff believe that this provision serves as a useful reminder of the tests necessary to maintain instruments that are used for determining the radioactive material dose prior to administration to the patient. Technologists are in the routine habit of performing such activities, and thus it is not considered a new practice. The requirements of this provision reiterate what is already in national standards. Additionally, it was necessary to change the wording of this section to be consistent with 7.16.2 and 7.16.4.

**Comment [JJ27]:** This and other items in this section changed to be consistent with 10 CFR Part 35.60(c).  
  
Item identified in NRC comments to CRCPD dated April 1, 2010 regarding SSR Part G draft.  
(Compatibility = H&S)

**Comment [JJ28]:** Additional wording is added for clarification and to be consistent with other changes in Section 7.16. (See other prior comments)

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- 614 (3) For logarithmic scale instruments, at mid-range of each decade and at 2 points of at  
615 least one decade;
- 616 (4) For digital instruments, at 3 points between 0.02 and 10 mSv (2 and 1000 mrem) per  
617 hour; and
- 618 (5) For dose rate instruments, so that an accuracy within plus or minus 20 percent of the  
619 true radiation dose rate can be demonstrated at each point checked.

620 7.17.2.3 Conspicuously note on the instrument the date of calibration.

621 7.17.3 The licensee shall not use survey instruments if the difference between the indicated exposure  
622 rate and the calculated exposure rate is greater than 20 percent.

623 7.17.4 The licensee shall retain a record of each survey instrument calibration required by 7.17 for 3  
624 years. The record shall include the:

625 7.17.4.1 Model and serial number of the instrument;

626 7.17.4.2 Date of the calibration;

627 7.17.4.3 Results of the calibration; and

628 7.17.4.4 Name of the individual who performed the calibration.

629 **7.18 Determination of Dosages of Radioactive Material for Medical Use.**

630 7.18.1 A licensee shall determine and record the activity of each dosage prior to medical use.

631 7.18.1.1 For photon-emitting radioactive material, this determination shall be within 30 minutes  
632 prior to medical use.

633 7.18.1.2 For all other radioactive material, this determination shall be within the period before  
634 medical use that is no greater than 10 percent of the physical half-life of the radioactive  
635 material.

636 7.18.2 For a unit dosage, the determination **required** by 7.18.1 shall be made **either** by:

637 **7.18.2.1** direct measurement of **radioactivity**; or

638 **7.18.2.2** **by**-a decay correction, based on the measurement made by:

639 **(1)** a manufacturer or preparer licensed pursuant to Part 3 of these regulations or  
640 equivalent provisions of another Agreement State, **a Licensing State** or NRC; **or**.

641 **(2) an NRC or Agreement State licensee for use in research in accordance with a**  
642 **Radioactive Drug Research Committee-approved protocol or an Investigational New Drug**  
643 **(IND) protocol accepted by FDA.**

644 7.18.3 For other than a unit dosage, the determination by 7.18.1 shall be made by:

645 **7.18.3.1** direct measurement of radioactivity; or

646 **7.18.3.2** by a combination of measurements of radioactivity and mathematical calculations; or

**Comment [JJ29]:** Added for clarity.

**Comment [JJ30]:** Language added consistent with 10 CFR 35.63.

**Comment [O31]:** Language added consistent with 10 CFR 35.63.  
NRC RATS ID=2007-3; Compatibility = H&S

**Comment [JJ32]:** Formatting of 7.18.3 changed to be consistent with 10 CFR 35.63(c)(3) and 7.18.2 format.  
NRC RATS ID=2007-3; Compatibility = H&S

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647 **7.18.3.3** by a combination of volumetric measurements and mathematical calculations, based on  
648 the measurement made by:

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649 **(1)** a manufacturer or preparer licensed pursuant to Part 3 of these regulations or  
650 equivalent provisions of another Agreement State, a Licensing State or NRC.

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651 7.18.4 Unless otherwise directed by the authorized user, a licensee shall not use a dosage if the dosage  
652 differs from the prescribed dosage by more than 20 percent.

653 7.18.5 A license shall retain a record of the each dosage determination required by 7.18.1 for 3 years.  
654 The record shall contain the:

655 7.18.5.1 Name of the radioactive drug;

656 7.18.5.2 Patient's or human research subject's name, and identification number if one has been  
657 assigned;

658 7.18.3.3 Prescribed dosage;

659 7.18.3.4 Determined dosage; or a notation that the total activity is less than 1.1 MBq (30 µCi);

660 7.18.3.5 Date and time of the dosage determination; and

661 7.18.3.6 Name of the individual who determined the dosage.

662 **7.19 Authorization for Calibration, Transmission and Reference Sources.**

663 Any person authorized by 7.3 for medical use of radioactive material may receive, possess, and  
664 use the following radioactive material for check, calibration and reference use:

665 7.19.1 Sealed sources manufactured and distributed by persons specifically licensed pursuant to Part 3  
666 of these regulations or equivalent provisions of the another Agreement State, a Licensing State,  
667 or NRC, and that do not exceed 1.1 GBq (30 mCi) each;

668 7.19.2 Any radioactive material with a half-life not longer than 120 days or less in individual amounts not  
669 to exceed 0.55 GBq (15 mCi);

670 7.19.3 Any radioactive material with a half life greater than 120 days in individual amounts not to exceed  
671 the smaller of:

672 7.19.3.1 7.4 MBq (200 µCi);

673 7.19.3.2 1000 times the quantities in ~~Appendix Part 3~~ **Schedule 3B**; and

Comment [JJ33]: Wording changed to "Schedule" consistent with April 2011 changes to Part 3.

674 7.19.4 Technetium-99m in amounts as needed.

675 **7.20 Requirements for Possession of Sealed Sources and Brachytherapy Sources.**

676 7.20.1 A licensee in possession of any sealed source or brachytherapy source shall follow the radiation  
677 safety and handling instructions supplied by the manufacturer or equivalent instructions approved  
678 by the Department and shall maintain the instructions for the duration of source use in a legible  
679 form convenient to users.

680 7.20.2 A licensee in possession of a sealed source shall test the source for leakage:

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681 7.20.2.1 In accordance with Part 4 of these regulations; and  
682 7.20.2.2 At intervals not to exceed 6 months or at intervals approved by the Department, another  
683 Agreement State, a Licensing State or the NRC in the Sealed Source and Device  
684 Registry.

685 **7.20.3 To satisfy the leak test requirements of 7.20, the licensee shall measure the sample so that**  
686 **the leak test can detect the presence of 185 Bq (0.005 uCi) of radioactive material in the**  
687 **sample.**

**Comment [JJ34]:** This section revised to be consistent with 10 CFR 35.67(c). This clarifies that the measurement method for the leak test must be capable of measuring 185 Bq.

[This item was identified in NRC comments to CRCPD dated April 1, 2010 pertaining to SSR Part G 2010 draft.]

(Compatibility = H&S)

688 7.20.43 If the leak test reveals the presence of 0.005 microcurie (185 Bq) or more of removable  
689 contamination, the licensee shall:

690 7.20.43.1 Immediately withdraw the sealed source from use and store, dispose or cause it to be  
691 repaired in accordance with the requirements of these regulations; and

692 7.20.43.2 File a written report with the Department within 5 days of receiving the leak test result,  
693 including the model number and serial number, if assigned, of the leaking source, the  
694 radionuclide and its estimated activity, the date and results of the test, and the action  
695 taken.

696 7.20.54 A licensee in possession of a sealed source or brachytherapy source, except for a gamma  
697 stereotactic radiosurgery source, shall conduct a semi-annual physical inventory of all such  
698 sources. The licensee shall retain each inventory record ~~for~~ 3 years. The inventory records shall  
699 contain the model number of each source, and serial number if one has been assigned, the  
700 identity of each source radionuclide and its estimated activity, the location of each source, and  
701 the name of the individual who performed the inventory.

**Comment [JJ35]:** Error correction – deletion of extra spaces.

702 **7.21 Reports and Notifications of Misadministrations.**

703 7.21.1 Other than events that result from intervention by a patient or human research subject, a licensee  
704 shall report any event in which the administration of radioactive material or radiation from  
705 radioactive material results in:

706 7.21.1.1 A dose that differs from the prescribed dose by more than 0.05 Sv (5 rem) effective  
707 dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose  
708 equivalent to the skin; and either

709 (1) The total dose delivered differs from the prescribed dose by 20 percent or more;

710 (2) The total dosage delivered differs from the prescribed dosage by 20 percent or more  
711 or falls outside the prescribed dosage range; or

712 (3) The fractionated dose delivered differs from the prescribed dose, for a single fraction,  
713 by 50 percent or more.

714 7.21.1.2 A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an  
715 organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the  
716 following:

717 (1) An administration of a wrong radioactive drug;

718 (2) An administration of a radioactive drug containing radioactive material by the wrong  
719 route of administration;

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- 720 (3) An administration of a dose or dosage to the wrong individual or human research  
721 subject;
- 722 (4) An administration of a dose or dosage delivered by the wrong mode of treatment; or
- 723 (5) A leaking sealed source.
- 724 7.21.1.3 A dose to the skin or an organ or tissue other than the treatment site that exceeds by  
725 0.5 Sievert (50 rem) to an organ or tissue and 50 percent of the dose expected from the  
726 administration defined in the written directive (excluding, for permanent implants, seeds  
727 that were implanted in the correct site but migrated outside the treatment site).
- 728 7.21.2 A licensee shall report any event resulting from intervention of a patient or human research  
729 subject in which the administration of radioactive material or radiation from radioactive material  
730 results, or will result in, unintended permanent functional damage to an organ or a physiological  
731 system, as determined by a physician.
- 732 7.21.3 The licensee shall notify the Agency by telephone no later than the next calendar day after  
733 discovery of the misadministration.
- 734 7.21.4 The licensee shall submit a written report to the Agency within 15 days after discovery of the  
735 misadministration.
- 736 7.21.4.1 The written report must include:
- 737 (1) The licensee's name;
- 738 (2) The name of the prescribing physician;
- 739 (3) A brief description of the event;
- 740 (4) Why the event occurred;
- 741 (5) The effect, if any, on the individual(s) who received the administration;
- 742 (6) Actions, if any, that have been taken, or are planned, to prevent recurrence;
- 743 (7) Certification that the licensee notified the individual (or the individual's responsible  
744 relative or guardian), and if not, why not.
- 745 7.21.4.2 The report may not contain the individual's name or any other information that could  
746 lead to identification of the individual.
- 747 7.21.5 The licensee shall provide notification of the misadministration to the referring physician and also  
748 notify the individual who is the subject of the misadministration no later than 24 hours after its  
749 discovery, unless the referring physician personally informs the licensee either that he or she will  
750 inform the individual or that, based on medical judgment, telling the individual would be harmful.  
751 The licensee is not required to notify the individual without first consulting the referring physician.  
752 If the referring physician or the affected individual cannot be reached within 24 hours, the  
753 licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any  
754 appropriate medical care for the individual, including any necessary remedial care as a result of  
755 the misadministration, because of any delay in notification. To meet the requirements of this  
756 paragraph, the notification of the individual who is the subject of the misadministration may be  
757 made instead to that individual's responsible relative or guardian. If a verbal notification is made,  
758 the licensee shall inform the individual, or appropriate responsible relative or guardian, that a

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759 written description of the event can be obtained from the licensee upon request. The licensee  
760 shall provide such a written description if requested.

761 7.21.6 Aside from the notification requirement, nothing in this section affects any rights or duties of  
762 licensees and physicians in relation to each other, to individuals affected by the  
763 misadministration, or to that individual's responsible relatives or guardians.

764 7.21.7 A licensee shall retain a record of a misadministration for 3 years. The record must contain:

765 7.21.7.1 The licensee's name;

766 7.21.7.1 Names of the individuals involved;

767 7.21.7.1 The social security number or other identification number if one has been assigned, of  
768 the individual who is the subject of the misadministration;

769 7.21.7.1 A brief description of the event and why it occurred;

770 7.21.7.1 The effect, if any, on the individual;

771 7.21.7.1 The actions, if any, taken, or planned, to prevent recurrence; and

772 7.21.7.1 Whether the licensee notified the individual (or the individual's responsible relative or  
773 guardian) and, if not, whether such failure to notify was based on guidance from the  
774 referring physician.

775 7.21.8 A copy of the record required under 7.21.7 shall be provided to the referring physician if other than  
776 the licensee, within 15 days after discovery of the misadministration.

777 **7.22 Notification to the Department of Deceased Patients or Human Research Subjects**  
778 **Containing Radioactive Material.**

779 7.22.1 The licensee shall notify the Department by telephone immediately upon discovery that a patient  
780 or human research subject containing radioactive material has died, and it is possible that any  
781 individual could receive exposures in excess of 4.14 as a result of the deceased's body.

782 7.22.2 The licensee shall submit a written report to the Department within 30 days after discovery that  
783 the patient or human research subject referenced in 7.22.1 has died. The written report must  
784 include the:

785 7.22.2.1 Licensee's name;

786 7.22.2.2 Date of death;

787 7.22.2.3 Radionuclide, chemical and physical form and calculated activity at time of death; and

788 7.22.2.4 Names (or titles) and address(es) of known individuals who might have received  
789 exposures exceeding 5 mSv (500 mrem).

790 7.22.3 The licensee shall retain a record of each written report required by 7.22 for 3 years.

791 **7.23 Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child.**

792 7.23.1 A licensee shall report any dose to an embryo/fetus that is greater than 5 mSv (500 mrem) dose  
793 equivalent that is a result of an administration of radioactive material or radiation from radioactive

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- 794 material to a pregnant individual unless the dose to the embryo/fetus was specifically approved,  
795 in advance, by the authorized user.
- 796 7.23.2 A licensee shall report any dose to a nursing child, that was not specifically approved, in advance,  
797 by the authorized user, that is a result of an administration of radioactive material to a breast  
798 feeding individual that:
- 799 7.23.2.1 Is greater than 5 millisievert (500 mrem) total effective dose equivalent; or
- 800 7.23.2.2 Has resulted in unintended permanent functional damage to an organ or a physiological  
801 system of the child, as determined by a physician.
- 802 7.23.3 The licensee shall notify by telephone the Agency no later than the next calendar day after  
803 discovery of a dose to the embryo/fetus or nursing child that requires a report in 7.23.1 or 7.23.2.
- 804 7.23.4 The licensee shall submit a written report to the Agency within 15 days after discovery of a dose  
805 to the embryo/fetus or nursing child that requires a report in 7.23.1 or 7.23.2.
- 806 7.23.4.1 The written report must include:
- 807 (1) The licensee's name;
- 808 (2) The name of the prescribing physician;
- 809 (3) A brief description of the event;
- 810 (4) Why the event occurred;
- 811 (5) The effect on the embryo/fetus or the nursing child;
- 812 (6) What actions, if any, have been taken, or are planned, to prevent recurrence; and
- 813 (7) Certification that the licensee notified the pregnant individual or mother (or the  
814 mother's or child's responsible relative or guardian), and if not, why not.
- 815 7.23.4.2 The report must not contain the individual's or child's name or any other information that  
816 could lead to identification of the individual or child.
- 817 7.23.5 The licensee shall notify the referring physician and also notify the pregnant individual or mother,  
818 both hereafter referred to as the mother, no later than 24 hours after discovery of an event that  
819 would require reporting under 7.23.1 or 7.23.2, unless the referring physician personally informs  
820 the licensee either that he or she will inform the mother or that, based on medical judgment,  
821 telling the mother would be harmful. The licensee is not required to notify the mother without first  
822 consulting with the referring physician. If the referring physician or mother cannot be reached  
823 within 24 hours, the licensee shall make the appropriate notifications as soon as possible  
824 thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for  
825 the nursing child, including any necessary remedial care as a result of the event, because of any  
826 delay in notification. To meet the requirements of this paragraph, the notification may be made to  
827 the mother's or child's responsible relative or guardian instead of the mother, when appropriate. If  
828 a verbal notification is made, the licensee shall inform the mother, or the mother's or child's  
829 responsible relative or guardian, that a written description of the event can be obtained from the  
830 licensee upon request. The licensee shall provide such a written description if requested.
- 831 7.23.6 A licensee shall retain a record of a dose to an embryo/fetus or a nursing child for 3 years. The  
832 record must contain:

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- 833 7.23.6.1 The licensee's name;
- 834 7.23.6.2 Names of all the individuals involved;
- 835 7.23.6.3 Social security number or other identification number if one has been assigned to the  
836 pregnant individual or nursing child who is the subject of the event;
- 837 7.23.6.4 A brief description of the event and why it occurred;
- 838 7.23.6.5 The effect, if any, on the embryo/fetus or nursing child;
- 839 7.23.6.6 The actions, if any, taken, or planned, to prevent recurrence; and
- 840 7.23.6.7 Whether the licensee notified the pregnant individual or mother (or the mother's or  
841 child's responsible relative or guardian) and, if not, whether such failure to notify was  
842 based on guidance from the referring physician.
- 843 7.23.7 A copy of the record required under 7.23.6 shall be provided to the referring physician, if other  
844 than the licensee, within 15 days after discovery of the event.

845 **7.24 Vial Shields and Labels.**

- 846 7.24.1 A licensee shall require each individual preparing or handling a vial that contains a  
847 radiopharmaceutical to keep the vial in a vial radiation shield.
- 848 7.24.2 Each syringe and vial that contains a radioactive drug shall be labeled to identify the radioactive  
849 drug, to include the isotope and amount of radioactivity. Each syringe shield and vial shield shall  
850 also be labeled unless the label on the syringe or vial is visible when shielded.

851 **7.25 Surveys for Contamination and Ambient Radiation Dose-Exposure Rate.**

852 **7.25.1 Surveys required by 7.25.2 and 7.25.3 are in addition to surveys required by Part 4.**

853 **7.25.2 Daily Survey Requirements**

854 **7.25.2.1** ~~Except as provided in 7.25.2, a~~ At the end of each day of use, a licensee shall survey,  
855 with an **exposure rate radiation detection** instrument, all areas where radioactive drugs  
856 containing radioactive material requiring a written directive were prepared for use or  
857 administered.

**(1) A licensee does not need to perform the surveys required by 7.25.2.1 in  
an area where patients or human research subjects are confined when they  
cannot be released pursuant to 7.26.**

861 **7.25.2.2** At the end of each day of use, a licensee shall survey for removable contamination  
862 all areas where generators and bulk radioactive drugs are prepared for use. An  
863 instrument capable of detecting **33.3 becquerels (2000 dpm)** of contamination on  
864 each wipe sample shall be used.

865 **7.25.3 Weekly Survey Requirements**

866 **7.25.3.1** At least once each week, a licensee shall survey, with an **n radiation detection exposure**  
867 **rate** instrument, all areas where radioactive drugs or radioactive wastes are stored.

**Comment [JJ36]:** Language change based on 10 CFR 35.70 and 2010 Draft SSR G.39. Language pertaining to contamination surveys from 2003 SSR Part G has been retained.

The proposed changes in this section do not change or increase the regulatory requirements for surveys.

**Comment [JJ37]:** Subsection header added for clarity.

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**Comment [JJ38]:** Language in this section is modified to add clarity and maintain compatibility with 10 CFR 35.70. The more explicit requirements of the current Part 7 are retained.

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**Comment [JJ39]:** Added SI units based on stakeholder comments.

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**Comment [JJ40]:** Subsection header added for clarity.

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868 **7.25.3.2 At least once each week, a licensee shall survey for removable contamination in**  
869 **all areas where radioactive materials other than sealed sources as defined in Part 7**  
870 **are stored. An instrument capable of detecting 33.3 becquerels (2000 dpm) of**  
871 **contamination on each wipe sample shall be used.**

**Comment [JJ41]:** Added SI units based on stakeholder comments.

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872 ~~7.25.3 A licensee shall conduct the surveys required by 7.25.1 and 7.25.2 using an instrument capable of~~  
873 ~~measuring dose rates as low as 1 μSv (0.1 mrem) per hour.~~

874 7.25.4 A licensee shall establish ~~dose rate~~ action levels for the surveys required by 7.25.24 and 7.25.23  
875 and shall require that the individual performing the survey immediately notify the Radiation Safety  
876 Officer if ~~a dose rate exceeds an~~ action levels **are exceeded**.

877 ~~7.25.5 Each day of use a licensee shall survey for removable contamination all areas where generators~~  
878 ~~and bulk radioactive drugs are prepared for use.~~

879 ~~7.25.6 Each week the licensee shall perform removable contamination surveys in all areas where~~  
880 ~~radioactive materials other than sealed sources as defined in Part 7 are stored.~~

881 ~~7.25.7 For the surveys required by 7.25.5 and 7.25.6, the licensee shall:~~

882 ~~7.25.7.1 Use instrumentation capable of detecting contamination on each wipe sample of 33.3~~  
883 ~~Bq (2000 disintegrations per minute);~~

884 ~~7.25.7.2 Establish removable contamination action levels; and~~

885 ~~7.25.7.3 Require that the individual performing the survey immediately notify the Radiation~~  
886 ~~Safety Officer if contamination exceeds action levels.~~

887 ~~7.25.8 A licensee does not need to perform the surveys required by 7.25.1 in an area where patients or~~  
888 ~~human research subjects are confined when they cannot be released pursuant to 7.26.~~

889 **7.25.59** A licensee shall retain a record of each survey required by 7.25.1, 7.25.2 and 7.25.36 for 3  
890 years. The record must include:

**Comment [JJ42]:** This section modified for clarity/formatting only.

891 **7.25.5.1** The date of the survey;

892 **7.25.5.2** The results of the survey;

893 **7.25.5.3** The instrument used to make the survey (including, if applicable, that the instrument  
894 was checked for consistent response with a dedicated check source prior to each daily  
895 use); and

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896 **7.25.5.4** The name of the individual who performed the survey.

897 **7.26 Release of Individuals Containing Radioactive Drugs or Implants.**

**Comment [JJ43]:** The changes to Section 7.26 will reduce the regulatory burden on licensees.

898 7.26.1 A licensee may authorize the release from the licensee's control of any individual who has been  
899 administered radioactive drugs or permanent implants containing radioactive material if the total  
900 effective dose equivalent to any other individual from exposure to the released individual is not  
901 likely to exceed 5 mSv (0.5 rem).<sup>1</sup>

902 <sup>1</sup> Appendix U of U.S. Nuclear Regulatory Commission NUREG-1556, Vol. 9, "Consolidated Guidance About Materials  
903 Licenses: Program Specific Guidance About Medical Licenses" describes methods for calculating doses to  
904 other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem).

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**Comment [JJ44]:** Revised language of footnote to be consistent with 10 CFR Part 35.75.

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905 7.26.2 ~~Instructions to Individuals:~~ **A licensee shall provide the released individual or the individual's**  
906 **parent or guardian with instructions, including written instructions on the actions**  
907 **recommended to maintain doses to other individuals as low as is reasonably achievable if**  
908 **the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1**  
909 **rem).**

**Comment [JJ45]:** Language from prior 7.26.2.1 plus additional language from 10 CFR 35.75.

910 ~~7.26.2.1 A licensee shall provide the released individual, or the individual's parent or guardian,~~  
911 ~~with oral and written safety instructions on actions recommended to maintain doses to~~  
912 ~~other individuals as low as is reasonably achievable.~~

**Comment [JJ46]:** Additional language added consistent with the approach used in 10 CFR Part 35.75. This adds a threshold below which oral and written safety instructions are no longer necessary.

913 7.26.2.12 ~~If the total effective dose equivalent to a breast-feeding-nursing~~ infant or child could  
914 ~~exceed 1 mSv (0.1 rem) assuming there were no interruption in breast-~~  
915 ~~feeding, receive a radiation dose as a result of the release of the patient, the~~ instructions  
916 shall also include:

*As a result of the added language, the proposed change reduces the regulatory burden on the licensee. This is a reversal of what is currently written in the regulations, but is consistent with what most other Agreement States and NRC have in their regulations and is consistent with what the Department has had in the past, prior to the 2005 revision of Part 7. The Department has determined that the requirements added in 2005 are likely not significantly justified from a radiation safety standpoint.*

917 (1) Guidance on the interruption or discontinuation of breast-feeding; and

918 (2) Information on the **potential** consequences, **if any**, of failure to follow the guidance.

919 **7.26.3 If the total effective dose equivalent to a nursing infant or child could exceed 5 mSv (0.5**  
920 **rem) from continued breast-feeding, the licensee shall maintain a record that the instructions**  
921 **required by 7.26.2 were provided to a breast-feeding woman.**

**Comment [JJ47]:** JJ 6/20/2011: The revised language is consistent with 10 CFR 35.75. The added language places a threshold below which instructions to the patient would not be required.

922 ~~7.26.3 Release of the patient must be approved by an individual listed as an authorized user on the~~  
923 ~~license from the Department who is approved for the type of radioactive material use in the patient being~~  
924 ~~released.~~

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925 7.26.4 The licensee shall maintain a record **of the basis for authorizing the release of an individual in**  
926 **accordance with 7.26, if the total effective dose equivalent is calculated by;** ~~signed by the~~  
927 ~~authorized user, for 3 years after the date of release, of:~~

**Comment [JJ48]:** 8/18/2011: New language added to 7.26.3 that is consistent with 10 CFR 35.2075(b) and SSR G (2010 draft).

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928 ~~7.26.4.1 The basis for authorizing the release of an individual~~

**Comment [JJ49]:** 8/17/2011: Elimination of this requirement is consistent with 10 CFR Part 35.75 and based on Radioactive Materials Unit staff direction.

929 **7.26.4.1 Using the retained activity rather than the administered activity;**

930 **7.26.4.2 Using an occupancy factor less than 0.25 at 1 meter;**

931 **7.26.4.3 Using the biological or effective half-life; and**

932 **7.26.4.4 Considering the shielding by tissue;** ~~and~~

**Comment [JJ50]:** 8/18/2011: New language added to 7.26.4 that is consistent with 10 CFR 35.2075(a) and SSR G (2010 draft).

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933 ~~7.26.4.2 Instructions that were provided to a breast-feeding woman.~~

934 **7.26.5 The records required by 7.26.3 and 7.26.4 must be retained for 3 years after the date of**  
935 **release of the individual.**

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**Comment [JJ51]:** Recordkeeping requirement consistent with 10 CFR 35.2075.

936 7.26.6 ~~5~~ Reports of Patient Departure Prior to Authorized Release.

937 7.26.6.1 The licensee shall notify the Department by telephone immediately upon discovery that  
938 a patient or human research subject has departed from the licensee's facility without  
939 authorization under 7.26.

940 7.26.6.2 The licensee shall submit a written report to the Department within 30 days after  
941 discovery of the unauthorized departure. The written report must include:

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- 942 (1) The licensee's name;
- 943 (2) The date and time of the unauthorized departure;
- 944 (3) The projected date and time when release would have occurred;
- 945 (4) The address of the patient's or human research subject's home or anticipated  
946 destination following departure;
- 947 (5) The radionuclide, chemical and physical form and calculated activity at time of  
948 release;
- 949 (6) The apparent reason(s) for the departure prior to authorized release; and
- 950 (7) A description of any changes in the licensee's patient release criteria or patient  
951 instructions that are designed to avoid a recurrence of such an event.

952 **7.27 Mobile Nuclear Medicine Service Technical Requirements.**

953 A licensee providing mobile nuclear medicine service shall:

- 954 7.27.1 Transport to each client's address of use only syringes or vials containing prepared drugs or  
955 radioactive materials that are intended for reconstitution of radioactive drug kits;
- 956 7.27.2 Bring into each client's address of use all radioactive material to be used and, before leaving,  
957 remove all unused radioactive material and associated radioactive waste;
- 958 7.27.3 Secure or keep under constant surveillance and immediate control all radioactive material when in  
959 transit or at a client's address of use;
- 960 7.27.4 Check instruments used to measure the activity of unsealed radioactive material for proper  
961 function before medical use at each client's address or on each day of use, whichever is more  
962 frequent. At a minimum, the check for proper function shall include a constancy check;
- 963 7.27.5 Check survey instruments for consistent response with a dedicated check source before use at  
964 each client's address;
- 965 7.27.6 Prior to leaving a client's address of use, perform area surveys and survey for removable  
966 contamination in all areas of use, to ensure compliance with Part 4 of these regulations; **and**
- 967 ~~7.27.7 Use radioactive gases only in areas of use and under conditions which have been evaluated and  
968 approved by the Department for compliance with airborne release standards; and~~
- 969 7.27.7~~8~~ Retain a record of each survey required by 7.27.6 for 3 years. The record must include the date  
970 of the survey, the results of the survey, the instrument used to make the survey, and the name of  
971 the individual who performed the survey.

**Comment [JJ52]:** This provision is adequately addressed in Section 7.34 and other provisions and is therefore deleted from section 7.27.

972 **7.28 Storage of Volatiles and Gases.**

- 973 7.28.1 A licensee shall store volatile radioactive materials and radioactive gases in a radiation shield and  
974 container.
- 975 7.28.2 A licensee shall store and use a multi-dose container in a properly functioning fume hood.

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976 7.28.3 A licensee who administers radioactive aerosols or gases shall do so with a system that will keep  
977 airborne concentrations within the limits prescribed in Part 4 of these regulations.

978 7.28.3.1 The system shall either be directly vented to the atmosphere through an air exhaust or  
979 provide for collection and decay or disposal of the aerosol or gas in a shielded container.

980 7.28.3.2 A licensee shall check the operation of collection systems monthly. Records of these  
981 checks shall be maintained for 3 years.

982 **7.29 Decay-In-Storage.**

983 7.29.1 A licensee may hold radioactive material with a physical half-life of less than ~~or equal to~~  
984 for decay-in-storage before disposal without regard for its radioactivity if the licensee:

**Comment [JJ53]:** Correction to clarify and match 35.92 per NRC comments – Nov 2011. [RATS 2007-1; Compatibility H&S; 35.92]

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985 7.29.1.1 Monitors radioactive material at the container surface before disposal and determines  
986 that its radioactivity cannot be distinguished from the background radiation level with a  
987 radiation detection survey instrument set on its most sensitive scale and with no  
988 interposed shielding;

989 7.29.1.3 Removes or obliterates all radiation labels, except for material that will be handled as  
990 biomedical waste after release; and

991 7.29.1.4 Separates and monitors each generator column individually with all radiation shielding  
992 removed to ensure that its contents have decayed to background radiation level before  
993 disposal.

994 7.29.2 Records of Decay-in-Storage.

995 For radioactive material disposed in accordance with 7.29.1, the licensee shall retain a record of  
996 each disposal for 3 years. The record must include the date of the disposal, the survey instrument  
997 used, the background radiation level, the radiation level measured at the surface of each waste  
998 container, and the name of the individual who performed the survey.

999 **SPECIFIC REQUIREMENTS FOR THE USE OF RADIOACTIVE MATERIAL FOR UPTAKE, DILUTION,  
1000 AND EXCRETION STUDIES**

1001 **7.30 Use of Unsealed Radioactive Material for Uptake, Dilution, and Excretion Studies for which a  
1002 Written Directive is Not Required.**

1003 7.30.1 A licensee may use any unsealed radioactive material, in quantities that do not require a written  
1004 directive, as described in 7.11, for a diagnostic use involving measurements of uptake, dilution, or  
1005 excretion that ~~is~~:

1006 7.30.1.1 ~~Is~~ ~~O~~btained from a manufacturer or preparer licensed pursuant to 3.12.10 or  
1007 equivalent regulations of another Agreement State, a Licensing State, or NRC; or;

1008 7.30.1.2 ~~Excluding production of PET radioactive material, is~~ ~~P~~repared by an authorized  
1009 nuclear pharmacist, a physician who is an authorized user and who meets the  
1010 requirements specified in ~~7.30.2~~ **Appendix 7E, Appendix 7F, or Appendix 7E3.1(2)(g)**,  
1011 or an individual under the supervision of either as specified in 7.10;

1012 7.30.1.3 ~~Is~~ ~~O~~btained from and prepared by a Department, Agreement State, Licensing State or  
1013 NRC licensee for use in research in accordance with a Radioactive Drug Research  
1014 Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by  
1015 FDA; or

**Comment [O54]:** Language is added consistent with 10 CFR 35.100(b). Unlike Agreement States, NRC did not previously regulate PET facilities/materials since this material was not considered byproduct material. When NRC began regulating PET materials, they added PET specific provisions. The intent of this provision is that unlike generators used by AU physicians at medical facilities, PET materials cannot be used the same way and must be generated by a facility licensed as a pharmacy/manufacturer. Similarly, a hospital based nuclear pharmacist could not prepare PET materials that is not already licensed as a PET production facility under Part 3.

[RATS 2007-3; Compatibility=H&S]

**Comment [O55]:** Language added consistent with 10 CFR 35.100(b)(2) based on NRC review of Draft 2 of Part 7.

The requirements for a physician preparing radiopharmaceuticals became more stringent, and requires a higher level of training.

NRC review – November 2011  
[RATS 2006-1; H&S]

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1016 7.30.1.4 **Is P**prepared by the licensee in accordance with a Radioactive Drug Research  
1017 Committee-approved application or an Investigational New Drug (IND) protocol accepted  
1018 by FDA for use in research.

1019 7.30.2 Authorized User Training For Uptake, Dilution, And Excretion Studies.

1020 The licensee shall require an authorized user of an unsealed radioactive material for the uses  
1021 authorized under 7.30 to meet the requirements of Appendix 7D.

1022 **7.31 Possession of Survey Instrument.**

1023 A licensee authorized to use radioactive material for uptake, dilution, and excretion studies shall  
1024 possess a portable radiation detection survey instrument capable of detecting dose rates over the  
1025 range 1.0 µSv (0.1 mrem) per hour to 500 µSv (50 mrem) per hour. The instrument shall be  
1026 operable and calibrated in accordance with 7.17.

1027 **SPECIFIC REQUIREMENTS FOR THE USE OF UNSEALED RADIOACTIVE MATERIAL - WRITTEN**  
1028 **DIRECTIVE NOT REQUIRED**

1029 **7.32 Use of Unsealed Radioactive Material for Imaging and Localization Studies for which a**  
1030 **Written Directive is Not Required.**

1031 7.32.1 A licensee may use, for imaging and localization studies, any radioactive material prepared for  
1032 medical use, in quantities that do not require a written directive, as described in 7.11, that ~~is:~~

1033 7.32.1.1 **Is O**btained from a manufacturer or preparer licensed pursuant to 3.12.10 or  
1034 equivalent regulations of another Agreement State, a Licensing State, or NRC; or;

1035 7.32.1.2 **Excluding production of PET radioactive material, is P**prepared by an authorized  
1036 nuclear pharmacist, a physician who is an authorized user and who meets the  
1037 requirements specified in ~~7.32.2~~ **Appendix 7E, or Appendix 7F and Appendix**  
1038 **7E3.1(2)(g),** or an individual under the supervision of either as specified in 7.10 ~~;~~

1039 7.32.1.3 **Is O**btained from and prepared by a Department, Agreement State, Licensing State or  
1040 NRC licensee for use in research in accordance with a Radioactive Drug Research  
1041 Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by  
1042 FDA; or

1043 7.32.1.4 **Is P**prepared by the licensee in accordance with a Radioactive Drug Research  
1044 Committee-approved application or an Investigational New Drug (IND) protocol accepted  
1045 by FDA for use in research.

1046 7.32.2 Authorized User Training for Imaging and Localization Studies for which a Written Directive is Not  
1047 Required.

1048 The licensee shall require an authorized user of an unsealed radioactive material for the uses  
1049 authorized under 7.32 to meet the requirements of Appendix 7E.

1050 **7.33 Radionuclide Contaminants.**

1051 7.33.1 A licensee shall not administer to humans a radioactive drug containing:

1052 7.33.1.1 More than 0.15 kBq of molybdenum-99 per MBq of technetium-99m (0.15 µCi of <sup>99</sup>Mo  
1053 per mCi of <sup>99m</sup>Tc).

**Comment [JJ56]:** Language is added consistent with 10 CFR 35.200(b). Unlike Agreement States, NRC did not previously regulate PET facilities/materials since this material was not considered byproduct material. When NRC began regulating PET materials, they added PET specific provisions. The intent of this provision is that unlike generators used by AU physicians at medical facilities, PET materials cannot be used the same way and must be generated by a facility licensed as a pharmacy/manufacturer. Similarly, a hospital based nuclear pharmacist could not prepare PET materials that is not already licensed as a PET production facility under Part 3.

[RATS 2007-3; Compatibility=H&S]

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**Comment [JJ57]:** Changed reference from 7.32.2 to specific sections of applicable appendices consistent with 35.200(b)(2).

NRC review – November 2011  
[RATS 2006-1; Compatibility H&S]

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1054 7.33.1.2 More than 0.02 kBq of strontium-82 per MBq of rubidium-82 chloride injection (0.02 µCi  
1055 of <sup>82</sup> Sr per mCi of <sup>82</sup> Rb chloride);

1056 7.33.1.3 More than 0.2 kBq of strontium-85 per MBq of rubidium-82 chloride injection (0.2 µCi of  
1057 <sup>85</sup> Sr per mCi of <sup>82</sup> Rb).

1058 7.33.2 To demonstrate compliance with 7.33.1, the licensee preparing radioactive drugs from  
1059 radionuclide generators shall measure the concentration of radionuclide contaminant in:

1060 7.33.2.1 ~~The first~~ Each eluate after receipt of a molybdenum-99/technetium-99m generator;

1061 7.33.2.2 Each eluate or extract, **before the first patient use of the day**, as appropriate for other  
1062 than molybdenum-99/technetium-99m generator systems.

1063 7.33.3 Records of Radionuclide Purity.

1064 A licensee who must measure radionuclide contaminant concentration shall retain a record of  
1065 each radionuclide contaminant test for 3 years. The record shall include, for each measured  
1066 elution of radionuclide used to prepare a radioactive drug, the ratio of the measures expressed as  
1067 kBq of contaminant per MBq of desired radionuclide (µCi/ mCi), the time and date of the test, and  
1068 the name of the individual who made the measurement.

1069 7.33.4 Immediate Report.

1070 A licensee shall report immediately to the Department each occurrence of radionuclide  
1071 contaminant concentration exceeding a limit specified in 7.33.1.

1072 **7.34 Aerosols and Gases.**

1073 Provided the conditions of 7.28 are met, a licensee shall use radioactive aerosols or gases only if  
1074 specific application is made to and approved by the Department.

1075 **7.35 Radiation Detection Capability.**

1076 A licensee authorized to use radioactive material pursuant to 7.32, 7.36, or 7.42 shall possess  
1077 portable radiation detection survey instrumentation capable of detecting dose rates over the  
1078 range 1.0 µSv (0.1 mrem) per hour to 500 µSv (50 mrem) per hour and over the range of 10 µSv  
1079 (1 mrem) per hour to 10 mSv (1 rem) per hour. Each instrument shall be operable and calibrated  
1080 in accordance with 7.17.

1081 **SPECIFIC REQUIREMENTS FOR THE USE OF UNSEALED RADIOACTIVE MATERIAL - WRITTEN**  
1082 **DIRECTIVE REQUIRED**

1083 **7.36 Use of Unsealed Radioactive Material for Which A Written Directive Is Required.**

1084 7.36.1 A licensee may use any unsealed radioactive material for diagnostic or therapeutic medical use  
1085 for which a written directive is required that ~~has been~~:

1086 7.36.1.1 ~~Is~~ **O**btained from a manufacturer or preparer licensed pursuant to 3.12.10 or  
1087 equivalent regulations of another Agreement State, a Licensing State, or NRC; or

1088 7.36.1.2 **Excluding production of PET radioactive material, is P**repared by an authorized  
1089 nuclear pharmacist, a physician who is an authorized user and who meets the  
1090 requirements specified in **Appendix 7E, or Appendix 7F** ~~7.36.2, 7.36.3 or 7.36.4~~, ~~—~~ or an  
1091 individual under the supervision of either as specified in 7.10;

**Comment [JJ58]:** Current Part 35 indicates that only the first eluate be evaluated. However, NRC is reconsidering this currently during proposed rulemaking for 10 CFR 35, and as a result of recent generator breakthrough incidents. Although this rulemaking process is in its early stages and proposed language has not been finalized, the general industry consensus participating in NRC stakeholder meetings is that most licensees using generators are evaluating each eluate, and is consistent with generator manufacturer recommendations. The revision to Part 7 prior to 2005 required each eluate be tested. The proposed change returns to this approach.

**Comment [JJ59]:** Clarification language added consistent with 10 CFR 35.204(c).

See NRC RATs 2007-3; 35.35.204, 30.34g. (Compatibility=D)

**Comment [JJ60]:** Language is added consistent with 10 CFR 35.300(b). Unlike Agreement States, NRC did not previously regulate PET facilities/materials since this material was not considered byproduct material. When NRC began regulating PET materials, they added PET specific provisions. The intent of this provision is that unlike generators used by AU physicians at medical facilities, PET materials cannot be used the same way and must be generated by a facility licensed as a pharmacy/manufacturer. Similarly, a hospital based nuclear pharmacist could not prepare PET materials that is not already licensed as a PET production facility under Part 3.

[RATs 2007-3; Compatibility=H&S]

**Comment [O61]:** Modified references, consistent with 10 CFR 35.300. Original references not correct. Used direct reference to Appendices rather than interim regulatory section.

NRC review – November 2011.  
[RATs 2006-1; Compatibility H&S]

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1092 7.36.1.3 **Is O**btained from and prepared by a Department, Agreement State, Licensing State or  
1093 NRC licensee for use in research in accordance with a Radioactive Drug Research  
1094 Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by  
1095 FDA; or

1096 7.36.1.4 **Is P**repared by the licensee in accordance with a Radioactive Drug Research  
1097 Committee-approved application or an Investigational New Drug (IND) protocol accepted  
1098 by FDA for use in research.

1099 7.36.2 Authorized User Training For Use Of Any Unsealed Radioactive Material For Diagnostic Or  
1100 Therapeutic Medical Use For Which A Written Directive Is Required.

1101 The licensee shall require an authorized user of an unsealed radioactive material for diagnostic or  
1102 therapeutic medical use for which a written directive is required under 7.36 to meet the  
1103 requirements of Appendix 7F.

1104 7.36.3 Authorized User Training For Oral Administration Of  $\leq 1.22 \text{ GBq } ^{131}\text{I}$  (33 mCi) Sodium Iodide  
1105 Requiring A Written Directive.

1106 The licensee shall require an authorized user of an unsealed radioactive material for oral  
1107 administration of  $\leq 1.22 \text{ GBq } ^{131}\text{I}$  (33 mCi) sodium iodide requiring a written directive under  
1108 7.36 to meet the requirements of Appendix 7G.

1109 7.36.4 Authorized User Training For Oral Administration Of  $> 1.22 \text{ GBq } ^{131}\text{I}$  (33 mCi) Sodium Iodide  
1110 Requiring A Written Directive.

1111 The licensee shall require an authorized user of an unsealed radioactive material for oral  
1112 administration of  $> 1.22 \text{ GBq } ^{131}\text{I}$  (33 mCi) sodium iodide requiring a written directive under  
1113 7.36 to meet the requirements of Appendix 7H.

1114 7.36.5 Authorized User Training For Parenteral Administration Requiring A Written Directive.

1115 The licensee shall require an authorized user of an unsealed radioactive material for parenteral  
1116 administration requiring a written directive under 7.36 to meet the requirements of Appendix 7I.

1117 **7.37 Safety Instruction.**

1118 In addition to the requirements of Part 10 of these regulations:

1119 7.37.1 The licensee shall provide radiation safety instruction, initially and at least annually, to personnel  
1120 caring for patients or human research subjects that have received therapy with a radioactive drug,  
1121 and cannot be released in accordance with 7.26.

1122 7.37.2 The instruction required by 7.37.1 shall be appropriate for the duties of the personnel and include:

1123 7.37.2.1 Patient or human research subject control;

1124 7.37.2.2 Visitor control, to include the following;

1125 (1) Routine visitation to hospitalized individuals in accordance with Part 4 of these  
1126 regulations;

1127 (2) Contamination control;

1128 (3) Waste control; and

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1129 (4) Notification of the RSO, or his or her designee, and the authorized user if the patient  
1130 or the human research subject dies or has a medical emergency.

1131 7.37.3 A licensee shall keep a record of individuals receiving instruction required by 7.37.1 and maintain  
1132 such records for 3 years. The record shall include a list of the topics covered, the date of  
1133 instruction, the names(s) of the attendee(s), and the name(s) of the individual(s) who gave the  
1134 instruction.

1135 **7.38 Safety Precautions.**

1136 7.38.1 For each patient or human research subject receiving radiopharmaceutical therapy and  
1137 hospitalized for compliance with 7.26, a licensee shall:

1138 7.38.1.1 Quarter the patient or the human research subject either in:

1139 (1) A private room with a private sanitary facility; or

1140 (2) A room, with a private sanitary facility, with another individual who also has received  
1141 similar radiopharmaceutical therapy and who cannot be released in accordance  
1142 with 7.26; and

1143 7.38.1.2 Visibly post the patient's or the human research subject's door with a "Caution:  
1144 Radioactive Material" sign and note on the door or on the patient's or the human research  
1145 subject's chart where and how long visitors may stay in the patient's or the human  
1146 research subject's room;

1147 7.38.1.3 Either monitor material and items removed from the patient's or the human research  
1148 subject's room to determine that their radioactivity cannot be distinguished from the  
1149 natural background radiation level with a radiation detection survey instrument set on its  
1150 most sensitive scale and with no interposed shielding, or handle such materials and items  
1151 as radioactive waste.

1152 7.38.2 A licensee shall notify the RSO , or his or her designee, and the authorized user immediately if  
1153 the hospitalized patient dies or has a medical emergency and notify the Department as required  
1154 by 7.39.

1155 **7.39 Emergency Notification.**

1156 The licensee shall notify the Department in accordance with 7.22 if it is possible that any  
1157 individual could receive exposures in excess of 4.14 as a result of a deceased's body.

1158 **SPECIFIC REQUIREMENTS FOR THE USE OF SEALED SOURCES FOR DIAGNOSIS**

1159 **7.40 Use of Sealed Sources for Diagnosis.**

1160 7.40.1 A licensee shall use for diagnostic medical uses only sealed sources:

1161 7.40.1.1 Approved in the Sealed Source and Device Registry; and

1162 7.40.1.2 Handled in accordance with the manufacturer's radiation safety and handling  
1163 instructions:

1164 7.40.2 Authorized User Training For Use Of Sealed Sources For Diagnosis.

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1165 The licensee shall require an authorized user under 7.40 to meet the requirements of Appendix  
1166 7J.

1167 **SPECIFIC REQUIREMENTS FOR THE USE OF SEALED SOURCES FOR MANUAL**  
1168 **BRACHYTHERAPY**

1169 **7.41 Calibration Measurements of Brachytherapy Sealed Sources.**

1170 7.41.1 Prior to the first medical use of a brachytherapy sealed source on or after October 25, 2005, a  
1171 licensee shall perform the following:

1172 7.41.1.1 Determine the source output or activity using a dosimetry system that meets the  
1173 requirements of 7.53;

1174 7.41.1.2 Determine source positioning accuracy within applicators; and

1175 7.41.1.3 Use published protocols accepted by nationally recognized bodies to meet the  
1176 requirements of 7.41.1.1 and 7.41.1.2.

1177 7.41.2 A licensee may use measurements provided by the source manufacturer or by a calibration  
1178 laboratory accredited by the American Association of Physicists in Medicine that are made in  
1179 accordance with 7.41.1.

1180 7.41.3 A licensee shall mathematically correct the outputs or activities determined in 7.41.1 for physical  
1181 decay at intervals consistent with 1.0 percent physical decay.

1182 7.41.4 An authorized medical physicist shall perform or review the measurements and calculations made  
1183 pursuant to 7.41.1, 7.41.2, or 7.41.3.

1184 7.41.5 Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is  
1185 used to determine the treatment times for ophthalmic treatments. The actual source output shall  
1186 consider decay based on the activity determined in accordance with paragraphs 7.41.1, 7.41.2, or  
1187 7.41.3.

1188 7.41.6 A licensee shall retain a record of each calibration on brachytherapy sources required by 7.41.1  
1189 for 3 years after the last use of the source. The record must include the date of the calibration; the  
1190 manufacturer's name, model number, and serial number for the source and the instruments used  
1191 to calibrate the source; the source output or activity; source positioning accuracy within  
1192 applicators; and the signature of the authorized medical physicist.

1193 7.41.7 A licensee shall retain a record of decay calculations required by 7.41.5 for the life of the source.  
1194 The record must include the date and initial activity of the source as determined under 7.41, and  
1195 for each decay calculation, the date, the source activity and the signature of the authorized  
1196 medical physicist.

1197 **7.42 Use of Sealed Sources For Manual Brachytherapy.**

1198 7.42.1 A licensee shall use for manual brachytherapy only sealed sources:

1199 7.42.1.1 Approved in the Sealed Source and Device Registry; or

1200 7.42.1.2 In research in accordance with an effective Investigational Device Exemption (IDE)  
1201 application accepted by the FDA provided the requirements of 7.14.1 are met.

1202 7.42.2 Authorized User Training For Use Of Sealed Sources For Manual Brachytherapy.

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- 1203 The licensee shall require an authorized user under 7.42 to meet the requirements of Appendix  
1204 7K.
- 1205 7.42.3 Authorized User Training For Use Of Strontium-90 Sealed Sources For Ophthalmic Uses.
- 1206 The licensee shall require an authorized user of strontium-90 sealed sources for ophthalmic uses  
1207 under 7.42 to meet the requirements of Appendix 7L.
- 1208 **7.43 Safety Instruction.**
- 1209 7.43.1 The licensee shall provide radiation safety instruction, initially and at least annually, to personnel  
1210 caring for patients or human research subjects that are undergoing implant therapy and cannot  
1211 be released in accordance with 7.26.
- 1212 7.43.2 The instruction required by 7.43.1 shall be commensurate with the duties of the personnel and  
1213 include:
- 1214 7.43.2.1 Size and appearance of the brachytherapy sources;
- 1215 7.43.2.2 Safe handling and shielding instructions in case of a dislodged source;
- 1216 7.43.2.3 Patient or human research subject control;
- 1217 7.43.2.4 Visitor control, including both;
- 1218 (1) Routine visitation to hospitalized individuals in accordance with 4.14.1.1; and
- 1219 (2) Visitation authorized in accordance with 4.14.3; and
- 1220 7.43.2.5 Notification of the RSO, or his or her designee, and the authorized user if the patient or  
1221 the human research subject dies or has a medical emergency .
- 1222 7.43.3 A licensee shall keep a record of individuals receiving instruction required by 7.43.1 and maintain  
1223 such records for 3 years. The record shall include a list of the topics covered, the date of  
1224 instruction, the names(s) of the attendee(s), and the name(s) of the individual(s) who gave the  
1225 instruction.
- 1226 **7.44 Safety Precautions.**
- 1227 7.44.1 For each patient or the human research subject that is receiving brachytherapy and cannot be  
1228 released in accordance with 7.26, a licensee shall:
- 1229 7.44.1.1 Not place the patient or the human research subject in the same room with a patient  
1230 who is not receiving radiation therapy;
- 1231 7.44.1.2 Visibly post the patient's or human research subject's door with a "Caution:  
1232 Radioactive Material" sign and note on the door or on the patient's or human research  
1233 subject's chart where and how long visitors may stay in the patient's or human research  
1234 subject's room.
- 1235 7.44.2 A licensee shall have emergency response equipment available near each treatment room to  
1236 respond to a source that inadvertently becomes:
- 1237 7.44.2.1 Dislodged from the patient; or

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- 1238 7.44.2.2 Lodged within the patient following removal of the source applicators.
- 1239 7.44.3 A licensee shall notify the RSO , or his or her designee, and the authorized user immediately if  
1240 the hospitalized patient dies or has a medical emergency and notify the Department as required  
1241 by 7.39.
- 1242 **7.45 Brachytherapy Sources Inventory.**
- 1243 7.45.1 A licensee shall maintain accountability at all times for all brachytherapy sources in storage or  
1244 use.
- 1245 7.45.2 Promptly after removing brachytherapy sources from a patient, a licensee shall return  
1246 brachytherapy sources to a secure storage area and count or otherwise verify the number  
1247 returned to ensure that all sources taken from the storage area have been returned.
- 1248 7.45.3 A licensee shall maintain a record of brachytherapy source accountability for 3 years.
- 1249 7.45.3.1 For temporary implants, the record must include the number and activity of sources:
- 1250 (1) Removed from storage, the time and date they were removed from storage, the  
1251 name of the individual who removed them from storage, and the location of use;  
1252 and
- 1253 (2) Not implanted, the time and date they were returned to storage, and the name of the  
1254 individual who returned them to storage.
- 1255 7.45.3.2 For permanent implants, the record must include the number and activity of sources:
- 1256 (1) Removed from storage, the date they were removed from storage, and the name of  
1257 the individual who removed them from storage;
- 1258 (2) Returned to storage, the date they were returned to storage, and the name of the  
1259 individual who returned them to storage; and
- 1260 (3) Permanently implanted in the patient or human research subject.
- 1261 **7.46 Surveys After Source Implant and Removal.**
- 1262 7.46.1 Immediately after implanting sources in a patient or a human research subject, the licensee shall  
1263 perform a survey to locate and account for all sources that have not been implanted.
- 1264 7.46.2 Immediately after removing the last temporary implant source from a patient or a human research  
1265 subject, the licensee shall perform a radiation survey of the patient with a radiation detection  
1266 survey instrument to confirm that all sources have been removed. The licensee shall not release  
1267 from confinement for medical care a patient treated by temporary implant until all sources have  
1268 been removed.
- 1269 7.46.3 A licensee shall maintain a record of patient surveys which demonstrate compliance with 7.46.1  
1270 and 7.6.2 for 3 years. Each record shall include the date and results of the survey, the survey  
1271 instrument used, and the name of the individual who made the survey.
- 1272 **7.47 Therapy-related Computer Systems.**
- 1273 7.47.1 The licensee shall perform acceptance testing on the treatment planning system in accordance  
1274 with published protocols accepted by nationally recognized bodies.

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1275 7.47.2 At a minimum, the acceptance testing required by 7.47.1 shall include, as applicable, verification  
1276 of:

1277 7.47.2.1 The source-specific input parameters required by the dose calculation algorithm;

1278 7.47.2.1 The accuracy of dose, dwell time, and treatment time calculations at representative  
1279 points;

1280 7.47.2.1 The accuracy of isodose plots and graphic displays; and

1281 7.47.2.1 The accuracy of the software used to determine radioactive source positions from  
1282 radiographic images.

1283 **SPECIFIC REQUIREMENTS FOR PHOTON-EMITTING REMOTE AFTERLOADER UNITS,**  
1284 **TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS**

1285 **7.48 Use of a Sealed Source in a Remote Afterloader Unit, Teletherapy Unit, or Gamma**  
1286 **Stereotactic Radiosurgery Unit.**

1287 7.48.1 A licensee shall use sealed sources in remote afterloader units, teletherapy units, or gamma  
1288 stereotactic radiosurgery units for therapeutic medical uses:

1289 7.48.1.1 Approved in the Sealed Source and Device Registry; and

1290 7.48.1.2 In research in accordance with an **effective active** Investigational Device Exemption  
1291 (IDE) application accepted by the FDA provided the requirements of 7.14.1 are met.

1292 7.48.2 Authorized User Training For Use of a Remote Afterloader Unit, Teletherapy Unit, or Gamma  
1293 Stereotactic Radiosurgery Unit.

1294 The licensee shall require an authorized user under 7.48 to meet the requirements of Appendix  
1295 7M.

1296 **7.49 Installation, Maintenance, Adjustment, and Repair.**

1297 7.49.1 Only a person specifically licensed by the Department, another Agreement State, or the NRC shall  
1298 install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma  
1299 stereotactic radiosurgery unit that involves work on the source(s) shielding, the source(s) driving  
1300 unit, or other electronic or mechanical component that could expose the source(s), reduce the  
1301 shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

1302 7.49.2 Except for low dose-rate remote afterloader units, only a person specifically licensed by the  
1303 Department, another Agreement State, a Licensing State, or the NRC shall install, replace,  
1304 relocate, or remove a sealed source or source contained in other remote afterloader units,  
1305 teletherapy units, or gamma stereotactic radiosurgery units.

1306 7.49.3 For a low dose-rate remote afterloader unit, only a person specifically licensed by the Department,  
1307 another Agreement State, a Licensing State, or the NRC, or an authorized medical physicist shall  
1308 install, replace, relocate, or remove a sealed source(s) contained in the unit.

1309 7.49.4 A licensee shall retain a record of the installation, maintenance, adjustment and repair done on  
1310 remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units for 3 years.  
1311 The record shall include the date, description of the service, and name(s) of the individual(s) who  
1312 performed the work.

**Comment [JJ62]:** Changed wording for clarification to be consistent with 10 CFR 35.600.  
[Change arose as a result of NRC review of draft SSR G in 2010.]  
NRC Compatibility = C

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1313 **7.50 Surveys of Patients and Human Research Subjects Treated with a Remote Afterloader Unit.**

1314 7.50.1 Before releasing a patient or a human research subject from licensee control, a licensee shall  
1315 make a survey of the patient or the human research subject and the remote afterloader unit with a  
1316 portable radiation detection survey instrument to confirm that the source(s) has been removed  
1317 from the patient or human research subject and returned to the safe, shielded position.

1318 7.50.24 A licensee shall maintain a record of patient surveys which demonstrate compliance with 7.50.1  
1319 for 3 years. Each record shall include the date and results of the survey, the survey instrument  
1320 used, and the name of the individual who made the survey.

**Comment [JJ63]:** Change to correct error in repeat numbering.

1321 **7.51 Safety Procedures and Instructions for a Remote Afterloader Unit, Teletherapy Unit, or**  
1322 **Gamma Stereotactic Radiosurgery Unit.**

1323 7.51.1 A licensee shall:

1324 7.51.1.1 Secure the unit, the console, the console keys, and the treatment room when not in use  
1325 or unattended;

1326 7.51.1.2 Permit only individuals approved by the authorized user, RSO, or authorized medical  
1327 physicist to be present in the treatment room during treatment with the source(s), if such  
1328 presence is necessary and justified;

1329 7.51.1.3 Prevent dual operation of more than one radiation producing device in a treatment  
1330 room, if applicable; and

1331 7.51.1.4 Develop, implement, and maintain written procedures for responding to an abnormal  
1332 situation when the operator is unable to place the source(s) in the shielded position, or  
1333 remove the patient or human research subject from the radiation field with controls from  
1334 outside the treatment room. This procedure must include:

1335 (1) Instructions for responding to equipment failures and the names of the individuals  
1336 responsible for implementing corrective actions;

1337 (2) The process for restricting access to and posting of the treatment area to minimize  
1338 the risk of inadvertent exposure; and

1339 (3) The names and telephone numbers of the authorized users, the authorized medical  
1340 physicist, and the RSO to be contacted if the unit or console operates  
1341 abnormally.

1342 7.51.2 A copy of the procedures required by 7.51.1.4 shall be physically located at the unit console.

1343 7.51.3 A licensee shall conspicuously post instructions at the unit console to inform the operator of the  
1344 names and telephone numbers of the authorized users, the authorized medical physicist, and the  
1345 RSO to be contacted if the unit or console operates abnormally.

1346 7.51.4 A licensee shall provide instruction, initially and at least annually, to all individuals who operate a  
1347 unit, as appropriate to the individual's assigned duties, in:

1348 7.51.4.1 The procedures identified in 7.51.1.4; and

1349 7.51.4.2 The operating procedures for the unit.

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- 1350 7.51.5 A licensee shall ensure that operators, authorized medical physicists, and authorized users  
1351 participate in drills of the emergency procedures, initially and at least annually.
- 1352 7.51.6 A licensee shall keep a record of individuals receiving instruction required by 7.51.4 and maintain  
1353 such records for 3 years. The record shall include a list of the topics covered, the date of  
1354 instruction, the names(s) of the attendee(s), and the name(s) of the individual(s) who gave the  
1355 instruction.
- 1356 **7.52 Doors, Interlocks, and Warning Systems.**
- 1357 7.52.1 A licensee shall control access to the treatment room by a door at each entrance.
- 1358 7.52.2 A licensee shall equip each entrance to the treatment room with an electrical interlock system that  
1359 shall:
- 1360 7.52.2.1 Prevent the operator from initiating the treatment cycle unless each treatment room  
1361 entrance door is closed;
- 1362 7.52.2.2 Cause the source(s) to be shielded promptly when an entrance door is opened; and
- 1363 7.52.2.3 Prevent the source(s) from being exposed following an interlock interruption until all  
1364 treatment room entrance doors are closed and the source(s)' on/off control is reset at the  
1365 console.
- 1366 7.52.3 A licensee shall require any individual entering the treatment room to assure, through the use of  
1367 appropriate radiation monitors, that radiation levels have returned to ambient levels.
- 1368 7.52.4 Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment  
1369 room with viewing and intercom systems to permit continuous observation of the patient or the  
1370 human research subject from the treatment console during irradiation.
- 1371 7.52.5 For licensed activities where sources are placed within the patient's or human research subject's  
1372 body, a licensee shall only conduct treatments which allow for expeditious removal of a  
1373 decoupled or jammed source.
- 1374 7.52.6 In addition to the requirements specified in 7.52.1 through 7.52.5, a licensee shall:
- 1375 7.52.6.1 For low dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units,  
1376 require:
- 1377 (1) An authorized medical physicist and either an authorized user or a physician, under  
1378 the supervision of an authorized user, who has been trained in the operation and  
1379 emergency response for the unit, to be physically present during the initiation of  
1380 all patient treatments involving the unit; and
- 1381 (2) An authorized medical physicist and either an authorized user or an individual, under  
1382 the supervision of an authorized user, who has been trained to remove the  
1383 source applicator(s) in the event of an emergency involving the unit, to be  
1384 immediately available during continuation of all patient treatments involving the  
1385 unit.
- 1386 7.52.6.2 For high dose-rate remote afterloader units, require:
- 1387 (1) An authorized user and an authorized medical physicist to be physically present  
1388 during the initiation of all patient treatments involving the unit; and

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1389 (2) An authorized medical physicist and either an authorized user or a physician, under  
1390 the supervision of an authorized user, who has been trained in the operation and  
1391 emergency response for the unit, to be physically present during continuation of  
1392 all patient treatments involving the unit.

1393 7.52.6.3 For gamma stereotactic radiosurgery units, require an authorized user and an  
1394 authorized medical physicist to be physically present throughout all patient treatments  
1395 involving the unit.

1396 7.52.6.4 If a patient or research subject suffers a medical emergency during radiation therapy:

1397 (1) Cease the therapy immediately;

1398 (2) Remove the source(s); and

1399 (3) Provide appropriate care to the patient or research subject.

1400 7.52.6.5 If the patient expires during treatment, remove the source(s) before further actions are  
1401 taken.

1402 7.52.6.6 Notify the RSO, or his or her designee, and an authorized user as soon as possible, if  
1403 the patient or human research subject has a medical emergency and, immediately, if the  
1404 patient dies.

1405 7.52.7 A licensee shall have emergency response equipment available near each treatment room, to  
1406 respond to a situation in which a source inadvertently:

1407 7.52.7.1 Remains in the unshielded position; or

1408 7.52.7.2 Lodges within the patient following completion of the treatment.

1409 **7.53 Dosimetry Equipment.**

1410 7.53.1 Except for low dose-rate remote afterloader sources where the source output or activity is  
1411 determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for  
1412 use. To satisfy this requirement, one of the following two conditions shall be met:

1413 7.53.1.1 The system shall have been calibrated using a system or source traceable to the  
1414 National Institute of Standards and Technology and published protocols accepted by  
1415 nationally recognized bodies, or by a calibration laboratory accredited by the American  
1416 Association of Physicists in Medicine. The calibration shall have been performed within  
1417 the previous 2 years and after any servicing that may have affected system calibration; or

1418 7.53.1.2 The system shall have been calibrated within the previous 4 years; 18 to 30 months  
1419 after that calibration, the system shall have been intercompared with another dosimetry  
1420 system that was calibrated within the past 24 months by the National Institute of  
1421 Standards and Technology or by a calibration laboratory accredited by the American  
1422 Association of Physicists in Medicine. The results of the intercomparison must have  
1423 indicated that the calibration factor of the licensee's system had not changed by more  
1424 than 2 percent. The licensee shall not use the intercomparison result to change the  
1425 calibration factor. When intercomparing dosimetry systems to be used for calibrating  
1426 sealed sources for therapeutic units, the licensee shall use a comparable unit with beam  
1427 attenuators or collimators, as applicable, and sources of the same radionuclide as the  
1428 source used at the licensee's facility.

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1429 7.53.2 The licensee shall have available for use a dosimetry system for spot-check output  
1430 measurements. To meet this requirement, the system may be compared with a system that has  
1431 been calibrated in accordance with 7.53.1. This comparison shall have been performed within  
1432 the previous year and after each servicing that may have affected system calibration. The spot-  
1433 check system may be the same system used to meet the requirement in 7.53.1.

1434 7.53.3 The licensee shall maintain a record of each calibration, intercomparison, and comparison for the  
1435 duration of the license. For each calibration, intercomparison, or comparison, the record shall  
1436 include:

1437 7.53.3.1 The date;

1438 7.53.3.2 The manufacturer's name, the model numbers and serial numbers of the instruments  
1439 that were calibrated, intercompared, or compared as required by 7.53.1 and 7.53.2;

1440 7.53.3.3 The correction factor that were determined from the calibration or comparison or the  
1441 apparent correction factor that was determined from an intercomparison;

1442 7.53.3.4 The names of the individuals who performed the calibration, intercomparison, or  
1443 comparison.

1444 **7.54 Full Calibration Measurements on Teletherapy Units.**

1445 7.54.1 A licensee authorized to use a teletherapy unit for medical use shall perform full calibration  
1446 measurements on each teletherapy unit:

1447 7.54.1.1 Before the first medical use of the unit;

1448 7.54.1.2 Before medical use under the following conditions:

1449 (1) Whenever spot-check measurements indicate that the output differs by more than 5  
1450 percent from the output obtained at the last full calibration corrected  
1451 mathematically for radioactive decay;

1452 (2) Following replacement of the source or following reinstallation of the teletherapy unit  
1453 in a new location; and

1454 (3) Following any repair of the teletherapy unit that includes removal of the source or  
1455 major repair of the components associated with the source exposure assembly;  
1456 and

1457 7.54.1.3 At intervals not exceeding 1 year.

1458 7.54.2 To satisfy the requirement of 7.54.1, full calibration measurements shall include determination of:

1459 7.54.2.1 The output within +/- 3 percent for the range of field sizes and for the distance or range  
1460 of distances used for medical use;

1461 7.54.2.2 The coincidence of the radiation field and the field indicated by the light beam localizing  
1462 device;

1463 7.54.2.3 The uniformity of the radiation field and its dependence on the orientation of the useful  
1464 beam;

1465 7.54.2.4 Timer accuracy, constancy, and linearity;

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- 1466 7.54.2.5 "On off" error; and
- 1467 7.54.2.6 The accuracy of all distance measuring and localization devices in medical use.
- 1468 7.54.3 A licensee shall use the dosimetry system described in 7.53 to measure the output for one set of  
1469 exposure conditions. The remaining radiation measurements required in 7.54.2.1 may then be  
1470 made using a dosimetry system that indicates relative dose rates.
- 1471 7.54.4 A licensee shall make full calibration measurements required by 7.54.1 in accordance with  
1472 published protocols accepted by nationally recognized bodies.
- 1473 7.54.5 A licensee shall correct mathematically the outputs determined in 7.54.2.1 for physical decay for  
1474 intervals not exceeding 1 month for cobalt 60, 6 months for cesium 137, or at intervals consistent  
1475 with 1 percent decay for all other nuclides.
- 1476 7.54.6 Full calibration measurements required by 7.54.1 and physical decay corrections required by  
1477 7.54.5 shall be performed by the authorized medical physicist.
- 1478 7.54.7 A licensee shall maintain a record of each calibration for the duration of the license. The record  
1479 shall include:
- 1480 7.54.7.1 The date of the calibration;
- 1481 7.54.7.2 The manufacturer's name, model number, and serial number for the teletherapy unit,  
1482 source(s), and instruments used to calibrate the teletherapy unit;
- 1483 7.54.7.3 The results and assessments of the full calibrations; and
- 1484 7.54.7.4 The signature of the authorized medical physicist who performed the full calibration.
- 1485 **7.55 Full Calibration Measurements on Remote Afterloader Units.**
- 1486 7.55.1 A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration  
1487 measurements on each unit:
- 1488 7.55.1.1 Before the first medical use of the unit;
- 1489 7.55.1.2 Before medical use under the following conditions:
- 1490 (1) Following replacement of the source or following reinstallation of the unit in a new  
1491 location outside the facility; and
- 1492 (2) Following any repair of the unit that includes removal of the source or major repair of  
1493 the components associated with the source exposure assembly; and
- 1494 7.55.1.3 At intervals not exceeding one (1) calendar quarter for high dose-rate, medium dose-  
1495 rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds  
1496 75 days; and
- 1497 7.55.1.4 At intervals not exceeding 1 year for low dose-rate remote afterloader units.
- 1498 7.55.2 To satisfy the requirement of 7.55.1, full calibration measurements must include, as applicable,  
1499 determination of:
- 1500 7.55.2.1 The output within +/- 5 percent;

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- 1501 7.55.2.2 Source positioning accuracy to within +/- 1 millimeter;
- 1502 7.55.2.3 Source retraction with backup battery upon power failure;
- 1503 7.55.2.4 Length of the source transfer tubes;
- 1504 7.55.2.5 Timer accuracy and linearity over the typical range of use;
- 1505 7.55.2.6 Length of the applicators; and
- 1506 7.55.2.7 Function of the source transfer tubes, applicators, and transfer tube-applicator  
1507 interfaces.
- 1508 7.55.3 In addition to the requirements for full calibrations for low dose-rate remote afterloader units in  
1509 7.55.2, a licensee shall perform an autoradiograph of the source(s) to verify inventory and  
1510 source(s) arrangement at intervals not exceeding one quarter.
- 1511 7.55.4 A licensee shall use the dosimetry system described in 7.53 to measure the output.
- 1512 7.55.5 A licensee shall make full calibration measurements required by 7.55.1 of this section in  
1513 accordance with published protocols accepted by nationally recognized bodies.
- 1514 7.55.6 For low dose-rate remote afterloader units, a licensee may use measurements provided by the  
1515 source manufacturer that are made in accordance with 7.55.1 through 7.55.5.
- 1516 7.55.7 A licensee shall mathematically correct the outputs determined in 7.55.2.1 for physical decay at  
1517 intervals consistent with 1 percent physical decay.
- 1518 7.55.8 Full calibration measurements required by 7.55.1 and physical decay corrections required by  
1519 7.55.7 must be performed by the authorized medical physicist.
- 1520 7.55.9 A licensee shall retain a record of each calibration for the duration of the license. The record  
1521 shall include:
- 1522 7.55.9.1 The date of the calibration;
- 1523 7.55.9.2 The manufacturer's name, model number, and serial number for the remote afterloader  
1524 unit, source(s), and instruments used to calibrate the remote afterloader unit;
- 1525 7.55.9.3 The results and assessments of the full calibrations;
- 1526 7.55.9.4 The results of the autoradiograph required for low dose-rate remote afterloader units;  
1527 and
- 1528 7.55.9.5 The signature of the authorized medical physicist who performed the full calibration.
- 1529 **7.56 Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units.**
- 1530 7.56.1 A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform  
1531 full calibration measurements on each unit:
- 1532 7.56.1.1 Before the first medical use of the unit;
- 1533 7.56.1.2 Before medical use under the following conditions:

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- 1534 (1) Whenever spot-check measurements indicate that the output differs by more than 5  
1535 percent from the output obtained at the last full calibration corrected  
1536 mathematically for radioactive decay;
- 1537 (2) Following replacement of the sources or following reinstallation of the gamma  
1538 stereotactic radiosurgery unit in a new location; and
- 1539 (3) Following any repair of the gamma stereotactic radiosurgery unit that includes  
1540 removal of the sources or major repair of the components associated with the  
1541 source assembly; and
- 1542 7.56.1.3 At intervals not exceeding 1 year, with the exception that relative helmet factors need  
1543 only be determined before the first medical use of a helmet and following any damage to  
1544 a helmet.
- 1545 7.56.2 To satisfy the requirement of 7.56.1, full calibration measurements must include determination of:
- 1546 7.56.2.1 The output within +/-3 percent;
- 1547 7.56.2.2 Relative helmet factors;
- 1548 7.56.2.3 Isocenter coincidence;
- 1549 7.56.2.4 Timer accuracy and linearity over the range of use;
- 1550 7.56.2.5 On-off error;
- 1551 7.56.2.6 Trunnion centricity;
- 1552 7.56.2.7 Treatment table retraction mechanism, using backup battery power or hydraulic  
1553 backups with the unit off;
- 1554 7.56.2.8 Helmet microswitches;
- 1555 7.56.2.9 Emergency timing circuits; and
- 1556 7.56.2.10 Stereotactic frames and localizing devices (trunnions).
- 1557 7.56.3 A licensee shall use the dosimetry system described in 7.53 to measure the output for one set of  
1558 exposure conditions. The remaining radiation measurements required in 7.56.2.1 may be made  
1559 using a dosimetry system that indicates relative dose rates.
- 1560 7.56.4 A licensee shall make full calibration measurements required by 7.56.1 in accordance with  
1561 published protocols accepted by nationally recognized bodies.
- 1562 7.56.5 A licensee shall mathematically correct the outputs determined in 7.56.2.1 at intervals not  
1563 exceeding 1 month for cobalt-60 and at intervals consistent with 1 percent physical decay for all  
1564 other radionuclides.
- 1565 7.56.6 Full calibration measurements required by 7.56.1 and physical decay corrections required by  
1566 7.56.5 must be performed by the authorized medical physicist.
- 1567 7.56.7 A licensee shall retain a record of each calibration for the duration of the license. The record  
1568 shall include:

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- 1569 7. 56.7.1 The date of the calibration;
- 1570 7. 56.7.2 The manufacturer's name, model number, and serial number for the gamma  
1571 stereotactic radiosurgery unit, source(s), and instruments used to calibrate the gamma  
1572 stereotactic radiosurgery unit;
- 1573 7. 56.7.3 The results and assessments of the full calibrations;
- 1574 7. 56.7.4 The signature of the authorized medical physicist who performed the full calibration.
- 1575 **7.57 Radiation Surveys of Therapeutic Treatment Units.**
- 1576 7.57.1 A licensee authorized to use radioactive material in remote afterloader units, teletherapy units,  
1577 and gamma stereotactic radiosurgery units shall possess a portable radiation detection survey  
1578 instrument capable of detecting dose rates over the range of 1  $\mu$ Sv (0.1 mrem) per hour to 500  
1579  $\mu$ Sv (50 mrem) per hour, and a portable radiation measurement survey instrument capable of  
1580 measuring dose rates over the range of 10  $\mu$ Sv (1 mrem) per hour to 10 mSv (1 rem) per hour.  
1581 The instruments shall be operable and calibrated in accordance with 7.17.
- 1582 7.57.2 In addition to the survey requirements in Part 4 of these regulations, a person licensed pursuant to  
1583 Part 7 shall make surveys to ensure that the maximum radiation levels and average radiation  
1584 levels from the surface of the main source safe with the source(s) in the shielded position does  
1585 not exceed the levels stated in the Sealed Source and Device Registry.
- 1586 7.57.3 The licensee shall make the survey required by 7.57.2 at installation of a new source and  
1587 following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or  
1588 mechanical component that could expose the source, reduce the shielding around the source(s),  
1589 or compromise the radiation safety of the unit or the source(s).
- 1590 7.57.4 A licensee shall retain a record of the radiation surveys required by 7.57.2 for the duration of use  
1591 of the unit. The record must include:
- 1592 7.57.4.1 The date of the measurements;
- 1593 7.57.4.2 The manufacturer's name, model number and serial number of the treatment unit,  
1594 source, and instrument used to measure radiation levels;
- 1595 7.57.4.3 Each dose rate measured around the source while the unit is in the off position and the  
1596 average of all measurements; and
- 1597 7.57.4.4 The signature of the authorized medical physicist who performed the test.
- 1598 **7.58 Periodic Spot Checks for Teletherapy Units.**
- 1599 7.58.1 A licensee authorized to use teletherapy units for medical use shall perform output spot checks on  
1600 each teletherapy unit once in each calendar month, including determination of:
- 1601 7.58.1.1 Timer accuracy and timer linearity over the range of use;
- 1602 7.58.1.2 "On off" error;
- 1603 7.58.1.3 The coincidence of the radiation field and the field indicated by the light beam localizing  
1604 device;
- 1605 7.58.1.4 The accuracy of all distance measuring and localization devices used for medical use;

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- 1606 7.58.1.5 The output for one typical set of operating conditions measured with the dosimetry  
1607 system described in 7.53; and
- 1608 7.58.1.6 The difference between the measurement made in 7.58.1.5 and the anticipated output,  
1609 expressed as a percentage of the anticipated output (i.e., the value obtained at last full  
1610 calibration corrected mathematically for physical decay).
- 1611 7.58.2 A licensee shall perform spot checks required by 7.58.1 in accordance with procedures  
1612 established by the authorized medical physicist. That individual need not actually perform the  
1613 output spot-check measurements.
- 1614 7.58.3 A licensee shall have the authorized medical physicist review the results of each spot check within  
1615 15 days. The authorized medical physicist shall promptly notify the licensee in writing of the  
1616 results of each spot check.
- 1617 7.58.4 A licensee authorized to use a teletherapy unit for medical use shall perform safety spot checks of  
1618 each teletherapy facility once in each calendar month and after each source installation to assure  
1619 proper operation of:
- 1620 7.58.4.1 Electrical interlocks at each teletherapy room entrance;
- 1621 7.58.4.2 Electrical or mechanical stops installed for the purpose of limiting use of the primary  
1622 beam of radiation restriction of source housing angulation or elevation, carriage or stand  
1623 travel, and operation of the beam "on off" mechanism;
- 1624 7.58.4.3 Source exposure indicator lights on the teletherapy unit, on the control console, and in  
1625 the facility;
- 1626 7.58.4.4 Viewing and intercom systems;
- 1627 7.58.4.5 Treatment room doors from inside and outside the treatment room; and
- 1628 7.58.4.6 Electrically assisted treatment room doors with the teletherapy unit electrical power  
1629 turned "off".
- 1630 7.58.5 If the results of the checks required in 7.58.4 indicate the malfunction of any system, a licensee  
1631 shall lock the control console in the "off" position and not use the unit except as may be  
1632 necessary to repair, replace, or check the malfunctioning system.
- 1633 7.58.6 A licensee shall maintain a record of each spot check required by 7.58.1 and 7.58.5 for 3 years.  
1634 The record shall include:
- 1635 7.58.6.1 The date of the spot check;
- 1636 7.58.6.2 The manufacturer's name, model number, and serial number for the teletherapy unit,  
1637 source, and instrument used to measure the output of the teletherapy unit;
- 1638 7.58.6.3 An assessment of timer linearity and constancy;
- 1639 7.58.6.4 The calculated "on off" error;
- 1640 7.58.6.5 A determination of the coincidence of the radiation field and the field indicated by the  
1641 light beam localizing device
- 1642 7.58.6.6 The determined accuracy of each distance measuring or localization device;

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- 1643 7.58.6.7 The difference between the anticipated output and the measured output;
- 1644 7.58.6.8 Notations indicating the operability of each entrance door electrical interlock, each  
1645 electrical or mechanical stop, each source exposure indicator light, and the viewing and  
1646 intercom system and doors; and
- 1647 7.58.6.9 The name of the individual who performed the periodic spot check and the signature of  
1648 the authorized medical physicist who reviewed the record of the spot check.

**1649 7.59 Periodic Spot Checks for Remote Afterloader Units.**

- 1650 7.59.1 A licensee authorized to use remote afterloader units for medical use shall perform spot checks of  
1651 each remote afterloader facility and on each unit:
- 1652 7.59.1.1 At the beginning of each day of use of a high dose-rate, medium dose-rate or pulsed  
1653 dose-rate remote afterloader unit;
- 1654 7.59.1.2 Prior to each patient treatment with a low dose-rate remote afterloader unit; and
- 1655 7.59.1.3 After each source installation.
- 1656 7.59.2 The licensee shall have the authorized medical physicist establish written procedures for  
1657 performing the spot checks required in 7.59.1. The authorized medical physicist need not actually  
1658 perform the spot-check measurements.
- 1659 7.59.3 A licensee shall have the authorized medical physicist review the results of each spot check within  
1660 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing  
1661 of the results of each spot check.
- 1662 7.59.4 To satisfy the requirements of 7.59.1, spot checks must, at a minimum, assure proper operation  
1663 of:

**1664 7.59.4.1 Emergency response equipment;**

**1665 7.59.4.2 Viewing and intercom systems in each high dose-rate, medium dose-rate and  
1666 pulsed dose-rate remote afterloader facility;**

**1667 7.59.4.3 Radiation monitors used to indicate the source position;**

**1668 7.59.4.4 Electrical interlocks at each remote afterloader unit room entrance;**

**1669 7.59.4.5 Source exposure indicator lights on the remote afterloader unit, on the control console,  
1670 and in the facility;**

~~1671 7.59.4.3 Viewing and intercom systems in each high dose-rate, medium dose-rate and pulsed  
1672 dose-rate remote afterloader facility;~~

~~1673 7.59.4.4 Emergency response equipment;~~

~~1674 7.59.4.5 Radiation monitors used to indicate the source position;~~

1675 7.59.4.6 Timer accuracy;

1676 7.59.4.7 Clock (date and time) in the unit's computer; and

**Comment [JJ64]:** This section was re-ordered based on the recommendation of Radioactive Materials Unit staff to list the required tests in a safer order or sequence. Although not required, some licensees perform the tests in the order shown in the regulations. There is no change in content or requirements in this section.

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- 1677 7.59.4.8 Decayed source(s) activity in the unit's computer.
- 1678 7.59.5 If the results of the checks required in 7.59.4 indicate the malfunction of any system, a licensee  
1679 shall lock the control console in the off position and not use the unit except as may be necessary  
1680 to repair, replace, or check the malfunctioning system.
- 1681 7.59.6 A licensee shall retain a record of each check required by 7.59.4 for 3 years. The record must  
1682 include, as applicable:
- 1683 7.59.6.1 The date of the spot check;
- 1684 7.59.6.2 The manufacturer's name, model number, and serial number for the remote afterloader  
1685 unit and source;
- 1686 7.59.6.3 An assessment of timer accuracy;
- 1687 7.59.6.4 Notations indicating the operability of each entrance door electrical interlock, radiation  
1688 monitors, source exposure indicator lights, viewing and intercom systems, and clock and  
1689 decayed source activity in the unit's computer; and
- 1690 7.59.6.5 The name of the individual who performed the periodic spot check and the signature of  
1691 the authorized medical physicist who reviewed the record of the spot check.
- 1692 **7.60 Additional Technical Requirements for Mobile Remote Afterloader Units.**
- 1693 7.60.1 A licensee providing mobile remote afterloader service shall:
- 1694 7.60.1.1 Check survey instruments for consistent response before medical use at each address  
1695 of use or on each day of use, whichever is more frequent; and
- 1696 7.60.1.2 Account for all sources before departure from a client's address of use.
- 1697 7.60.2 In addition to the periodic spot checks required by 7.59, a licensee authorized to use mobile  
1698 afterloaders for medical use shall perform checks on each remote afterloader unit before use at  
1699 each address of use. At a minimum, checks must be made to verify the operation of:
- 1700 7.60.2.1 Electrical interlocks on treatment area access points;
- 1701 7.60.2.2 Source exposure indicator lights on the remote afterloader unit, on the control console,  
1702 and in the facility;
- 1703 7.60.2.3 Viewing and intercom systems;
- 1704 7.60.2.4 Applicators, source transfer tubes, and transfer tube-applicator interfaces;
- 1705 7.60.2.5 Radiation monitors used to indicate room exposures;
- 1706 7.60.2.6 Source positioning (accuracy); and
- 1707 7.60.2.7 Radiation monitors used to indicate whether the source has returned to a safe shielded  
1708 position.
- 1709 7.60.3 In addition to the requirements for checks in 7.60.2, a licensee shall ensure overall proper  
1710 operation of the remote afterloader unit by conducting a simulated cycle of treatment before use  
1711 at each address of use.

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1712 7.60.4 If the results of the checks required in 7.60.2 indicate the malfunction of any system, a licensee  
1713 shall lock the control console in the off position and not use the unit except as may be necessary  
1714 to repair, replace, or check the malfunctioning system.

1715 7.60.5 A licensee shall retain a record of each check required by 7.60.2 for 3 years. The record must  
1716 include:

1717 7.60.5.1 The date of the check;

1718 7.60.5.2 The manufacturer's name, model number, and serial number of the remote afterloader  
1719 unit;

1720 7.60.5.3 Notations accounting for all sources before the licensee departs from a facility;

1721 7.60.5.4 Notations indicating the operability of each entrance door electrical interlock, radiation  
1722 monitors, source exposure indicator lights, viewing and intercom system, applicators and  
1723 source transfer tubes, and source positioning accuracy; and

1724 7.60.5.5 The signature of the individual who performed the check.

1725 **7.61 Periodic Spot Checks for Gamma Stereotactic Radiosurgery Units.**

1726 7.61.1 A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform  
1727 spot checks of each gamma stereotactic radiosurgery facility and on each unit:

1728 7.61.1.1 Monthly;

1729 7.61.1.2 At the beginning of each day of use; and

1730 7.61.1.3 After each source installation.

1731 7.61.2 The licensee shall have the authorized medical physicist:

1732 7.61.2.1 Establish written procedures for performing the spot checks required in 7.61.1; and

1733 7.61.2.2 Review the results of each spot check required by 7.61.1.1 within 15 days of the check.  
1734 The authorized medical physicist need not actually perform the spot-check  
1735 measurements. The authorized medical physicist shall notify the licensee as soon as  
1736 possible, in writing, of the results of the spot check.

1737 7.61.3 To satisfy the requirements of 7.61.1.1 spot checks must, at a minimum:

1738 7.61.3.1 Assure proper operation of:

1739 (1) Treatment table retraction mechanism, using backup battery power or hydraulic  
1740 backups with the unit off;

1741 (2) Helmet microswitches;

1742 (3) Emergency timing circuits; and

1743 (4) Stereotactic frames and localizing devices (trunnions).

1744 7.61.3.2 Determine:

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- 1745 (1) The output for one typical set of operating conditions measured with the dosimetry  
1746 system described in 7.53.2;
- 1747 (2) The difference between the measurement made in 7.61.3.2(1) and the anticipated  
1748 output, expressed as a percentage of the anticipated output (i.e., the value  
1749 obtained at last full calibration corrected mathematically for physical decay);
- 1750 (3) Source output against computer calculation;
- 1751 (4) Timer accuracy and linearity over the range of use;
- 1752 (5) On-off error; and
- 1753 (6) Trunnion centricity.
- 1754 7.61.4 To satisfy the requirements of 7.61.1.2 and 7.61.1.3, spot checks must assure proper operation  
1755 of:
- 1756 7.61.4.1 Electrical interlocks at each gamma stereotactic radiosurgery room entrance;
- 1757 7.61.4.2 Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the  
1758 control console, and in the facility;
- 1759 7.61.4.3 Viewing and intercom systems;
- 1760 7.61.4.4 Timer termination;
- 1761 7.61.4.5 Radiation monitors used to indicate room exposures; and
- 1762 7.61.4.6 Emergency off buttons.
- 1763 7.61.5 A licensee shall arrange for prompt repair of any system identified in 7.61.3 that is not operating  
1764 properly.
- 1765 7.61.6 If the results of the checks required in 7.61.4 indicate the malfunction of any system, a licensee  
1766 shall lock the control console in the off position and not use the unit except as may be necessary  
1767 to repair, replace, or check the malfunctioning system.
- 1768 7.61.7 A licensee shall retain a record of each check required by 7.61.3 and 7.61.4 for 3 years. The  
1769 record must include:
- 1770 7.61.7.1 The date of the spot check;
- 1771 7.61.7.2 The manufacturer's name, model number, and serial number for the gamma stereotactic  
1772 radiosurgery unit and the instrument used to measure the output of the unit;
- 1773 7.61.7.3 An assessment of timer linearity and accuracy;
- 1774 7.61.7.4 The calculated on-off error;
- 1775 7.61.7.5 A determination of trunnion centricity;
- 1776 7.61.7.6 The difference between the anticipated output and the measured output;
- 1777 7.61.7.7 An assessment of source output against computer calculations;

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1778 7.61.7.8 Notations indicating the operability of radiation monitors, helmet microswitches,  
1779 emergency timing circuits, emergency off buttons, electrical interlocks, source exposure  
1780 indicator lights, viewing and intercom systems, timer termination, treatment table  
1781 retraction mechanism, and stereotactic frames and localizing devices (trunnions); and

1782 7.61.7.9 The name of the individual who performed the periodic spot check and the signature of  
1783 the authorized medical physicist who reviewed the record of the spot check.

1784 **7.62 Other Medical Uses of Radioactive Material or Radiation From Radioactive Material.**

1785 7.62.1 A licensee may use radioactive material or a radiation source approved for medical use that is not  
1786 specifically addressed in Part 7 if:

1787 7.62.1.1 The applicant or licensee has submitted the information required by 7.3.4.2, 7.3.4.3, and  
1788 7.3.4.4; and

1789 7.62.1.2 The applicant or licensee has received written approval from the an Agreement State,  
1790 Licensing State, or NRC in a license and uses the material in accordance with the  
1791 regulations and specific conditions that the Agreement State, Licensing State, or NRC  
1792 considers necessary for the medical use of the material.

1793 **7.63 Five Year Inspection.**

1794 7.63.1 A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully  
1795 inspected and serviced during source replacement or at intervals not to exceed 5 years,  
1796 whichever comes first, to assure proper functioning of the source exposure mechanism.

1797 7.63.2 This inspection and servicing shall only be performed by persons specifically licensed to do so by  
1798 the Department, another Agreement State, a Licensing State, or the NRC.

1799 7.63.3 A licensee shall keep a record of the inspection and servicing for the duration of the license. The  
1800 record shall contain:

1801 7.63.3.1 The inspector's radioactive materials license number;

1802 7.63.3.2 The date of inspection;

1803 7.63.3.3 The manufacturer's name and model number and serial number of both the treatment  
1804 unit and source;

1805 7.63.3.4 A list of components inspected and serviced;

1806 7.63.3.5 A list of components inspected and serviced, and the type of service;

1807 7.63.3.6 A list of components replaced; and

1808 7.63.3.7 The signature of the inspector.  
1809

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1810 **PART 7, APPENDIX 7A: TRAINING FOR RADIATION SAFETY OFFICER (RSO)-ADEQUATE**  
1811 **RADIATION SAFETY TRAINING AND EXPERIENCE**

**Comment [JJ65]:** NOTE TO READER: THIS AND APPENDICES B THROUGH M HAVE BEEN REVISED TO FOLLOW THE SEQUENCE AND CURRENT REQUIREMENTS CONTAINED IN 10 CFR PART 35.

1812 **The licensee shall require the individual fulfilling the responsibilities of the Radiation Safety**  
1813 **Officer (RSO) as provided in 7.7 to be an individual who:**

ALSO NOTE THAT IN 10 CFR PART 35, SECTIONS 35.57 (EXPERIENCED INDIVIDUALS) AND 35.59 (RECENTNESS OF TRAINING) ARE STAND-ALONE SECTIONS WHEREAS IN THIS PART 7, SIMILAR PROVISIONS APPEAR AND ARE REPEATED IN EACH APPENDIX.

1814 **7A1** ~~Has provided:~~ **Is certified by a specialty board whose certification process has been**  
1815 **recognized by NRC or an Agreement State and who meets the requirements in paragraphs**  
1816 **7A4 and 7A5 of this Appendix. NRC recognized specialty boards are posted on the NRC**  
1817 **website at <http://www.nrc.gov/materials/miau/med-use/toolkit/spec-board-cert.html>. To**  
1818 **have its certification process recognized, a specialty board shall require all candidates for**  
1819 **certification to:**

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1820 **7A1.1** ~~(1) Evidence of current certification in health physics or medical physics by a recognized~~  
1821 ~~specialty board (see 7A5); and~~ **Hold a bachelor's or graduate degree from an**  
1822 **accredited college or university in physical science or engineering or biological**  
1823 **science with a minimum of 20 college credits in physical science;**

1824 **and**

1825 **(2) Have 5 or more years of professional experience in health physics, provided:**

1826 **(a) At least 3 years are in applied health physics;**

1827 **and**

1828 **(b) Graduate training may substitute for no more than 2 years of the**  
1829 **required 5 years of experience;**

1830 **and**

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1831 **(3) Pass an examination administered by diplomates of the specialty board, which**  
1832 **evaluates knowledge and competence in radiation physics and instrumentation,**  
1833 **radiation protection, mathematics pertaining to the use and measurement of**  
1834 **radioactivity, radiation biology, and radiation dosimetry;**

1835 **or**

1836 **7A1.2** **(1) Hold a master's or doctor's degree in physics, medical physics, other physical**  
1837 **science, engineering, or applied mathematics from an accredited college or**  
1838 **university;**

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1839 **and**

1840 **(2) Have 2 years of full-time practical training and/or supervised experience in**  
1841 **medical physics that is:**

1842 **(a) Under the supervision of a medical physicist who is certified in medical**  
1843 **physics by a specialty board recognized by an Agreement State or**  
1844 **NRC;**

1845 **or**

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(b) In clinical nuclear medicine facilities providing diagnostic and / or therapeutic services under the general supervision of physicians who meet the requirements for Authorized Users in 7A7, Appendix 7E or Appendix 7F;

and

(3) Pass an examination administered by diplomates of the specialty board that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety.

~~7A1.2 Written attestation(s), signed by a preceptor RSO, that the individual has achieved a level of radiation safety knowledge sufficient to function independently as an RSO for a medical use licensee;~~

~~(1) Each preceptor RSO supervising the training required by Appendix 7A shall meet the requirements for an RSO for the type(s) of use for which the individual is seeking authorization; and~~

~~7A1.3 Evidence of documented experience with the radiation safety aspects of the type(s) of use or similar type(s) of use of radioactive material for which the individual is seeking to have RSO responsibilities.~~

~~(1) For a new type of use under 7.62, acceptable training under 7A2.2 is sufficient, unless the Department determines otherwise;~~

or

**7A2** Has satisfied the following criteria:

7A2.1 Has ~~provided written attestation(s), signed by a preceptor RSO, that the individual has completed a structured educational program~~ **consisting of that includes:**

(1) 200 hours of classroom and laboratory training in the following areas:

- (a) Radiation physics and instrumentation;
- (b) Radiation protection;
- (c) Mathematics pertaining to the use and measurement of radioactivity;
- (d) Radiation biology; and
- (e) Radiation dosimetry;

and

(2) 1 year of full-time radiation safety experience, under the supervision of **the individual identified as an RSO or Alternate RSO, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, on an Agreement State or NRC license or permit issued by a NRC master material licensee** that authorizes similar type(s) of use of radioactive material, involving the following:

- (a) Shipping, receiving, and performing related radiation surveys;

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Comment [JJ66]: Original references not consistent with references made in 10 CFR 35.50(a)(2)(ii)(B).

Comment [JJ67]: Correction to references to match 35.50 based on NRC comments - Nov 2011. [RATS 2009-1; Compatibility B]

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- 1883 (b) Using and performing checks for proper operation of dose calibrators, survey  
1884 meters, and, if appropriate, instruments used to measure radionuclides;
- 1885 (c) Securing and controlling radioactive material;
- 1886 (d) Using administrative controls to avoid mistakes in the administration of  
1887 radioactive material;
- 1888 (e) Using procedures to prevent or minimize radioactive contamination and using  
1889 proper decontamination procedures;
- 1890 (f) Using emergency procedures to control radioactive material; and
- 1891 (g) Disposing of radioactive material; ~~and~~

1892 or

1893 **7A3 Meets the following requirements:**

1894 **7A3.1 Is a medical physicist who has been certified by a specialty board whose**  
1895 **certification process has been recognized by the NRC or an Agreement State**  
1896 **under Appendix 7B1 and has experience in radiation safety for similar types of use**  
1897 **of radioactive material for which the licensee is seeking the approval of the**  
1898 **individual as Radiation Safety Officer and who meets the requirements in 7A4 and**  
1899 **7A5.**

1900 or

1901 **7A3.2 Is an authorized user, authorized medical physicist, or authorized nuclear**  
1902 **pharmacist identified on the licensee's license and has experience with the**  
1903 **radiation safety aspects of similar types of use of radioactive materials for which**  
1904 **the individual has RSO responsibilities;**

1905 and

1906 **7A4 Has provided written attestation(s), signed by a preceptor RSO, that the individual has**  
1907 **satisfactorily completed the requirements in 7A5 and in 7A1.1(1) and 7A1.1(2) or 7A1.2(1)**  
1908 **and 7A1.2(2) or 7A2.1 or 7A3.1 or 7A3.2, and has achieved a level of radiation safety**  
1909 **knowledge sufficient to function independently as an RSO for a medical use licensee;**

1910 and

1911 **7A5 7A2.2** Has ~~experiential~~ training in the radiation safety, regulatory issues, and emergency procedures  
1912 for the type(s) of use for which ~~the a~~ licensee ~~is seeking~~ approval. **This training**  
1913 **requirement may be satisfied by completing for example,** training that is supervised  
1914 by an RSO, **Alternate RSO**, authorized medical physicist, authorized nuclear pharmacist,  
1915 or authorized user, **as appropriate, who is authorized** on an Agreement State or NRC  
1916 license ~~that authorizes similar~~ for the type(s) of use of radioactive material **for which the**  
1917 **licensee is seeking approval.** ~~and~~

1918 ~~7A2.3~~ Has provided written attestation(s), signed by a preceptor RSO, that the individual has  
1919 achieved a level of radiation safety knowledge sufficient to function independently as an  
1920 RSO for a medical use licensee;

1921 or

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1922 ~~7A3~~ Has demonstrated adequate prior experience as:

1923 ~~7A3.1~~ An experienced medical physicist who has provided written attestation(s), signed by a

1924 ~~preceptor RSO, that the medical physicist:~~

1925 ~~(1) Is certified by a specialty board whose certification process has been recognized~~

1926 ~~under 7A5.2; and~~

1927 ~~(2) Has satisfied 7A1.2, 7A2.2 and 7A2.3;~~

1928 ~~or~~

1929 ~~7A3.2~~ An authorized user, authorized medical physicist, or authorized nuclear pharmacist who:

1930 ~~(1) Is identified on the licensee's current license; and~~

1931 ~~(2) Has satisfied 7A1.2, 7A2.2 and 7A2.3;~~

1932 ~~or~~

1933 and

1934 **7A6 Meets the following recency of training requirements:**

1935 **7A6.1 The training and experience required by Appendix 7A shall have been obtained**

1936 **within the 7 years preceding the date of license application or amendment request;**

1937 **or**

1938 **7A6.2 The individual must have had related, documented continuing education and**

1939 **experience since the required training and experience was obtained.**

**Comment [JJ68]:** JJ 6/20/2011: Changes to 7A4 requested by staff (JG) to clarify requirement and make language consistent w/NRC.

**Comment [JJ69]:** JJ 6/21/2011: The term "or amendment request" is added for clarity, since many additions of RSO's occur during license amendment requests as well as during license applications.

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1940 or

1941 **7A7 Meets the following requirements for an experienced Radiation Safety Officer:**

1942 ~~7A7.13.3~~ An individual identified as a Radiation Safety Officer on a license issued by the

1943 ~~NRC or Agreement State, a permit issued under an NRC or Agreement State broad~~

1944 ~~scope license before October 25, 2005, are not required to comply with the training~~

1945 ~~requirements of 7A1 through 7A6. experienced RSO who was identified before October~~

1946 ~~25, 2005 (and thus need not comply with 7A1, 7A2.1 or 7A2.2) either on:~~

1947 ~~(1) An Agreement State or NRC license that authorizes medical use; or~~

1948 ~~(2) A permit issued by an Agreement State or NRC broad scope licensee that authorizes~~

1949 ~~medical use; or on~~

1950 ~~(3) An equivalent permit or license recognized by the Department for similar types and~~

1951 ~~uses of radioactive material.~~

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**Comment [JJ70]:** Additional language added to be compatible with 10 CFR 35.57 (c). This provision effectively allows or clarifies that experienced individuals who are "grandfathered" may serve as preceptors for others.

(NRC RATS 2009-1; Compatibility=B)

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1952 **7A7.2 Individuals not required to comply with the training requirements of 7A1 through**

1953 **7A6 may serve as preceptors for, and supervisors of, applicants seeking**

1954 **authorization on licenses for the same uses for which these individuals are**

1955 **authorized.**

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1956 ~~7A4. Training and experience required by Appendix 7A, shall have been obtained:~~

1957 ~~7A4.1 Within the 7 years preceding the date of license application; or~~

1958 ~~7A4.2 Through documented subsequent continuing education and experience.~~

1959 ~~7A5 To be recognized by an Agreement State or the U.S. Nuclear Regulatory Commission (posted by~~

1960 ~~NRC at <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>) a specialty~~

1961 ~~board shall require that each candidate for certification:~~

1962 ~~7A5.1 With a health physics background:~~

1963 ~~(1) Hold a bachelor's or graduate degree from an accredited college or university in~~

1964 ~~physical science or engineering or biological science with a minimum of 20~~

1965 ~~college credits in physical science; and~~

1966 ~~(2) Have 5 or more years of professional experience in health physics, provided:~~

1967 ~~(a) At least 3 years are in applied health physics; and~~

1968 ~~(b) Graduate training may be substituted for no more than 2 years of the~~

1969 ~~required 5 years of experience; and~~

1970 ~~(3) Pass an examination administered by diplomates of the specialty board that~~

1971 ~~evaluates knowledge and competence in radiation physics and instrumentation,~~

1972 ~~radiation protection, mathematics pertaining to the use and measurement of~~

1973 ~~radioactivity, radiation biology, and radiation dosimetry;~~

1974 ~~7A5.2 With a medical physics background:~~

1975 ~~(1) Hold a master's or doctor's degree in physics, medical physics, other physical~~

1976 ~~science, engineering, or applied mathematics from an accredited college or~~

1977 ~~university; and~~

1978 ~~(2) Have 2 years of full-time practical training and/or supervised experience in medical~~

1979 ~~physics;~~

1980 ~~(a) Under the supervision of a medical physicist who is certified in medical~~

1981 ~~physics by a specialty board recognized by an Agreement State or NRC;~~

1982 ~~or~~

1983 ~~(b) In clinical nuclear medicine facilities providing diagnostic and / or therapeutic~~

1984 ~~services under the general supervision of physicians who meet the~~

1985 ~~requirements of Appendix 7E or Appendix 7G; and~~

1986 ~~(3) Pass an examination administered by diplomates of the specialty board that~~

1987 ~~assesses knowledge and competence in clinical diagnostic radiological or~~

1988 ~~nuclear medicine physics and in radiation safety.~~

1989

1990

**Comment [JJ71]:** JJ 6/20/2011: Changes to 7A4 requested by staff (JG) to clarify requirement and make language consistent w/NRC.

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**Comment [JJ72]:** JJ 6/27/2011: Original references not consistent with references made in 10 CFR 35.50(a)(2)(ii)(B).

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**PART 7, APPENDIX 7B: TRAINING FOR AUTHORIZED MEDICAL PHYSICIST (AMP)-ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE**

The licensee shall require each authorized medical physicist to be an individual who:

**7B1** ~~Has provided:~~ **Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in paragraph 7B2.3 and 7B3 of this Appendix. NRC recognized specialty boards are posted on the NRC website at <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>.**

**7B1.1 To have its certification process recognized, a specialty board shall require all candidates for certification to:**

**(1) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;**

**and**

**(2) Have 2 years of full-time practical training and/or supervised experience in medical physics:**

**(a) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by an Agreement State or NRC;**

**or**

**(b) In clinical radiation facilities providing high energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in 7B5, Appendix 7K or Appendix 7M;**

**and**

**(3) Pass an examination administered by diplomates of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery;**

**Evidence of current certification by a recognized specialty board (see 7B5); and**

**7B1.2 Written attestation(s), signed by a preceptor medical physicist, that the individual has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status;**

**(1) Each preceptor medical physicist supervising the training required by Appendix 7B shall meet the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization;**

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2029 ~~(2) The Department may, upon application or upon its own initiative, accept as being~~  
2030 ~~adequate:~~

2031 ~~(a) Documentation that the equivalent component of an Agreement State or~~  
2032 ~~NRC requirement has been met; or~~

2033 ~~(b) Equivalent approval by another state or agency; and~~

2034 ~~7B1.3 Written attestation(s), signed by a preceptor medical physicist, that the individual has~~  
2035 ~~adequate training for the type(s) of use for which authorization is sought:~~

2036 ~~(1) Including:~~

2037 ~~(a) Hands on device operation;~~

2038 ~~(b) Safety procedures;~~

2039 ~~(c) Clinical use; and~~

2040 ~~(d) Treatment planning system operation; and~~

2041 ~~(2) Provided by either:~~

2042 ~~(a) Satisfactorily completing a vendor training program; or~~

2043 ~~(b) Being supervised by an authorized medical physicist authorized for the~~  
2044 ~~type(s) of use for which the individual is seeking authorization; and~~

2045 or

2046 **7B2** Has **satisfied the following criteria** ~~provided written attestation(s), signed by a preceptor medical~~  
2047 ~~physicist, that the individual:~~

2048 7B2.1 Holds a master's or doctor's degree in physics, medical physics, other physical science,  
2049 engineering, or applied mathematics from an accredited college or university;

2050 **and**

2051 7B2.2 Has **satisfactorily** completed **21** years of **full-time** training **in medical physics** and **an**  
2052 **additional year of full-time** work experience **under the supervision of an individual**  
2053 **who meets the requirements for an authorized medical physicist for the type(s) of**  
2054 **use for which the individual is seeking authorization.**

2055 **(1) The training and work experience of 7B2.2 must be that:**

2056 ~~(1) Include one year of full time training in medical physics; and~~

2057 ~~(2) Include an additional year of full time practical experience;~~

2058 ~~(3) Are e~~Conducted in clinical radiation facilities that provide high-energy, external beam  
2059 **therapy** (photons or electrons **with energies greater than or equal to** ~~1~~ **1**  
2060 **MeV) ~~therapy~~ and brachytherapy services **and must include**;**

2061 ~~(4) And include:~~

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Comment [JJ73]: The change from 2 years to 1 year is consistent with recent changes to 10 CFR 35.51.

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- 2062 (a) Performing sealed source leak tests and inventories;
- 2063 (b) Performing decay corrections;
- 2064 (c) Performing full calibration and periodic spot checks of external beam  
2065 treatment units, stereotactic radiosurgery units, and remote afterloading  
2066 units as applicable;
- 2067 and
- 2068 (d) Conducting radiation surveys around external beam treatment units,  
2069 stereotactic radiosurgery units, and remote afterloading units as  
2070 applicable;

2071 and

2072 7B2.3 **Has obtained written attestation that the individual has satisfactorily completed the**  
2073 **requirements in:**

2074 (1) **7B3 and 7B1.1(1) and 7B1.1(2);**

2075 or

2076 (2) **7B2 and 7B3;**

2077 and

2078 (3) **Has achieved a level of competency sufficient to function independently as an**  
2079 **authorized medical physicist for each type of therapeutic medical unit for**  
2080 **which the individual is requesting authorized medical physicist status. The**  
2081 **written attestation must be signed by a preceptor authorized medical physicist**  
2082 **who meets the requirements in this Appendix (7B), 7B5, or equivalent NRC or**  
2083 **Agreement State requirements for an authorized medical physicist for each**  
2084 **type of therapeutic medical unit for which the individual is requesting**  
2085 **authorized medical physicist status;**

2086 and

2087 **Has also satisfied 7B1.1 and 7B4.2.**

2088 or

2089 **7B3 Has met the following requirements:**

2090 **7B3.1 Has training for the type(s) of use for which authorization is sought that includes:**

2091 (1) **Hands-on device operation,**

2092 (2) **Safety procedures,**

2093 (3) **Clinical use,**

2094 and

2095 (4) **The operation of a treatment planning system.**

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**7B3.2 The training required by 7B3.1 may be satisfied by:**

**(1) Satisfactorily completing a training program provided by the vendor;**

**or**

**Through training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.**

**and**

**7B4 Meets the following recentness of training requirements:**

**7B4.1 Training and experience required by Appendix 7B shall have been obtained within the 7 years preceding the date of license application or amendment request;**

**or**

**7B4.2 The individual must have had related, documented, continuing education and experience since the required training and experience was obtained.**

**or**

**7B53 Meets the following requirements for an experienced authorized medical physicist: Has demonstrated adequate prior experience as:**

**7B35.1 An individual identified as an authorized medical physicist on a license issued by the NRC or Agreement State, a permit issued under an NRC or Agreement State broad scope license before October 25, 2005, are not required to comply with the training requirements of 7B1 through 7B4. authorized medical physicist identified on a current license or permit, either on:**

**(1) A specific medical license or equivalent permit issued by the Department, another Agreement State, a Licensing State, or NRC; or**

**(2) A permit issued by a Department, Agreement State, Licensing State, or NRC specific medical use licensee of broad scope that is authorized to permit the use of radioactive material;**

**or**

**7B3.2 An experienced medical physicist who was identified before October 25, 2005 (and thus need not comply with the training and experience requirements of 7B1 or 7B2) either on:**

**(1) An NRC or Agreement State license; or**

**(2) A permit issued under an NRC or Agreement State broad scope license that authorizes medical use;**

**or**

**7B35.23 An experienced medical physicist who has demonstrated to the Department experience in the type(s) of use for which the individual is requesting authorized medical physicist**

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**Comment [JJ74]:** JJ 6/21/2011: The term "or amendment request" is added for clarity, since many additions of authorized users occur during license amendment requests as well as during license applications.

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2130 status (and thus need not comply with the specific training and experience requirements  
2131 of 7B1 through 7B42):

2132 (1) Having been certified before October 25, 2005 by the American Board of Radiology  
2133 in:

2134 (a) Therapeutic radiological physics;

2135 (b) Roentgen ray and gamma ray physics;

2136 (c) X-ray and radium physics;

2137 or

2138 (d) Radiological physics;

2139 or

2140 (2) Having been certified before October 25, 2005 by the American Board of Medical  
2141 Physics in radiation oncology physics;

2142 and

2143 (3) And having Has sufficient work experience that includes the tasks listed in 7.13.2  
2144 and/or other sections of these regulations related to medical physics, as  
2145 applicable (having also satisfied 7B2.1 and being trained in therapeutic  
2146 radiological physics).

2147 **7B5.3 Individuals not required to comply with the training requirements of 7B1 through**  
2148 **7B4 may serve as preceptors for, and supervisors of, applicants seeking**  
2149 **authorization on licenses for the same uses for which these individuals are**  
2150 **authorized.**

2151 ~~7B4 Training and experience required by Appendix 7B shall have been obtained:~~

2152 ~~7B4.1 Within the 7 years preceding the date of license application; or~~

2153 ~~7B4.2 Through documented subsequent continuing education and experience.~~

2154 ~~7B5 To be recognized by an Agreement State or the U.S. Nuclear Regulatory Commission (posted by~~  
2155 ~~NRC at <http://www.nrc.gov/materials/miau/med-use/toolkit/spec-board-cert.html>), a specialty~~  
2156 ~~board shall require that each candidate for certification:~~

2157 ~~7B5.1 Hold a master's or doctor's degree in physics, medical physics, other physical science,~~  
2158 ~~engineering, or applied mathematics from an accredited college or university; and~~

2159 ~~7B5.2 Have 2 years of full-time practical training and/or supervised experience in medical~~  
2160 ~~physics;~~

2161 (1) Under the supervision of a medical physicist who is certified in medical physics by a  
2162 specialty board recognized by an Agreement State or NRC; or

2163 (2) In clinical radiation facilities providing high-energy, external beam therapy and  
2164 brachytherapy services under the direction of physicians who meet the  
2165 requirements for authorized users in Appendix 7K or Appendix 7M; and

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Comment [O75]: NOTE: The certifications referenced in this section (which are not being changed) do not appear in Part 35. However, the certifications referenced in this section are believed to have been placed in Part 7 to address the concern that prior to the 2005 Part 7 revision, the term "authorized medical physicist" did not appear in regulation or on radioactive materials licenses.

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Comment [JJ76]: Additional language added to be compatible with 10 CFR 35.57 (c). This provision effectively allows or clarifies that experienced individuals who are "grandfathered" may serve as preceptors for others.

(NRC RATS 2009-1; Compatibility=B)

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~~7B5.3 Pass an examination administered by diplomates of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery.~~

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2171 PART 7, APPENDIX 7C: **TRAINING FOR AUTHORIZED NUCLEAR PHARMACIST (ANP)**  
2172 **ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE**

2173 **The licensee shall require each authorized nuclear pharmacist to be a pharmacist who has a**  
2174 **current active Colorado State Board of Pharmacy license and who:**

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2175 **7C1** ~~Has provided:~~ **Is certified by a medical specialty board whose certification process has been**  
2176 **recognized by the NRC or an Agreement State and who meets the requirements in**  
2177 **paragraph 7C2.2 of this Appendix. NRC recognized specialty boards are posted on the**  
2178 **NRC website at <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>.**

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2179 **7C1.1 To have its certification process recognized, a specialty board shall require all**  
2180 **candidates for certification to:**

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2181 **(1) Have graduated from a pharmacy program accredited by the American Council**  
2182 **on Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy**  
2183 **Graduate Examination Committee (FPGEC) examination;**

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2184 **(2) Hold a current, active license to practice pharmacy;**

2185 **(3) Provide evidence of having acquired at least 4000 hours of training/experience**  
2186 **in nuclear pharmacy practice (academic training may be substituted for no**  
2187 **more than 2000 hours of the required training and experience);**

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2188 **and**

2189 **(4) Pass an examination, in nuclear pharmacy administered by diplomates of the**  
2190 **specialty board, which assesses knowledge and competency in procurement,**  
2191 **compounding, quality assurance, dispensing, distribution, health and safety,**  
2192 **radiation safety, provision of information and consultation, monitoring patient**  
2193 **outcomes, and research and development.**

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2194 **Evidence of:**

2195 ~~(1) Current Board of Pharmaceutical Specialties Certification as a Nuclear Pharmacist; or~~

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2196 ~~(2) Current certification by a recognized specialty board (see 7C5); and~~

2197 ~~7C1.2 Written attestation(s), signed by a preceptor nuclear pharmacist, that the individual has~~  
2198 ~~achieved a level of competency sufficient to function independently as a nuclear~~  
2199 ~~pharmacist;~~

2200 ~~(1) Each preceptor nuclear pharmacist supervising the experiential training required by Appendix~~  
2201 ~~7C shall meet the requirements for an authorized nuclear pharmacist;~~

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2202 **or**

2203 **7C2** Has satisfied the following criteria:

2204 **7C2.1** Has ~~provided written attestation(s), signed by a preceptor nuclear pharmacist, that the~~  
2205 ~~individual has~~ completed 700 hours in a structured educational program that includes:

2206 **(1) 200 hours of classroom and laboratory training in the following areas:**

**\*DRAFT 5 –02/16/2012\***

- 2207 (a) Radiation physics and instrumentation;
- 2208 (b) Radiation protection;
- 2209 (c) Mathematics pertaining to the use and measurement of radioactivity;
- 2210 (d) Chemistry of radioactive material for medical use; and
- 2211 (e) Radiation biology;
- 2212 and
- 2213 (2) Supervised practical experience in nuclear pharmacy involving:
- 2214 (a) Shipping, receiving, and performing related radiation surveys;
- 2215 (b) Using and performing checks for proper operation of instruments to
- 2216 determine the activity of dosages, survey meters, and, if appropriate,
- 2217 instruments used to measure alpha- or beta-emitting radionuclides;
- 2218 (c) Calculating, assaying, and safely preparing dosages for patients or human
- 2219 research subjects;
- 2220 (d) Using administrative controls to avoid misadministrations in the
- 2221 administration of radioactive material;
- 2222 and
- 2223 (e) Using procedures to prevent or minimize radioactive contamination and using
- 2224 proper decontamination procedures;

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- 2225 and
- 2226 7C2.2 Has provided written attestation(s), signed by a preceptor **authorized** nuclear pharmacist,
- 2227 that the individual has **satisfactorily completed the requirements in 7C1.1(1),**
- 2228 **7C1.1(2), and 7C1.1(3) or 7C2, and has** achieved a level of competency sufficient to
- 2229 function independently as an **authorized** nuclear pharmacist.

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- 2230 **and**
- 2231 **7C3 Meets the following recentness of training requirements:**

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- 2232 **7C3.1 The training and experience required by Appendix 7C shall have been obtained**
- 2233 **within the 7 years preceding the date of license application or amendment request;**
- 2234 **or**
- 2235 **7C3.2 The individual must have had related, documented, continuing education and**
- 2236 **experience since the required training and experience was obtained.**

**Comment [JJ77]:** The term "or amendment request" is added for clarity, since many additions of authorized users occur during license amendment requests as well as during license applications.

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- 2237 **or**
- 2238 **7C43 Meets the following requirements for an experienced authorized nuclear pharmacist. Has**
- 2239 **demonstrated adequate prior experience as:**

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**\*DRAFT 5 –02/16/2012\***

2240 ~~7C4.3.1~~ An **individual identified as an authorized nuclear pharmacist on a license issued by**  
2241 **the NRC or Agreement State, a permit issued under an NRC or Agreement State**  
2242 **broad scope license before October 25, 2005, are not required to comply with the**  
2243 **training requirements of 7C1 through 7C3, authorized nuclear pharmacist identified on**  
2244 **a current facility license or permit, either on:**

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2245 ~~(1)~~ A specific license or equivalent permit that authorizes medical use or the practice of  
2246 pharmacy issued by the Department, an Agreement State, Licensing State, or NRC; or

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2247 ~~(2)~~ A permit issued under a Department, Agreement State, Licensing State, or NRC-specific  
2248 license of broad scope that is authorized to permit the use of radioactive material;

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2249 ~~or~~

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2250 ~~7C3.2~~ Is an experienced nuclear pharmacist who was identified before October 25, 2005 (and  
2251 thus need not comply with the requirements of 7C2) either on:

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2252 ~~(1)~~ An NRC or Agreement State license; or

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2253 ~~(2)~~ A permit issued under an NRC or Agreement State broad scope license that authorizes the  
2254 practice of nuclear pharmacy;

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2255 ~~7C4.2~~ **Individuals not required to comply with the training requirements of 7C1 through**  
2256 **7C3 may serve as preceptors for, and supervisors of, applicants seeking**  
2257 **authorization on licenses for the same uses for which these individuals are**  
2258 **authorized.**

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2259 ~~7C4~~ Training and experience required by Appendix 7C shall have been obtained:

**Comment [JJ78]:** Additional language added to be compatible with 10 CFR 35.57 (c). This provision effectively allows or clarifies that experienced individuals who are "grandfathered" may serve as preceptors for others.

2260 ~~7C4.1~~ Within the 7 years preceding the date of license application; or

(NRC RATS 2009-1; Compatibility=B)

2261 ~~7C4.2~~ Through documented subsequent continuing education and experience.

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2262 ~~7C5~~ To be recognized by an Agreement State or the U.S. Nuclear Regulatory Commission (posted by  
2263 NRC at <http://www.nrc.gov/materials/miau/med-use/toolkit/spec-board-cert.html>), a specialty  
2264 board shall require that each candidate for certification:

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2265 ~~7C5.1~~ Have graduated from a pharmacy program accredited by the American Council on  
2266 Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate  
2267 Examination Committee (FPGEC) examination;

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2268 ~~7C5.2~~ Hold a current, active license to practice pharmacy;

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2269 ~~7C5.3~~ Provide evidence of having acquired at least 4000 hours of training/experience in nuclear  
2270 pharmacy practice (academic training may be substituted for no more than 2000 hours of  
2271 the required training and experience); and

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2272 ~~7C5.4~~ Pass an examination, in nuclear pharmacy administered by diplomates of the specialty  
2273 board, which assesses knowledge and competency in procurement, compounding,  
2274 quality assurance, dispensing, distribution, health and safety, radiation safety, provision  
2275 of information and consultation, monitoring patient outcomes, and research and  
2276 development.

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2278 PART 7, APPENDIX 7D: AUTHORIZED USER **TRAINING** FOR UPTAKE, DILUTION AND  
2279 EXCRETION STUDIES (7.30 **USES**) ~~ADEQUATE RADIATION SAFETY TRAINING AND~~  
2280 ~~EXPERIENCE~~

2281 The licensee shall require an authorized user of an unsealed radioactive material for the uses  
2282 authorized under 7.30 to be a physician who has a current active State of Colorado license and:

2283 7D1 ~~Has provided~~ Is certified by a medical specialty board whose certification process has been  
2284 recognized by the NRC or an Agreement State and who meets the requirements in  
2285 paragraph 7D3.2 of this Appendix. NRC recognized specialty boards are posted on the  
2286 NRC website at <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>.

2287 7D1.1 To have its certification process recognized, a specialty board shall require that all  
2288 candidates for certification to:

(1) Complete 60 hours of training and ~~experience~~ in basic radionuclide handling  
techniques and radiation safety applicable to the medical use of unsealed  
radioactive materials for uptake, dilution, and excretion studies as described in  
7D3.1(1) through 7D3.1(2)(f);

and

(2) Pass an examination, administered by diplomates of the specialty board, that  
assesses knowledge and competence in radiation safety, radionuclide handling,  
and quality control.

~~Evidence of current certification by a recognized specialty board (see 7D5); and~~

~~7D1.2 Written attestation(s), signed by a preceptor authorized user, that the individual has  
achieved a level of competency sufficient to function independently as an authorized user  
for the medical uses authorized under 7.30;~~

~~(1) Each preceptor authorized user supervising the experiential training required by  
Appendix 7D shall meet the requirements of Appendix 7D, Appendix 7E or  
Appendix 7F, or equivalent Agreement State or NRC requirements.~~

2304 or

2305 7D2 Is an authorized user under Appendix 7E, Appendix 7F, or equivalent Agreement State or  
2306 NRC requirements; or 7D3

2307 or

2308 7D3 Has satisfied the following criteria:

2309 7D23.1 Has ~~provided written attestation(s), signed by a preceptor authorized user, that the~~  
2310 ~~individual has~~ satisfactorily completed 60 hours of training and experience including a  
2311 minimum of 8 hours of classroom and laboratory training, in basic radionuclide  
2312 handling techniques applicable to the medical use of unsealed radioactive materials for  
2313 uptake, dilution, and excretion studies. The training and experience must include:

2314 (1) ~~8 hours of~~ Classroom and laboratory training in the following areas:

(a) Radiation physics and instrumentation;

Comment [079]: Words "and experience" added consistent with 10 CFR 35.190 per NRC review of Draft 2.

[RATS 2007-1, 2009-1; Compatibility B]

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- 2316 (b) Radiation protection;
- 2317 (c) Mathematics pertaining to the use and measurement of radioactivity;
- 2318 (d) Chemistry of radioactive material for medical use; and
- 2319 (e) Radiation biology;
- 2320 and
- 2321 (2) Work experience **under the supervision of an authorized user who meets the**
- 2322 **requirements of 7D54, 7D, 7E, 7F, or equivalent Agreement State or NRC**
- 2323 **requirements**, involving:
  - 2324 (a) Ordering, receiving, and unpacking radioactive materials safely and
  - 2325 performing the related radiation surveys;
  - 2326 (b) Performing quality control procedures on instruments used to determine the
  - 2327 activity of dosages and performing checks for proper operation of survey
  - 2328 meters;
  - 2329 (c) Calculating, measuring, and safely preparing patient or human research
  - 2330 subject dosages;
  - 2331 (d) Using administrative controls to prevent a misadministration involving the use
  - 2332 of unsealed radioactive material;
  - 2333 (e) Using procedures to contain spilled radioactive material safely and using
  - 2334 proper decontamination procedures; and
  - 2335 (f) Administering dosages to patients or human research subjects;

**Comment [JJ80]:** Correction of misnumbering / typographical errors.

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**Comment [O81]:** Corrected reference to be consistent with 10 CFR 35.190. (Reference was shown as 7D4, but should have been 7D5).

NRC review – November 2011.  
[RATS 2007-1, 2009-1; Compatibility B]

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**and**

7D23.2 Has provided written attestation(s), signed by a preceptor authorized user **who meets the requirements of 7D54, Appendix 7D, Appendix 7E, or Appendix 7F, or equivalent Agreement State or NRC requirements**, that the individual has **satisfactorily completed the requirements in 7D1.1(1) or 7D3.1, and has** achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 7.30.

**Comment [O82]:** Corrected reference to be consistent with 10 CFR 35.190. (Reference was shown as 7D4, but should have been 7D5).

NRC review – November 2011.  
[RATS 2007-1, 2009-1; Compatibility B]

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**and**

**7D4 Meets the following recentness of training requirements:**

**7D4.1 The training and experience required by Appendix 7D shall have been obtained within the 7 years preceding the date of license application or amendment request;**

**or**

**7D4.2 The individual must have had related, documented, continuing education and experience since the required training and experience was obtained.**

**Comment [JJ83]:** The term “or amendment request” is added for clarity, since many additions of authorized users occur during license amendment requests as well as during license applications.

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**or**

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2351 ~~7D35~~ Meets the following requirements for an experienced authorized user for 7.30 uses:Has  
2352 demonstrated adequate prior experience as:

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2353 ~~7D35.1~~ An individual identified as an authorized user for the medical use of radioactive  
2354 material on a license issued by the NRC or Agreement State, a permit issued under  
2355 an NRC or Agreement State broad scope license that authorizes medical use  
2356 before October 25, 2005, who perform only those medical uses for which they were  
2357 authorized on that date are not required to comply with the training requirements  
2358 of 7D1 through 7D4, authorized user identified on a current facility license or permit  
2359 under Appendix 7E or Appendix 7F (and also meets the requirements specified in  
2360 7E3.1.7), or under equivalent Agreement State or NRC requirements, and has achieved  
2361 a level of competency sufficient to function independently as an authorized user for the  
2362 medical uses authorized under 7.30;

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2363 ~~or~~

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2364 ~~7D3.2~~ An experienced authorized user for uptake, dilution and excretion studies who:

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2365 ~~(1)~~ Was identified before October 25, 2005 (and thus need not comply with the  
2366 requirements of 7D2) either on:

2367 ~~(a)~~ An NRC or Agreement State license;

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2368 ~~or~~

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2369 ~~(b)~~ A permit issued under an NRC or Agreement State broad scope license that  
2370 authorizes medical use or the practice of nuclear pharmacy;

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2371 ~~(2)~~ Performs only those medical uses for which the authorized user identified in accord  
2372 with 7D3.2(1) was authorized on October 25, 2005.

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2373 ~~7D5.2~~ Individuals not required to comply with the training requirements of 7D1 through  
2374 7D4 may serve as preceptors for, and supervisors of, applicants seeking  
2375 authorization on licenses for the same uses for which these individuals are  
2376 authorized.

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2377 ~~7D4~~ Training and experience required by Appendix 7D shall have been obtained:

**Comment [JJ84]:** Additional language added to be compatible with 10 CFR 35.57 (c). This provision effectively allows or clarifies that experienced individuals who are "grandfathered" may serve as preceptors for others.

(NRC RATS 2009-1; Compatibility=B)

2378 ~~7D4.1~~ Within the 7 years preceding the date of license application; or

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2379 ~~7D4.2~~ Through documented subsequent continuing education and experience.

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2380 ~~7D5~~ To be recognized by an Agreement State or the U.S. Nuclear Regulatory Commission (posted by  
2381 NRC at <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>), a specialty  
2382 board shall require that each candidate for certification:

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2383 ~~7D5.1~~ Complete 60 hours in basic radionuclide handling techniques applicable to the medical use of  
2384 unsealed radioactive materials for uptake, dilution, and excretion studies (including the topics  
2385 specified in 7D2.1); and

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2386 ~~7D5.2~~ Pass an examination, administered by diplomates of the specialty board, which assesses  
2387 knowledge and competence in radiation safety, radionuclide handling, and quality control.

2388

2389

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2390 PART 7, APPENDIX 7E: AUTHORIZED USER TRAINING FOR IMAGING AND LOCALIZATION  
2391 STUDIES (7.32 USES) ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE

2392 The licensee shall require an authorized user of an unsealed radioactive material for the uses  
2393 authorized under 7.32 to be a physician who has a current active State of Colorado license and:

2394 7E1 ~~Has provided:~~ Is certified by a medical specialty board whose certification process has been  
2395 recognized by the NRC or an Agreement State and who meets the requirements in  
2396 paragraph 7E3.2 of this Appendix. NRC recognized specialty boards are posted on the  
2397 NRC website at <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>.

2398 7E1.1 To have its certification process recognized, a specialty board shall require all  
2399 candidates for certification to:

2400 (1) Complete 700 hours of training and experience in basic radionuclide handling  
2401 techniques and radiation safety applicable to the medical use of unsealed  
2402 radioactive materials for imaging and localization studies as described in 7E3.1(1)  
2403 through 7E3.1(2)(g);

2404 and

2405 (2) Pass an examination, administered by diplomates of the specialty board, which  
2406 assesses knowledge and competence in radiation safety, radionuclide handling,  
2407 and quality control;

2408 ~~Evidence of current certification by a recognized specialty board (see 7E5); and~~

2409 7E1.2 ~~Written attestation(s), signed by a preceptor authorized user, that the individual has~~  
2410 ~~achieved a level of competency sufficient to function independently as an authorized user~~  
2411 ~~for the medical uses authorized under 7.30 and 7.32;~~

2412 (1) ~~Each preceptor authorized user supervising the experiential training required by~~  
2413 ~~Appendix 7E shall meet the requirements of this Appendix 7E, or Appendix 7F,~~  
2414 ~~and also the requirements specified in 7E2.1(2)(g), or equivalent Agreement~~  
2415 ~~State or NRC requirements.~~

2416 or

2417 7E2 Is an authorized user under Appendix 7F and meets the requirements in 7E3.1(2)(g), or  
2418 equivalent Agreement State or NRC requirements;

2419 or

2420 7E3 Has satisfied the following criteria:

2421 7E3.1 Has ~~provided written attestation(s), signed by a preceptor authorized user, that the~~  
2422 ~~individual has~~ satisfactorily completed 700 hours, including a minimum of 80 hours of  
2423 classroom and laboratory training in basic radionuclide handling techniques  
2424 applicable to the medical use of unsealed radioactive materials for imaging and  
2425 localization studies.; **The training must includeing at a minimum:**

2426 (1) ~~At least 80 hours of~~ Classroom and laboratory training in the following areas:

2427 (a) Radiation physics and instrumentation;

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Comment [O85]: "of training and experience"  
added consistent with language of 10 CFR 35.290.

NRC review – November 2011  
[RATS 2006-1, 2007-1, 2009-1; Compatibility B]

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- 2428 (b) Radiation protection;
- 2429 (c) Mathematics pertaining to the use and measurement of radioactivity;
- 2430 (d) Chemistry of radioactive material for medical use; and
- 2431 (e) Radiation biology;
- 2432 and
- 2433 (2) Work experience **under the supervision of an authorized user who meets the**  
2434 **requirements of 7E5, 7E, or 7F and 7E3.1(2)(g), or equivalent Agreement**  
2435 **State or NRC requirements**, involving:
  - 2436 (a) Ordering, receiving, and unpacking radioactive materials safely and  
2437 performing the related radiation surveys;
  - 2438 (b) Performing quality control procedures on instruments used to determine the  
2439 activity of dosages and performing checks for proper operation of survey  
2440 meters;
  - 2441 (c) Calculating, measuring, and safely preparing patient or human research  
2442 subject dosages;
  - 2443 (d) Using administrative controls to prevent a misadministration involving the use  
2444 of unsealed radioactive material;
  - 2445 (e) Using procedures to contain spilled radioactive material safely and using  
2446 proper decontamination procedures; and
  - 2447 (f) Administering dosages to patients or human research subjects;
  - 2448 (g) Eluting generator systems appropriate for preparation of radioactive drugs for  
2449 imaging and localization studies, measuring and testing the eluate for  
2450 radiochemical purity, and processing the eluate with reagent kits to  
2451 prepare labeled radioactive drugs;

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2452 and

2453 **7E23.2** Has provided written attestation(s), signed by a preceptor authorized user **who meets**  
2454 **the requirements of 7E5, Appendix 7E, or Appendix 7F and 7E3.1(2)(g), or**  
2455 **equivalent Agreement State or NRC requirements**, that the individual has  
2456 **satisfactorily completed the requirements in 7E1.1(1) or 7E3, and has** achieved a  
2457 level of competency sufficient to function independently as an authorized user for the  
2458 medical uses authorized under 7.30 and 7.32.

Comment [O86]: Modified reference from 7E1.1 to 7E1.1(1), consistent with 10 CFR 35.290.

NRC Review – November 2011.  
[RATS 2006-1, 2007-1, 2009-1; Compatibility B]

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2459 **and**

2460 **7E4 Meets the following recentness of training requirements:**

2461 **7E4.1 The training and experience required by Appendix 7E shall have been obtained**  
2462 **within the 7 years preceding the date of license application or amendment request;**

Comment [JJ87]: The term "or amendment request" is added for clarity, since many additions of authorized users occur during license amendment requests as well as during license applications.

2463 **or**

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2464 **7E4.2 The individual must have had related, documented, continuing education and**  
2465 **experience since the required training and experience was obtained.**

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2466 or

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2467 **7E3.5 Meets the following requirements for an experienced authorized user for 7.32 uses:Has**  
2468 **demonstrated adequate prior experience as:**

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2469 **7E5.3.1 An individual identified as an authorized user for the medical use of radioactive**  
2470 **material on a license issued by the NRC or Agreement State, a permit issued under**  
2471 **an NRC or Agreement State broad scope license that authorizes medical use**  
2472 **before October 25, 2005, who perform only those medical uses for which they were**  
2473 **authorized on that date are not required to comply with the training requirements**  
2474 **of 7E1 through 7E4.**~~authorized user identified on a current facility license or permit~~  
2475 ~~under Appendix 7F (and also meets the requirements specified in 7E2.1(2)(g)), or under~~  
2476 ~~equivalent Agreement State or NRC requirements, and has provided written~~  
2477 ~~attestation(s), signed by a preceptor authorized user, that the individual has achieved a~~  
2478 ~~level of competency sufficient to function independently as an authorized user for the~~  
2479 ~~medical uses authorized under 7.30 and 7.32; or~~

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2480 ~~7E3.2 An experienced authorized user for imaging and localization studies who:~~

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2481 ~~(1) Was identified before October 25, 2005 (and thus need not comply with the~~  
2482 ~~requirements of 7E2) either on:~~

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2483 ~~(a) An NRC or Agreement State license; or~~

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2484 ~~(b) A permit issued under an NRC or Agreement State broad scope license that~~  
2485 ~~authorizes medical use or the practice of nuclear pharmacy;~~

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2486 ~~(2) Performs only those medical uses for which the authorized user identified in accord~~  
2487 ~~with 7E3.2(1) was authorized on October 25, 2005.~~

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2488 **7E5.2 Individuals not required to comply with the training requirements of 7E1 through**  
2489 **7E4 may serve as preceptors for, and supervisors of, applicants seeking**  
2490 **authorization on licenses for the same uses for which these individuals are**  
2491 **authorized.**

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2492 ~~7E4 Training and experience required by Appendix 7E shall have been obtained:~~

**Comment [JJ88]:** Additional language added to be compatible with 10 CFR 35.57 (c). This provision effectively allows or clarifies that experienced individuals who are "grandfathered" may serve as preceptors for others.

2493 ~~7E4.1 Within the 7 years preceding the date of license application; or~~

(NRC RATS 2009-1; Compatibility=B)

2494 ~~7E4.2 Through documented subsequent continuing education and experience.~~

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2495 ~~7E5 To be recognized by an Agreement State or the U.S. Nuclear Regulatory Commission (posted by~~  
2496 ~~NRC at <http://www.nrc.gov/materials/miau/med-use/toolkit/spec-board-cert.html>), a specialty~~  
2497 ~~board shall require that each candidate for certification:~~

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2498 ~~7E5.1 Complete 700 hours in basic radionuclide handling techniques applicable to the medical use of~~  
2499 ~~unsealed radioactive materials for imaging and localization studies (including the topics specified~~  
2500 ~~in 7E2.1); and~~

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2501 ~~7E5.2 Pass an examination, administered by diplomates of the specialty board, which assesses~~  
2502 ~~knowledge and competence in radiation safety, radionuclide handling, and quality control.~~

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2504 PART 7, APPENDIX 7F: AUTHORIZED USER **TRAINING** FOR DIAGNOSTIC OR THERAPEUTIC  
2505 USE OF UNSEALED RADIOACTIVE MATERIAL REQUIRING A WRITTEN DIRECTIVE (7.36.2  
2506 **USES) ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE**

2507 The licensee shall require an authorized user of an unsealed radioactive material for the uses  
2508 authorized under 7.36.2 to be a physician who has a current active State of Colorado license and:

2509 7F1 ~~Has provided:~~ **Is certified by a medical specialty board whose certification process has been**  
2510 **recognized by the NRC or an Agreement State and who meets the requirements in**  
2511 **paragraph 7F2.1(2)(f) and 7F2.2 of this Appendix. NRC recognized specialty boards are**  
2512 **posted on the NRC website at [http://www.nrc.gov/materials/miau/med-use-toolkit/spec-](http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html)**  
2513 **board-cert.html.**

2514 7F1.1 **To have its certification process recognized, a specialty board shall require all**  
2515 **candidates for certification to:**

2516 (1) **Successfully complete residency training in a radiation therapy or nuclear**  
2517 **medicine training program or a program in a related medical specialty. These**  
2518 **residency training programs must include 700 hours of training and experience**  
2519 **as described in 7F2.1(1) through 7F2.1(2)(e). Eligible training programs must be**  
2520 **approved by the Residency Review Committee of the Accreditation Council for**  
2521 **Graduate Medical Education, the Royal College of Physicians and Surgeons of**  
2522 **Canada, or the Committee on Post-Graduate Training of the American**  
2523 **Osteopathic Association;**

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2524 **and**

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2525 (2) **Pass an examination, administered by diplomates of the specialty board, which**  
2526 **tests knowledge and competence in radiation safety, radionuclide handling,**  
2527 **quality assurance, and clinical use of unsealed radioactive material for which a**  
2528 **written directive is required;**

2529 ~~Evidence of current certification by a recognized specialty board (see 7F5); and~~

2530 ~~7F1.2 Written attestation(s), signed by a preceptor authorized user, that the individual has~~  
2531 ~~achieved a level of competency sufficient to function independently as an authorized user~~  
2532 ~~for the medical uses authorized under 7.36;~~

2533 ~~(1) Each preceptor authorized user supervising the experiential training required by~~  
2534 ~~Appendix 7F shall meet the requirements of this Appendix 7F, including~~  
2535 ~~experience in administering dosages in the same dosage category or categories~~  
2536 ~~listed in 7F2.1(3), or equivalent Agreement State or NRC requirements.~~

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2537 or

2538 7F2 Has satisfied the following criteria:

2539 7F2.1 Has ~~provided written attestation(s), signed by a preceptor authorized user, that the~~  
2540 ~~individual has~~ satisfactorily completed 700 hours **of training and experience, including**  
2541 **a minimum of 200 hours of classroom and laboratory training,** in basic radionuclide  
2542 handling techniques applicable to the medical use of unsealed radioactive material  
2543 requiring a ~~medical-written~~ directive., **The training must include:**

2544 (1) ~~At least 200 hours of c~~Classroom and laboratory training in the following areas:

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- 2545 (a) Radiation physics and instrumentation;
- 2546 (b) Radiation protection;
- 2547 (c) Mathematics pertaining to the use and measurement of radioactivity;
- 2548 (d) Chemistry of radioactive material for medical use; and
- 2549 (e) Radiation biology;
- 2550 and
- 2551 (2) Work experience, **under the supervision of an authorized user who meets the**  
2552 **requirements of 7F4, or 7F, or equivalent Agreement State or NRC**  
2553 **requirements. A supervising authorized user, who meets the requirements**  
2554 **in 7F2.1, must also have experience in administering dosages in the same**  
2555 **dosage category or categories (i.e., 7F2.1(2)(f)) as the individual requesting**  
2556 **authorized user status. The work experience must involveing:**
- 2557 (a) Ordering, receiving, and unpacking radioactive materials safely and  
2558 performing the related radiation surveys;
- 2559 (b) Performing quality control procedures on instruments used to determine the  
2560 activity of dosages and performing checks for proper operation of survey  
2561 meters;
- 2562 (c) Calculating, measuring, and safely preparing patient or human research  
2563 subject dosages;
- 2564 (d) Using administrative controls to prevent a misadministration involving the use  
2565 of unsealed radioactive material;
- 2566 (e) Using procedures to contain spilled radioactive material safely and using  
2567 proper decontamination procedures;
- 2568 and
- 2569 **(f) Administering dosages of radioactive drugs to patients or human**  
2570 **research subjects involving a minimum of 3 cases in each of the following**  
2571 **categories for which the individual is requesting authorized user status:**
- 2572 ~~(3) Has administered dosages of radioactive drugs to patients or human research~~  
2573 ~~subjects:~~
- 2574 ~~(a) That include a minimum of 3 cases in each of the following categories for~~  
2575 ~~which the individual is requesting authorized user status;~~
- 2576 (i) Oral administration of less than or equal to 1.22 GBq (33 mCi) of Na  
2577 I-131 for which a written directive is required; ~~and~~
- 2578 (ii) Oral administration of greater than 1.22 GBq (33 mCi) of -Na I-131  
2579 for which a written directive is required [experience with at least  
2580 3 cases in 7F2.1(23)(fa)(ii) also satisfies the requirement in  
2581 category 7F2.1(23)(fa)(i)]; ~~and~~

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2582 (iii) Parenteral administration of any beta emitter, or a photon-emitting  
2583 radionuclide with a photon energy less than 150 keV, for which a  
2584 written directive is required;

2585 and/or

2586 (iv) Parenteral administration of any other radionuclide for which a  
2587 written directive is required;

2588 and

~~(b) Provided that the experience required by 7F2.1(3) may be obtained  
concurrently with the supervised work experience required by 7F2.1(2);~~

2591 7F2.2 Has provided written attestation(s), ~~signed by a preceptor authorized user,~~ that the  
2592 individual has **satisfactorily completed the requirements in 7F1.1(1) and 7F2.1(2)(f)**  
2593 **or 7F2.1, and has** achieved a level of competency sufficient to function independently as  
2594 an authorized user for the medical uses authorized under 7.36. **The written attestation**  
2595 **must be signed by a preceptor authorized user who:**

**(1) Meets the requirements in 7F4, Appendix 7F, or equivalent NRC or Agreement  
State requirements; and**

~~(1)(2)~~ **(2) The preceptor authorized user, who meets the requirements in 7F2.1 must  
have experience in administering dosages in the same dosage category or  
categories (i.e., 7F2.1(2)(f)) as the individual requesting authorized user status.**

2601 and

2602 **7F3 Meets the following recentness of training requirements:**

2603 **7F3.1 The training and experience required by Appendix 7F shall have been obtained:**  
2604 **within the 7 years preceding the date of license application or amendment request;**

2605 or

2606 **7F3.2 The individual must have had related, documented, continuing education and**  
2607 **experience since the required training and experience was obtained.**

2608 or

2609 ~~**7F4.3 Meets the following requirements for an experienced authorized user for 7.36.2 uses: Has**~~  
2610 ~~**demonstrated adequate prior experience as:**~~

2611 ~~**7F4.3.1 An individual identified as an authorized user for the medical use of radioactive**~~  
2612 ~~**material on a license issued by the NRC or Agreement State, a permit issued under**~~  
2613 ~~**an NRC or Agreement State broad scope license that authorizes medical use**~~  
2614 ~~**before October 25, 2005, who perform only those medical uses for which they were**~~  
2615 ~~**authorized on that date are not required to comply with the training requirements**~~  
2616 ~~**of 7F1 through 7F3. authorized user identified on a current facility license or permit under**~~  
2617 ~~**Appendix 7F for uses listed in Appendix 7F, or under equivalent Agreement State or NRC**~~  
2618 ~~**requirements, and has provided written attestation(s), signed by a preceptor authorized**~~  
2619 ~~**user, that the individual has achieved a level of competency sufficient to function**~~  
2620 ~~**independently as an authorized user for the medical uses authorized under 7.36;**~~

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Comment [O89]: Modified reference consistent with equivalent reference in 10 CFR 35.390 – added parenthetical item (1).

NRC review – November 2011 [RATS 2009-1; Compatibility B]

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Comment [JJ90]: The term “or amendment request” is added for clarity, since many additions of authorized users occur during license amendment requests as well as during license applications.

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2621 ~~or~~

2622 ~~7F3.2 An experienced authorized user for use of unsealed radioactive material who:~~

2623 ~~(1) Was identified before October 25, 2005 (and thus need not comply with the requirements of~~

2624 ~~7F2) either on:~~

2625 ~~(a) An NRC or Agreement State license; or~~

2626 ~~(b) A permit issued under an NRC or Agreement State broad scope license that authorizes~~

2627 ~~medical use or the practice of nuclear pharmacy;~~

2628 ~~(2) Performs only those medical uses for which the authorized user identified in accord with~~

2629 ~~7F3.2(1) was authorized on October 25, 2005.~~

2630 ~~**7F4.2 Individuals not required to comply with the training requirements of 7F1 through**~~

2631 ~~**7F3 may serve as preceptors for, and supervisors of, applicants seeking authorization on**~~

2632 ~~**licenses for the same uses for which these individuals are authorized.**~~

2633 ~~7F4 Training and experience required by Appendix 7F shall have been obtained:~~

2634 ~~7F4.1 Within the 7 years preceding the date of license application; or~~

2635 ~~7F4.2 Through documented subsequent continuing education and experience.~~

2636 ~~7F5 To be recognized by an Agreement State or the U.S. Nuclear Regulatory Commission (posted by~~

2637 ~~NRC at <http://www.nrc.gov/materials/miau/med-use/toolkit/spec-board-cert.html>), a specialty~~

2638 ~~board shall require that each candidate for certification:~~

2639 ~~7F5.1 Successfully complete residency training in a radiation therapy or nuclear medicine training~~

2640 ~~program or a program in a related medical specialty that includes 700 hours of training and~~

2641 ~~experience as described in 7F2.1. Eligible training programs must be approved by the Residency~~

2642 ~~Review Committee of the Accreditation Council for Graduate Medical Education or Royal College~~

2643 ~~of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the~~

2644 ~~American Osteopathic Association; and~~

2645 ~~7F5.2 Pass an examination, administered by diplomates of the specialty board, which tests knowledge~~

2646 ~~and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of~~

2647 ~~unsealed byproduct material.~~

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**Comment [JJ91]:** Additional language added to be compatible with 10 CFR 35.57 (c). This provision effectively allows or clarifies that experienced individuals who are "grandfathered" may serve as preceptors for others.

(NRC RATS 2009-1; Compatibility=B)

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2650 PART 7, APPENDIX 7G: AUTHORIZED USER TRAINING FOR THE ORAL ADMINISTRATION (7.36)  
2651 OF SODIUM IODIDE I-131 REQUIRING A WRITTEN DIRECTIVE IN QUANTITIES LESS THAN  
2652 OR EQUAL TO 1.22 Gbq I-131 (33 mCi) SODIUM IODIDE ADEQUATE RADIATION SAFETY  
2653 TRAINING AND EXPERIENCE (7.36.3 USES)

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2654 The licensee shall require an authorized user ~~of for~~ the oral administration ~~of sodium iodide I-131~~  
2655 ~~requiring a written directive in quantities of less than or equal to 1.22 GBq (33 mCi), of Na I-131~~  
2656 ~~for which a written directive is required~~ to be a physician who has a current active State of  
2657 Colorado license and:

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2658 7G1 ~~Has provided:~~ Is certified by a medical specialty board whose certification process includes  
2659 all of the requirements in 7G3.1 and 7G3.1(2) of this Appendix and whose certification  
2660 process has been recognized by the NRC or an Agreement State and who meets the  
2661 requirements in paragraph 7G3.1(3) of this Appendix. NRC recognized specialty boards  
2662 are posted on the NRC website at [http://www.nrc.gov/materials/miau/med-use-toolkit/spec-](http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html)  
2663 [board-cert.html](http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html).

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2664 ~~7G1.1 Evidence of current certification by a recognized medical specialty board (see 7G5); and~~

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2665 7G1.2 ~~Written attestation(s), signed by a preceptor authorized user, that the individual has~~  
2666 ~~achieved a level of competency sufficient to function independently as an authorized user~~  
2667 ~~for the medical uses of unsealed radioactive materials using Na I-131 authorized under~~  
2668 ~~7.36;~~

2669 (1) ~~Each preceptor authorized user supervising the experiential training required by~~  
2670 ~~Appendix 7G shall meet the requirements of Appendix 7G, or Appendix 7F~~  
2671 ~~(including experience in administering dosages in the same dosage category or~~  
2672 ~~categories listed in 7F2.1(3)), or Appendix 7H, or equivalent Agreement State or~~  
2673 ~~NRC requirements.~~

2674 or

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2675 7G2 ~~Is an authorized user under Appendix 7F for uses listed in 7F2.1(2)(f)(i) or 7F2.1(2)(f)(ii),~~  
2676 ~~Appendix 7H, or equivalent NRC or Agreement State requirements;~~

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2677 or

2678 7G32 Has satisfied the following criteria:

2679 7G32.1 ~~Has provided written attestation(s), signed by a preceptor authorized user, that the~~  
2680 ~~individual has satisfactorily completed 80 hours of classroom and laboratory training,~~  
2681 ~~in basic radionuclide handling techniques applicable to the medical use of sodium iodide~~  
2682 ~~I-131 for procedures requiring a written directive, including:~~

2683 (1) ~~At least The~~ 80 hours of classroom and laboratory training ~~must include in the~~  
2684 ~~following areas:~~

2685 (a) Radiation physics and instrumentation;

2686 (b) Radiation protection;

2687 (c) Mathematics pertaining to the use and measurement of radioactivity;

2688 (d) Chemistry of radioactive material for medical use; and

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- 2689 (e) Radiation biology;
- 2690 and
- 2691 (2) **Has work experience under the supervision of an authorized user who meets**  
2692 **the requirements of 7G5, or Appendix 7F, Appendix 7G, Appendix 7H or**  
2693 **equivalent Agreement State or NRC requirements. A supervising**  
2694 **authorized user, who meets the requirements in 7F2.1, must also have**  
2695 **experience in administering dosages as specified in 7F2.1(2)(f)(i) or**  
2696 **7F2.1(2)(f)(ii) as the individual requesting authorized user status. The work**  
2697 **experience must involveing:**
- 2698 (a) Ordering, receiving, and unpacking radioactive materials safely and  
2699 performing the related radiation surveys;
- 2700 (b) Performing quality control procedures on instruments used to determine the  
2701 activity of dosages and performing checks for proper operation of survey  
2702 meters;
- 2703 (c) Calculating, measuring, and safely preparing patient or human research  
2704 subject dosages;
- 2705 (d) Using administrative controls to prevent a misadministration involving the use  
2706 of unsealed radioactive material;
- 2707 (e) Using procedures to contain spilled radioactive material safely and using  
2708 proper decontamination procedures;
- 2709 and
- 2710 **(f) Administering dosages to patients or human research subjects that**  
2711 **includes at least 3 cases involving the oral administration of less than or**  
2712 **equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131;**
- 2713 ~~(3) Has administered dosages of radioactive drugs to patients or human research~~  
2714 ~~subjects:~~
- 2715 ~~(a) That include a minimum of 3 cases involving the oral administration of less than or~~  
2716 ~~equal to 1.22 GBq (33 mCi) of Na I-131; and~~
- 2717 ~~(b) Provided that the experience required by 7G2.1(3) may be obtained concurrently with~~  
2718 ~~the supervised work experience required by 7G2.1(2);~~
- 2719 and
- 2720 **7G2.2(3) Has provided written attestation(s), signed by a preceptor authorized user, that the**  
2721 **individual has completed the requirements of 7G3.1(1) and 7G3.1(2), and has**  
2722 **achieved a level of competency sufficient to function independently as an authorized user**  
2723 **for the medical uses of unsealed radioactive materials using Na I-131 authorized under**  
2724 **7.36. The written attestation must be signed by a preceptor authorized user who:**
- 2725 **(a) Meets the requirements in 7G5, Appendix 7F, Appendix 7G, or**  
2726 **Appendix 7H, or equivalent NRC or Agreement State requirements;**
- 2727 and

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Comment [JJ92]: Corrected reference, consistent with 10 CFR 35.392.

NRC review – November 2011 [RATS 2009-1; Compatibility B]

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Comment [JJ93]: Changed reference from 7.36.3 to the broader reference of 7.36.

NRC review – November 2011 [RATS 2009-1; Compatibility B]

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(+) (b) The preceptor authorized user, who meets the requirements in 7F2.1, must have experience in administering dosages as specified in 7F2.1(2)(f)(i) or 7F2.1(2)(f)(ii).

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**7G4 Meets the following recentness of training requirements:**

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**7G4.1 The training and experience required by Appendix 7G shall have been obtained within the 7 years preceding the date of license application or amendment request;**

**Comment [JJ94]:** The term "or amendment request" is added for clarity, since many additions of authorized users occur during license amendment requests as well as during license applications.

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or

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**7G4.2 The individual must have had related, documented, continuing education and experience since the required training and experience was obtained.**

2738

or

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**7G5.3 Meets the following requirements for an experienced authorized user for 7.36.3 uses: Has demonstrated adequate prior experience as:**

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**7G5.3.1 An individual identified as an authorized user for the medical use of radioactive material on a license issued by the NRC or Agreement State, a permit issued under an NRC or Agreement State broad scope license that authorizes medical use before October 25, 2005, who perform only those medical uses for which they were authorized on that date are not required to comply with the training requirements of 7G1 through 7G4, authorized user identified on a current facility license or permit under Appendix 7F for uses listed in 7F2.1(3), under Appendix 7H for uses listed in 7H2.1(3), or under equivalent Agreement State or NRC requirements, and has provided written attestation(s), signed by a preceptor authorized user, that the individual has achieved a level of competency sufficient to function independently as an authorized user for the medical uses of unsealed radioactive materials using Na I-131 authorized under 7.36;**

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or

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**7G3.2 An experienced authorized user for the medical use of unsealed radioactive materials using Na I-131 who:**

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**(1) Was identified before October 25, 2005 (and thus need not comply with the requirements of 7G2) either on:**

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**(a) An NRC or Agreement State license; or**

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**(b) A permit issued under an NRC or Agreement State broad scope license that authorizes medical use or the practice of nuclear pharmacy; and**

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**(2) Performs only those medical uses for which the authorized user identified in accord with 7G3.2(1) was authorized on October 25, 2005.**

**Comment [JJ95]:** Additional language added to be compatible with 10 CFR 35.57 (c). This provision effectively allows or clarifies that experienced individuals who are "grandfathered" may serve as preceptors for others.

(NRC RATS 2009-1; Compatibility=B)

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**7G5.2 Individuals not required to comply with the training requirements of 7G1 through 7G4 may serve as preceptors for, and supervisors of, applicants seeking authorization on licenses for the same uses for which these individuals are authorized.**

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2767 ~~7G4 Training and experience required by Appendix 7G shall have been obtained:~~

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2768 ~~7G4.1 Within the 7 years preceding the date of license application; or~~

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2769 ~~7G4.2 Through documented subsequent continuing education and experience.~~

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2770 ~~7G5 To be recognized by an Agreement State or the U.S. Nuclear Regulatory Commission (posted by~~  
2771 ~~NRC at <http://www.nrc.gov/materials/miau/med-use/toolkit/spec-board-cert.html>), for purposes of~~  
2772 ~~Appendix 7G, a medical specialty board shall require that each candidate for certification to meet~~  
2773 ~~all of the requirements of 7G2.~~  
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2775 PART 7, APPENDIX 7H: AUTHORIZED USER TRAINING FOR THE ORAL ADMINISTRATION OF  
2776 SODIUM IODIDE I-131 REQUIRING A WRITTEN DIRECTIVE IN QUANTITIES (7.36) OF  
2777 GREATER THAN 1.22 GBq (33 mCi) (7.36.4 USES) SODIUM IODIDE ADEQUATE  
2778 RADIATION SAFETY TRAINING AND EXPERIENCE

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2779 The licensee shall require an authorized user ~~foref~~ the oral administration of sodium iodide I-131  
2780 requiring a written directive in quantities greater than 1.22 GBq (33 mCi), ~~of Na I-131 for which a~~  
2781 ~~written directive is required~~ to be a physician who has a current active State of Colorado license  
2782 and:

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2783 7H1 ~~Has provided:~~ Is certified by a medical specialty board whose certification process includes  
2784 all of the requirements in 7H3.1, and 7H3.1(2) and whose certification has been recognized  
2785 by the NRC or an Agreement State, and who meets the requirements in paragraph 7H3.2 of  
2786 this Appendix. NRC recognized specialty boards are posted on the NRC website at  
2787 <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>.

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2788 7H1.1 ~~Evidence of current certification by a recognized medical specialty board (see 7H5); and~~

2789 7H1.2 ~~Written attestation(s), signed by a preceptor authorized user, that the individual has~~  
2790 ~~achieved a level of competency sufficient to function independently as an authorized user~~  
2791 ~~for the medical uses of unsealed radioactive materials using Na I-131 in activities greater~~  
2792 ~~than 1.22 GBq (33 mCi) authorized under 7.36;~~

2793 ~~(1) Each preceptor authorized user supervising the experiential training required by~~  
2794 ~~Appendix 7H shall meet the requirements of Appendix 7H, or Appendix 7F~~  
2795 ~~(including experience in administering dosages in the same dosage category or~~  
2796 ~~categories listed in 7F2.1(3)), or equivalent Agreement State or NRC~~  
2797 ~~requirements.~~

2798 or

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2799 7H2 Is an authorized user under Appendix 7F for uses listed in 7F2.1(2)(f)(ii), or equivalent NRC  
2800 or Agreement State requirements;

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2801 or

2802 7H32 Has satisfied the following criteria:

2803 7H23.1 Has ~~provided written attestation(s), signed by a preceptor authorized user, that the~~  
2804 ~~individual has~~ satisfactorily completed 80 hours of classroom and laboratory training,  
2805 ~~in basic radionuclide handling techniques~~ applicable to the medical use of sodium iodide  
2806 I-131 for procedures requiring a written directive, ~~including:~~

2807 (1) ~~The~~ ~~At least~~ 80 hours of classroom and laboratory training ~~in the following areas~~ must  
2808 include:

2809 (a) Radiation physics and instrumentation;

2810 (b) Radiation protection;

2811 (c) Mathematics pertaining to the use and measurement of radioactivity;

2812 (d) Chemistry of radioactive material for medical use; and

**\*DRAFT 5 –02/16/2012\***

- 2813 (e) Radiation biology;
- 2814 and
- 2815 (2) **Has work experience, under the supervision of an authorized user who meets**  
2816 **the requirements of 7H5, Appendix 7F, Appendix 7H or equivalent**  
2817 **Agreement State or NRC requirements. A supervising authorized user,**  
2818 **who meets the requirements in 7F2.1, must also have experience in**  
2819 **administering dosages as specified in 7F2.1(2)(f)(ii). The work experience**  
2820 **must involve:**
- 2821 (a) Ordering, receiving, and unpacking radioactive materials safely and  
2822 performing the related radiation surveys;
- 2823 (b) Performing quality control procedures on instruments used to determine the  
2824 activity of dosages and performing checks for proper operation of survey  
2825 meters;
- 2826 (c) Calculating, measuring, and safely preparing patient or human research  
2827 subject dosages;
- 2828 (d) Using administrative controls to prevent a misadministration involving the use  
2829 of unsealed radioactive material;
- 2830 (e) Using procedures to contain spilled radioactive material safely and using  
2831 proper decontamination procedures;
- 2832 and
- 2833 (3f) **Administering** ~~Has administered~~ dosages of radioactive drugs to patients  
2834 or human research subjects, **that includes at least 3 cases involving the oral**  
2835 **administration of greater than 1.22 gigabecquerels (33 millicuries) of**  
2836 **sodium iodide I-131;**
- 2837 ~~(a) That include a minimum of 3 cases involving the oral administration of~~  
2838 ~~greater than 1.22 GBq (33 mCi) of Na I-131; and~~
- 2839 ~~(b) Provided that the experience required by 7H2.1(3) may be obtained~~  
2840 ~~concurrently with the supervised work experience required by 7H2.1(2);~~
- 2841 and
- 2842 ~~7H2.2~~ (3) Has provided written attestation(s), ~~signed by a preceptor authorized user,~~ that the  
2843 individual has **completed the requirements of 7H3.1(1) and 7H3.1(2), and has**  
2844 achieved a level of competency sufficient to function independently as an authorized user  
2845 for the medical uses of unsealed radioactive materials using Na I-131 in activities greater  
2846 than 1.22 GBq (33 mCi) authorized under 7.36. **The written attestation must be signed**  
2847 **by a preceptor authorized user who;**
- 2848 (1) **Meets the requirements in 7H5, Appendix 7F, or Appendix 7H, or equivalent**  
2849 **NRC or Agreement State requirements;**
- 2850 and

**Comment [JJ96]:** Changed reference from 7.36.4 to the broader reference of 7.36, consistent with 10 CFR 35.394.

NRC review – November 2011  
[RATS 2009-1; Compatibility B]

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2851 (2) The preceptor authorized user, who meets the requirements in 7F2.1 must have  
2852 experience in administering dosages as specified in 7F2.1(2)(f)(ii).

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2854 7H4 Meets the following recentness of training requirements:

2855 7H4.1 The training and experience required by Appendix 7H shall have been obtained  
2856 within the 7 years preceding the date of license application or amendment request;

Comment [JJ97]: The term "or amendment request" is added for clarity, since many additions of authorized users occur during license amendment requests as well as during license applications.

2857 or

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2858 7H4.2 The individual must have had related, documented, continuing education and  
2859 experience since the required training and experience was obtained.

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2861 7H53 Meets the following requirements for an experienced authorized user for 7.36.4 usesHas  
2862 demonstrated adequate prior experience as:

2863 7H35.1 An individual identified as an authorized user for the medical use of radioactive  
2864 material on a license issued by the NRC or Agreement State, a permit issued under  
2865 an NRC or Agreement State broad scope license that authorizes medical use  
2866 before October 25, 2005, who perform only those medical uses for which they were  
2867 authorized on that date are not required to comply with the training requirements  
2868 of 7H1 through 7H4, authorized user identified on a current facility license or permit  
2869 under Appendix 7H, under Appendix 7F for uses listed in 7F2.1(3), or under equivalent  
2870 Agreement State or NRC requirements, and has provided written attestation(s), signed by  
2871 a preceptor authorized user, that the individual has achieved a level of competency  
2872 sufficient to function independently as an authorized user for the medical uses of  
2873 unsealed radioactive materials using Na I-131 in activities greater than 1.22 GBq (33  
2874 mCi) authorized under 7.36;

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2876 7H3.2 An experienced authorized user for the medical use of unsealed radioactive materials  
2877 using Na I-131 in activities greater than 1.22 GBq (33 mCi) who:

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2878 (1) Was identified before October 25, 2005 (and thus need not comply with the requirements of  
2879 7H2) either on:

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2880 (a) An NRC or Agreement State license; or

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2881 (b) A permit issued under an NRC or Agreement State broad scope license that authorizes  
2882 medical use or the practice of nuclear pharmacy; and

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2883 (2) Performs only those medical uses for which the authorized user identified in accord with  
2884 7H3.2(1) was authorized on October 25, 2005.

Comment [JJ98]: Additional language added to be compatible with 10 CFR 35.57 (c). This provision effectively allows or clarifies that experienced individuals who are "grandfathered" may serve as preceptors for others.

(NRC RATS 2009-1; Compatibility=B)

2885 7H5.2 Individuals not required to comply with the training requirements of 7H1 through  
2886 7H4 may serve as preceptors for, and supervisors of, applicants seeking  
2887 authorization on licenses for the same uses for which these individuals are  
2888 authorized.

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2889 7H4 Training and experience required by Appendix 7H shall have been obtained:

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2890 ~~7H4.1 Within the 7 years preceding the date of license application; or~~

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2891 ~~7H4.2 Through documented subsequent continuing education and experience.~~

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2892 ~~7H5—To be recognized by an Agreement State or the U.S. Nuclear Regulatory Commission (posted by~~  
2893 ~~NRG at <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>) for purposes of~~  
2894 ~~Appendix 7H, a medical specialty board shall require that each candidate for certification to meet~~  
2895 ~~all of the requirements of 7H2.~~  
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**\*DRAFT 5 –02/16/2012\***

2897 PART 7, APPENDIX 7I: AUTHORIZED USER TRAINING FOR THE PARENTERAL  
2898 ADMINISTRATION ~~(7.36)~~ OF UNSEALED RADIOACTIVE MATERIAL REQUIRING A  
2899 WRITTEN DIRECTIVE ~~(7.36.5 USES)~~ ADEQUATE RADIATION SAFETY TRAINING AND  
2900 EXPERIENCE

2901 The licensee shall require an authorized user for parenteral administration of unsealed radioactive  
2902 material for which a written directive is required to be a physician who has a current active State  
2903 of Colorado license and:

2904 7I1 Is an authorized user under Appendix 7F for uses listed in 7F2.1(2)(f)(iii) or 7F2.1(2)(f)(iv), or  
2905 equivalent NRC or Agreement State requirements;

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2906 ~~or~~

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2907 7I2 Is an authorized user under Appendix 7K, Appendix 7M, or equivalent NRC or Agreement  
2908 State requirements and who meets the requirements in 7I4;

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2909 ~~or~~

2910 7I3 Is certified by a medical specialty board whose certification process has been recognized by  
2911 the NRC, or an Agreement State under Appendix 7K or Appendix 7M, and who meets the  
2912 requirements in paragraph 7I4 of this section.

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2913 Has provided:

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2914 7I4.1 Evidence of current certification by a recognized medical specialty board (see 7I5); and

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2915 7I4.2 Written attestation(s), signed by a preceptor authorized user, that the individual has  
2916 achieved a level of competency sufficient to function independently as an authorized user  
2917 for parenteral administration of unsealed radioactive material for which a written directive  
2918 authorized under 7.36;

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2919 (1) Each preceptor authorized user supervising the experiential training required by  
2920 Appendix 7I shall meet the requirements of Appendix 7I, or Appendix 7F  
2921 (including experience in administering dosages in the same dosage category or  
2922 categories listed in 7F2.1(3)), or equivalent Agreement State or NRC  
2923 requirements.

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2924 or

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2925 7I4.2 Has satisfied the following criteria:

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2926 7I4.2.1 Has provided written attestation(s), signed by a preceptor authorized user, that the  
2927 individual has satisfactorily completed 80 hours of classroom and laboratory training in  
2928 basic radionuclide handling techniques applicable to parenteral administrations, for  
2929 which requiring a written directive is required, of any beta emitter, or any photon-  
2930 emitting radionuclide with a photon energy less than 150 keV, and/or parenteral  
2931 administration of any other radionuclide for which a written directive is required.  
2932 including:

2933 (1) At least 80 hours of eThe training must include classroom and laboratory training in  
2934 the following areas:

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- 2935 (a) Radiation physics and instrumentation;
- 2936 (b) Radiation protection;
- 2937 (c) Mathematics pertaining to the use and measurement of radioactivity;
- 2938 (d) Chemistry of radioactive material for medical use;
- 2939 and
- 2940 (e) Radiation biology;

2941 and

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2942 (2) **Has work experience under the supervision of an authorized user who meets**  
2943 **the requirements of 716, Appendix 7F, Appendix 7I, or equivalent**  
2944 **Agreement State or NRC requirements, in the parenteral administration, for**  
2945 **which a written directive is required, of any beta emitter, or any photon-**  
2946 **emitting radionuclide with a photon energy less than 150 keV, and/or**  
2947 **parenteral administration of any other radionuclide for which a written**  
2948 **directive is required. A supervising authorized user, who meets the**  
2949 **requirements in 7F, must have experience in administering dosages as**  
2950 **specified in 7F2.1(2)(f)(iii) and/or 7F2.1(2)(f)(iv). The work experience must**  
2951 **involveing:**

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- 2952 (a) Ordering, receiving, and unpacking radioactive materials safely and  
2953 performing the related radiation surveys;
- 2954 (b) Performing quality control procedures on instruments used to determine the  
2955 activity of dosages and performing checks for proper operation of survey  
2956 meters;
- 2957 (c) Calculating, measuring, and safely preparing patient or human research  
2958 subject dosages;
- 2959 (d) Using administrative controls to prevent a misadministration involving the use  
2960 of unsealed radioactive material;
- 2961 (e) Using procedures to contain spilled radioactive material safely and using  
2962 proper decontamination procedures;

2963 and

2964 (3) ~~Has (f) Administering~~ dosages ~~of radioactive drugs~~ to patients or human research  
2965 subjects **that include:**

(ai) **At least 3 cases involving the Pparenteral administration, for**  
which a written directive is required, of any beta emitter, or **any**  
photon-emitting radionuclide with a photon energy less than 150  
keV;

2970 and/or

(bii) **At least 3 cases involving the Pparenteral administration of any**  
other radionuclide, for which a written directive is required;

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and

**712.2 (3)** Has provided written attestation(s); signed by a preceptor authorized user, that the individual has **completed the requirements in 712 or 713, and has** achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed radioactive materials **requiring a written directive authorized under 7.36. The written attestation must be signed by a preceptor authorized user who:**

**(a) Meets the requirements in 716, Appendix F, or Appendix I, or equivalent NRC or Agreement State requirements;**

and

**(b) Meets the requirements in Appendix 7F must have experience in administering dosages as specified in 7F2.1(2)(f)(iii) and/or 7F2.1(2)(f)(iv).**

and

**715 Meets the following recentness of training requirements:**

**715.1 The training and experience required by Appendix 7I shall have been obtained within the 7 years preceding the date of license application or amendment request;**

or

**715.2 The individual must have had related, documented, continuing education and experience since the required training and experience was obtained.**

or

**716.3 Meets the following requirements for an experienced authorized user for 7.36.5 uses: Has demonstrated adequate prior experience as:**

**713.6.1 An individual identified as an authorized user for the medical use of radioactive material on a license issued by the NRC or Agreement State, a permit issued under an NRC or Agreement State broad scope license that authorizes medical use before October 25, 2005, who perform only those medical uses for which they were authorized on that date are not required to comply with the training requirements of 711 through 715, authorized user identified on a current facility license or permit under Appendix 7I, Appendix 7F for uses listed in 7F2.1(3), Appendix 7K, or Appendix 7M, or under equivalent Agreement State or NRC requirements, and has provided written attestation(s), signed by a preceptor authorized user, that the individual has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed radioactive materials authorized under 7.36;**

or

**713.2 An experienced authorized user for the parenteral administration of unsealed radioactive materials who:**

**(1) Was identified before October 25, 2005 (and thus need not comply with the requirements of 712) either on:**

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Comment [JJ99]: The term "or amendment request" is added for clarity, since many additions of authorized users occur during license amendment requests as well as during license applications.

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3012 (a) An NRC or Agreement State license; or  
3013 (b) A permit issued under an NRC or Agreement State broad scope license that authorizes  
3014 medical use or the practice of nuclear pharmacy; and  
3015 (2) Performs only those medical uses for which the authorized user identified in accord with  
3016 713.2(1) was authorized on October 25, 2005.  
3017 **716.2. Individuals not required to comply with the training requirements of 711 through 715**  
3018 **may serve as preceptors for, and supervisors of, applicants seeking authorization**  
3019 **on licenses for the same uses for which these individuals are authorized.**  
3020 ~~714. Training and experience required by Appendix 71 shall have been obtained:~~  
3021 ~~714.1 Within the 7 years preceding the date of license application; or~~  
3022 ~~714.2 Through documented subsequent continuing education and experience.~~  
3023 ~~715. To be recognized by an Agreement State or the U.S. Nuclear Regulatory Commission (posted by~~  
3024 ~~NRC at <http://www.nrc.gov/materials/miau/med-use/toolkit/spec-board-cert.html>) for purposes of~~  
3025 ~~Appendix 71, a medical specialty board shall require that each candidate for certification to meet~~  
3026 ~~all of the requirements of 712.~~  
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**Comment [JJ100]:** Correction to reference appropriate section per NRC comments – Nov 2011.  
[RATS 2009-1; Compatibility B; 35.57]

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**Comment [JJ101]:** Additional language added to be compatible with 10 CFR 35.57 (c). This provision effectively allows or clarifies that experienced individuals who are "grandfathered" may serve as preceptors for others.  
(NRC RATS 2009-1; Compatibility=B)

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3028 PART 7, APPENDIX 7J: AUTHORIZED USER **TRAINING** FOR USE OF SEALED SOURCES FOR  
3029 DIAGNOSIS (7.40 **USES**) ~~ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE~~

3030 **The licensee shall require an authorized user of a diagnostic sealed source for use in a device**  
3031 **authorized under 7.40 to be a physician, dentist or podiatrist who has a current active State of**  
3032 **Colorado license and:**

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3033 **7J1** ~~Has provided~~ **Is certified by evidence of current certification by a recognized a medical** specialty  
3034 ~~board~~ **whose certification process includes all of the requirements in 7J2 and 7J3, and**  
3035 **whose certification process has been recognized by the NRC or an Agreement State. (see**  
3036 **7J5); NRC recognized specialty boards are posted on the NRC website at**  
3037 **<http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>.**

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3039 **7J2** Has satisfied the following criteria:

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3040 7J2.1 Has ~~satisfactorily~~ completed **8 hours of classroom and laboratory** training in basic  
3041 radionuclide handling techniques specifically applicable to the use of the device.;  
3042 ~~including:~~

3043 (1) ~~At least 8 hours of classroom and laboratory training in the following areas~~ **The**  
3044 **training must include:**

3045 (a) Radiation physics and instrumentation;

3046 (b) Radiation protection;

3047 (c) Mathematics pertaining to the use and measurement of radioactivity;

3048 (d) Radiation biology;

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3049 and

3050 ~~7J3(2)~~ **Has completed** ~~T~~ training in the use of the device for the uses requested.

3051 ~~7J2.2~~ ~~Has provided written attestation(s), signed by a preceptor authorized user, that the~~  
3052 ~~individual has achieved a level of competency sufficient to function independently as an~~  
3053 ~~authorized user of a diagnostic sealed source for use in a device authorized under 7.40.~~

3054 (1) ~~Each preceptor authorized user supervising the experiential training required by~~  
3055 ~~Appendix 7J shall meet the requirements of Appendix 7K or Appendix 7L, or~~  
3056 ~~equivalent Agreement State or NRC requirements.~~

3057 and

3058 **7J4 Meets the following recentness of training requirements:**

3059 **7J4.1 The training and experience required by Appendix 7J shall have been obtained**  
3060 **within the 7 years preceding the date of license application or amendment request;**

Comment [JJ102]: The term "or amendment request" is added for clarity, since many additions of authorized users occur during license amendment requests as well as during license applications.

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**7J4.2 The individual must have had related, documented, continuing education and experience since the required training and experience was obtained.**

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**7J53 Meets the following requirements for an experienced authorized user for 7.40 uses** Has demonstrated adequate prior experience as:

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**7J53.1 An individual identified as an authorized user for the medical use of radioactive material on a license issued by the NRC or Agreement State, a permit issued under an NRC or Agreement State broad scope license that authorizes medical use before October 25, 2005, who perform only those medical uses for which they were authorized on that date are not required to comply with the training requirements of 7J1 through 7J4, authorized user identified on a current facility license or permit under this Appendix 7J for uses listed in Appendix 7J, or under equivalent Agreement State or NRC requirements, and has provided written attestation(s), signed by a preceptor authorized user, that the individual has achieved a level of competency sufficient to function independently as an authorized user of a diagnostic sealed source for use in a device authorized under 7.40;**

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**7J3.2 An experienced authorized user of a diagnostic sealed source for use in a device authorized under 7.40 who:**

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**(1) Was identified before October 25, 2005 (and thus need not comply with the requirements of 7J2) either on:**

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**(a) An NRC or Agreement State license; or**

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**(b) A permit issued under an NRC or Agreement State broad scope license that authorizes medical use or the practice of nuclear pharmacy; and**

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**(2) Performs only those medical uses for which the authorized user identified in accord with 7J3.2(1) was authorized on October 25, 2005.**

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**7J5.2 Individuals not required to comply with the training requirements of 7J1 through 7J4 may serve as preceptors for, and supervisors of, applicants seeking authorization on licenses for the same uses for which these individuals are authorized.**

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**7J54 Training and experience required by Appendix 7J shall have been obtained:**

**Comment [JJ103]:** Additional language added to be compatible with 10 CFR 35.57 (c). This provision effectively allows or clarifies that experienced individuals who are "grandfathered" may serve as preceptors for others.

(NRC RATS 2009-1; Compatibility=B)

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**7J4.1 Within the 7 years preceding the date of license application; or**

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**7J4.2 Through documented subsequent continuing education and experience.**

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**7J5 To be recognized by an Agreement State or the U.S. Nuclear Regulatory Commission (posted by NRC at <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>) for purposes of Appendix 7J, a medical specialty board shall require that each candidate for certification to meet all of the requirements of 7J2.1(1).**

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3099 PART 7, APPENDIX 7K: AUTHORIZED USER TRAINING FOR THE USE OF MANUAL  
3100 BRACHYTHERAPY SOURCES USE (7.42 USES) ADEQUATE RADIATION SAFETY  
3101 TRAINING AND EXPERIENCE

3102 The licensee shall require an authorized user of a manual brachytherapy source for the uses  
3103 authorized under 7.42 to be a physician who has a current active State of Colorado license and:

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3104 7K1 Has provided: Is certified by a medical specialty board whose certification process has been  
3105 recognized by the NRC or an Agreement State, and who meets the requirements in  
3106 paragraph 7K2.3 of this Appendix. NRC recognized specialty boards are posted on the  
3107 NRC website at <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>.

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3108 7K1.1 To have its certification process recognized, a specialty board shall require all  
3109 candidates for certification to:

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3110 (1) Successfully complete a minimum of 3 years of residency training in a  
3111 radiation oncology program approved by the Residency Review Committee of  
3112 the Accreditation Council for Graduate Medical Education or the Royal College  
3113 of Physicians and Surgeons of Canada or the Committee on Post-Graduate  
3114 Training of the American Osteopathic Association; and

3115 (2) Pass an examination, administered by diplomats of the specialty board, that  
3116 tests knowledge and competence in radiation safety, radionuclide handling,  
3117 treatment planning, quality assurance, and clinical use of manual  
3118 brachytherapy;

3119 meet the requirements of 10 CFR 35.490(a)(1) and 10 CFR 35.490(a)(2). NRC recognized  
3120 specialty boards are posted on the NRC website at  
3121 <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>. Evidence  
3122 of current certification by a recognized specialty board (see 7K5); and

3123 7K1.2 Written attestation(s), signed by a preceptor authorized user, that the individual has  
3124 achieved a level of competency sufficient to function independently as an authorized user  
3125 of an manual brachytherapy source for the uses authorized under 7.42;

3126 (1) Each preceptor authorized user supervising the experiential training required by  
3127 Appendix 7K shall meet the requirements of Appendix 7K, or equivalent  
3128 Agreement State or NRC requirements.

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3129 or

3130 7K2 Has satisfied the following criteria:

3131 7K2.1 Has provided written attestation(s), signed by a preceptor authorized user, that the  
3132 individual has satisfactorily completed 700 total hours in a structured educational  
3133 program in basic radionuclide handling techniques applicable to the medical use of  
3134 manual brachytherapy sources, that includes:

3135 (1) At least 200 hours of classroom and laboratory training in the following areas:

3136 (a) Radiation physics and instrumentation;

3137 (b) Radiation protection;

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3138 (c) Mathematics pertaining to the use and measurement of radioactivity;

3139 (d) Radiation biology;

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3141 (2) 500 hours of supervised work experience, under the supervision of an authorized  
3142 user who meets the requirements in 7K4, Appendix 7K, or equivalent NRC  
3143 or Agreement State requirements at a medical institution, involving:

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3144 (a) Ordering, receiving, and unpacking radioactive materials safely and  
3145 performing the related radiation surveys;

3146 (b) Checking survey meters for proper operation;

3147 (c) Preparing, implanting, and removing brachytherapy sources;

3148 (d) Maintaining running inventories of material on hand;

3149 (e) Using administrative controls to prevent a misadministration involving the use  
3150 of unsealed radioactive material;

Comment [JJ104]: 02/16/2012 Correction of typo error. Approved by BOH during BOH hearing. This is the only change following the BOH hearing and is the only change between Draft 4 and Draft 5.

3151 (f) Using emergency procedures to control radioactive material;

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3153 **7K2.2** (3) ~~Or he~~ has completed 3 years of supervised clinical experience in radiation oncology,  
3154 under the supervision of an authorized user who meets the requirements in 7K4, of this  
3155 Appendix 7K, or equivalent Agreement State or NRC requirements, provided that the  
3156 experience:

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3157 (a) Is part of a formal training program approved by the Residency Review  
3158 Committee of the Accreditation Council for Graduate Medical Education  
3159 or Royal College of Physicians and Surgeons of Canada or the Council  
3160 on Postdoctoral Training of the American Osteopathic Association;

3161 and

3162 (b) May be obtained concurrently with the supervised work experience required  
3163 by 7K2.1(2).

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3164 and

3165 **7K2.32** Has provided written attestation(s), signed by a preceptor authorized user who meets  
3166 the requirements in 7K4, Appendix 7K, or equivalent Agreement State or NRC  
3167 requirements, that the individual has satisfactorily completed the requirements in  
3168 7K1.1(1), or paragraphs 7K2.1 and 7K2.2, and has achieved a level of competency  
3169 sufficient to function independently as an authorized user of manual brachytherapy  
3170 sources for the medical uses authorized under 7.42.

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Comment [JJ105]: Changed reference from 7K1 to the more specific reference of 7K1.1(1), consistent with 10 CFR 35.490.

3171 and

NRC review – November 2011  
[RATS 2009-1; Compatibility B]

3172 **7K3 Meets the following recentness of training requirements:**

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3173 **7K3.1 The training and experience required by Appendix 7K shall have been obtained:**  
3174 **within the 7 years preceding the date of license application or amendment request;**

**Comment [JJ106]:** The term "or amendment request" is added for clarity, since many additions of authorized users occur during license amendment requests as well as during license applications.

3175 **or**

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3176 **7K3.2 The individual must have had related, documented, continuing education and**  
3177 **experience since the required training and experience was obtained.**

3178 **or**

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3179 **7K43 Meets the following requirements for an experienced authorized user for 7.42 uses:Has**  
3180 **demonstrated adequate prior experience as:**

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3181 **7K43.1 An individual identified as an authorized user for the medical use of radioactive**  
3182 **material on a license issued by the NRC or Agreement State, a permit issued under**  
3183 **an NRC or Agreement State broad scope license that authorizes medical use**  
3184 **before October 25, 2005, who perform only those medical uses for which they were**  
3185 **authorized on that date are not required to comply with the training requirements**  
3186 **of 7K1 through 7K3, authorized user identified on a current facility license or permit**  
3187 **under Appendix 7K for uses listed in Appendix 7K, or under equivalent Agreement State**  
3188 **or NRC requirements, and has provided written attestation(s), signed by a preceptor**  
3189 **authorized user, that the individual has achieved a level of competency sufficient to**  
3190 **function independently as an authorized user of an manual brachytherapy source for the**  
3191 **uses authorized under 7.42;**

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3192 **or**

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3193 **7K3.2 An experienced authorized user of an manual brachytherapy source for the uses**  
3194 **authorized under 7.42 who:**

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3195 **(1) Was identified before October 25, 2005 (and thus need not comply with the**  
3196 **requirements of 7K2) either on:**

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3197 **(a) An NRC or Agreement State license; or**

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3198 **(b) A permit issued under an NRC or Agreement State broad scope license that**  
3199 **authorizes medical use or the practice of nuclear pharmacy;**

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3200 **(2) Performs only those medical uses for which the authorized user identified in accord with**  
3201 **7K3.2(1) was authorized on October 25, 2005.**

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3202 **7K4.2 Individuals not required to comply with the training requirements of 7K1 through**  
3203 **7K3 may serve as preceptors for, and supervisors of, applicants seeking**  
3204 **authorization on licenses for the same uses for which these individuals are**  
3205 **authorized.**

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3206 **7K4 Training and experience required by Appendix 7K shall have been obtained:**

**Comment [JJ107]:** Additional language added to be compatible with 10 CFR 35.57 (c). This provision effectively allows or clarifies that experienced individuals who are "grandfathered" may serve as preceptors for others.

(NRC RATS 2009-1; Compatibility=B)

3207 **7K4.1 Within the 7 years preceding the date of license application; or**

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3208 **7K4.2 Through documented subsequent continuing education and experience.**

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3209 **7K5 To be recognized by an Agreement State or the U.S. Nuclear Regulatory Commission (posted by**  
3210 **NRC at <http://www.nrc.gov/materials/miau/med-use/toolkit/spec-board-cert.html>), a specialty**  
3211 **board shall require that each candidate for certification:**

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3212 ~~7K5.1 Successfully complete a minimum of 3 years of residency training in a radiation oncology program~~  
3213 ~~approved by the Residency Review Committee of the Accreditation Council for Graduate Medical~~  
3214 ~~Education or Royal College of Physicians and Surgeons of Canada, or the Committee on Post-~~  
3215 ~~Graduate Training of the American Osteopathic Association; and~~

3216 ~~7K5.2 Pass an examination, administered by diplomates of the specialty board, which tests knowledge~~  
3217 ~~and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of~~  
3218 ~~manual brachytherapy.~~  
3219

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**\*DRAFT 5 –02/16/2012\***

3220 PART 7, APPENDIX 7L: AUTHORIZED USER **TRAINING** FOR OPHTHALMIC USE OF  
3221 **STRONTIUM-90 (7.42 USES)-ADEQUATE RADIATION SAFETY TRAINING AND**  
3222 **EXPERIENCE**

3223 ~~The licensee shall require an authorized user of an~~ **Strontium-90 source for ophthalmic**  
3224 **radiotherapy authorized under 7.42 to be a physician who has a current active State of Colorado**  
3225 **license and:**

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3226 **7L1** Is an authorized user under Appendix 7K **or equivalent NRC or Agreement State**  
3227 **requirements**; ~~and has provided written attestation(s), signed by a preceptor authorized user, that~~  
3228 ~~the individual has achieved a level of competency sufficient to function independently as an~~  
3229 ~~authorized user of strontium-90 for ophthalmic radiotherapy uses authorized under 7.42;~~

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3230 ~~(1) Each preceptor authorized user supervising the experiential training required by Appendix 7L shall~~  
3231 ~~meet the requirements of Appendix 7K or Appendix 7L, or equivalent Agreement State or NRC~~  
3232 ~~requirements.~~

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3233 or

3234 **7L2** Has satisfied the following criteria:

3235 7L2.1 Has satisfactorily completed **24 hours of classroom and laboratory** training ~~in basic~~  
3236 ~~radionuclide handling techniques specifically~~ applicable to the **medical** use of strontium-  
3237 90 for ophthalmic radiotherapy, ~~including:~~

3238 (1) **The training must include** ~~At least 24 hours of classroom and laboratory training in~~  
3239 ~~the following areas:~~

- 3240 (a) Radiation physics and instrumentation;
- 3241 (b) Radiation protection;
- 3242 (c) Mathematics pertaining to the use and measurement of radioactivity;
- 3243 (d) Radiation biology;

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3244 and

3245 (2) ~~Has satisfactorily completed~~ Supervised clinical training **in ophthalmic**  
3246 **radiotherapy under the supervision of an authorized user at a medical**  
3247 **institution, clinic, or private practice** that includes the use of strontium-90 for  
3248 the ophthalmic treatment of five individuals, ~~that~~ **This supervised clinical**  
3249 **training must involve** ~~includes:~~

- 3250 (a) Examination of each individual to be treated;
- 3251 (b) Calculation of the dose to be administered;
- 3252 (c) Administration of the dose; and
- 3253 (d) Follow-up and review of each individual's case history;

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3254 **and**

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3255 7L2.2 (3) Has provided written attestation(s), signed by a preceptor authorized user **who**  
3256 **meets the requirements in 7L4, Appendix 7K, Appendix 7L, or equivalent NRC or**  
3257 **Agreement State requirements**, that the individual has **satisfactorily completed the**  
3258 **requirements of 7L2 and has** achieved a level of competency sufficient to function  
3259 independently as an authorized user of strontium-90 for ophthalmic radiotherapy uses  
3260 authorized under 7.42.

3261 and

3262 7L3 Meets the following recentness of training requirements:

3263 7L3.1 The training and experience required by Appendix 7L shall have been obtained  
3264 within the 7 years preceding the date of license application or amendment request;

3265 or

3266 7L3.2 The individual must have had related, documented, continuing education and  
3267 experience since the required training and experience was obtained.

3268 or

3269 7L43 Meets the following requirements for an experienced authorized user for 7.42 ophthalmic  
3270 radiotherapy uses: ~~Has demonstrated adequate prior experience as:~~

3271 7L34.1 An individual identified as an authorized user for the medical use of radioactive  
3272 material on a license issued by the NRC or Agreement State, a permit issued under  
3273 an NRC or Agreement State broad scope license that authorizes medical use  
3274 before October 25, 2005, who perform only those medical uses for which they were  
3275 authorized on that date are not required to comply with the training requirements  
3276 of 7L1 through 7L3, authorized user identified on a current facility license or permit under  
3277 this Appendix 7L for uses listed in Appendix 7L, or under equivalent Agreement State or  
3278 NRC requirements, and has provided written attestation(s), signed by a preceptor  
3279 authorized user, that the individual has achieved a level of competency sufficient to  
3280 function independently as an authorized user of strontium-90 for ophthalmic radiotherapy  
3281 uses authorized under 7.42;

3282 ~~or~~

3283 7L3.2 An experienced authorized user of strontium-90 for ophthalmic radiotherapy uses  
3284 authorized under 7.42 who:

3285 ~~(1) Was identified before October 25, 2005 (and thus need not comply with the requirements of~~  
3286 ~~7L2) either on:~~

3287 ~~(a) An NRC or Agreement State license; or~~

3288 ~~(b) A permit issued under an NRC or Agreement State broad scope license that authorizes~~  
3289 ~~medical use or the practice of nuclear pharmacy; and~~

3290 ~~(2) Performs only those medical uses for which the authorized user identified in accord with~~  
3291 ~~7L3.2(1) was authorized on October 25, 2005.~~

3292 7L4.2 Individuals not required to comply with the training requirements of 7L1 through  
3293 7L3 may serve as preceptors for, and supervisors of, applicants seeking

Comment [JJ108]: The term "or amendment request" is added for clarity, since many additions of authorized users occur during license amendment requests as well as during license applications.

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3294 authorization on licenses for the same uses for which these individuals are  
3295 authorized.

3296 ~~7L4 Training and experience required by Appendix 7L shall have been obtained:~~

3297 ~~7L4.1 Within the 7 years preceding the date of license application; or~~

3298 ~~7L4.2 Through documented subsequent continuing education and experience.~~  
3299

**Comment [JJ109]:** Additional language added to be compatible with 10 CFR 35.57 (c). This provision effectively allows or clarifies that experienced individuals who are "grandfathered" may serve as preceptors for others.

(NRC RATS 2009-1; Compatibility=B)

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3300 PART 7, APPENDIX 7M: AUTHORIZED USER **TRAINING** FOR USE OF SEALED SOURCES IN  
3301 REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND GAMMA STEREOTACTIC  
3302 RADIOSURGERY UNITS (7.48 **USES**) ~~ADEQUATE RADIATION SAFETY TRAINING AND~~  
3303 ~~EXPERIENCE~~

3304 The licensee shall require an authorized user of a sealed source for use in a device authorized  
3305 under 7.48 to be a physician who has a current active State of Colorado license and:

3306 **7M1 Is certified by a medical specialty board whose certification process has been recognized by**  
3307 **the NRC or an Agreement State and who meets the requirements in paragraph 7M2.3 and**  
3308 **7M3 of this Appendix, NRC recognized specialty boards are posted on the NRC website at**  
3309 **<http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>.~~Has provided:~~**

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3310 7M1.1 **To have its certification process recognized, a specialty board shall require all**  
3311 **candidates for certification to:**

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3312 **(1) Successfully complete a minimum of 3 years of residency training in a radiation**  
3313 **therapy program approved by the Residency Review Committee of the**  
3314 **Accreditation Council for Graduate Medical Education or the Royal College of**  
3315 **Physicians and Surgeons of Canada or the Committee on Post-Graduate**  
3316 **Training of the American Osteopathic Association;**

3317 **and**

3318 **(1) Pass an examination, administered by diplomats of the specialty board, which**  
3319 **tests knowledge and competence in radiation safety, radionuclide handling,**  
3320 **treatment planning, quality assurance, and clinical use of stereotactic**  
3321 **radiosurgery, remote afterloaders and external beam therapy;**

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3322 ~~Evidence of current certification by a recognized specialty board (see 7M5); and~~

3323 ~~7M1.2 Written attestation(s), signed by a preceptor authorized user, that the individual has~~  
3324 ~~achieved a level of competency sufficient to function independently as an authorized user~~  
3325 ~~for each type of the therapeutic medical unit for which the individual is requesting~~  
3326 ~~authorized user status for the medical uses authorized under 7.48;~~

3327 ~~(1) Each preceptor authorized user supervising the experiential training required by Appendix 7M~~  
3328 ~~shall meet the requirements of this Appendix 7M, or equivalent Agreement State or NRC~~  
3329 ~~requirements.~~

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3330 or

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3331 **7M2** Has satisfied the following criteria:

3332 7M2.1 ~~Has provided written attestation(s), signed by a preceptor authorized user, that the~~  
3333 ~~individual has satisfactorily completed 700 total hours in a structured educational~~  
3334 ~~program in **basic** radionuclide handling techniques applicable to the **medical**-use of~~  
3335 ~~sealed sources in a **therapeutic medical unit** remote afterloader units, teletherapy units,~~  
3336 ~~and gamma stereotactic radiosurgery units, that includes:~~

3337 (1) ~~At least~~ 200 hours of classroom and laboratory training in the following areas:

3338 (a) Radiation physics and instrumentation;

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- 3339 (b) Radiation protection;
- 3340 (c) Mathematics pertaining to the use and measurement of radioactivity;
- 3341 (d) Radiation biology;
- 3342 and

3343 (2) 500 hours of supervised work experience, **under the supervision of an authorized**  
3344 **user who meets the requirements in 7M5, Appendix 7M, or equivalent**  
3345 **Agreement State or NRC requirements at a medical institution**, involving:

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- 3346 (a) Reviewing full calibration measurements and periodic spot checks;
- 3347 (b) Preparing treatment plans and calculating treatment doses and times;
- 3348 (c) Using administrative controls to prevent a misadministration involving the use  
3349 of **unsealed**-radioactive material;
- 3350 (d) Implementing emergency procedures to **be** followed in the event of the  
3351 abnormal operation of the medical unit or console;
- 3352 (e) Checking and using survey meters; and
- 3353 (f) Selecting the proper dose and how it is to be administered;

3354 **and**

3355 **7M2.2 Has completed 3 years of supervised clinical experience in radiation therapy, under**  
3356 **an authorized user who meets the requirements in 7M5, Appendix 7M, or**  
3357 **equivalent Agreement State or NRC requirements, as part of a formal training**  
3358 **program approved by the Residency Review Committee for Radiation Oncology of**  
3359 **the Accreditation Council for Graduate Medical Education or the Royal College of**  
3360 **Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of**  
3361 **the American Osteopathic Association. This experience may be obtained**  
3362 **concurrently with the supervised work experience required by paragraph 7M2.1(2)**  
3363 **of this section;**

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3364 **and**

3365 **7M2.32** Has provided written attestation(s) ~~signed by a preceptor authorized user~~, that the  
3366 individual has satisfactorily completed ~~the requirements of 7M1 or 7M2.1 and 7M2.2,~~  
3367 **and 7M3, and has achieved a level of competency sufficient to function**  
3368 **independently as an authorized user of each type of therapeutic medical unit for**  
3369 **which the individual is requesting authorized user status. The written attestation**  
3370 **must be signed by a preceptor authorized user who meets the requirements in**  
3371 **7M5, Appendix 7M, or equivalent Agreement State or NRC requirements for an**  
3372 **authorized user for each type of therapeutic medical unit for which the individual is**  
3373 **requesting authorized user status;**

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3374 **and**

3375 **7M3 Has received** training **in device operation, safety procedures, and clinical use** for the type(s) of  
3376 use for which authorization is sought, ~~that~~ **This training requirement may be satisfied by:**

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- 3377 (1) Includes:
- 3378 (a) Hands-on device operation;
- 3379 (b) Safety procedures;
- 3380 (c) Clinical use, and
- 3381 (d) Treatment planning system operation; and
- 3382 (2) Is provided by either:

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3383 **7M3.1(a)** Satisfactorily completing a vendor training program;

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3384 or

3385 **7M3.2(b)** By receiving training Being supervised by an **authorized user or** authorized medical  
3386 physicist, **as appropriate, who is** authorized for the type(s) of use for which the  
3387 individual is seeking authorization;

3388 ~~7M2.3 Or h~~Has completed 3 years of supervised clinical experience in radiation therapy, under  
3389 the supervision of an authorized user who meets the requirements of this Appendix 7M,  
3390 or equivalent Agreement State or NRC requirements, provided that the experience:

3391 (1) Is part of a formal training program approved by the Residency Review Committee of  
3392 the Accreditation Council for Graduate Medical Education or Royal College of  
3393 Physicians and Surgeons of Canada, or the Committee on Post-Graduate  
3394 Training of the American Osteopathic Association; and

3395 (2) May be obtained concurrently with the supervised work experience required by  
3396 7M2.1(2); and

3397 ~~7M2.4~~ Has provided written attestation(s), signed by a preceptor authorized user, that the  
3398 individual has achieved a level of competency sufficient to function independently as an  
3399 authorized user for each type of the therapeutic medical unit for which the individual is  
3400 requesting authorized user status for the medical uses authorized under 7.48.

3401 and

3402 **7M4 Meets the following recentness of training requirements:**

3403 **7M4.1 The training and experience required by Appendix 7M shall have been obtained**  
3404 **within the 7 years preceding the date of license application or amendment request;**

3405 or

3406 **7M4.2 The individual must have had related, documented, continuing education and**  
3407 **experience since the required training and experience was obtained.**

3408 or

3409 ~~**7M53** Meets the following requirements for an experienced authorized user for 7.48 uses, Has~~  
3410 ~~demonstrated adequate prior experience as:~~

**Comment [JJ110]:** The term "or amendment request" is added for clarity, since many additions of authorized users occur during license amendment requests as well as during license applications.

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3411 ~~7M53.1~~ An individual identified as an authorized user for the medical use of radioactive  
3412 material on a license issued by the NRC or Agreement State, a permit issued under  
3413 an NRC or Agreement State broad scope license that authorizes medical use  
3414 before October 25, 2005, who perform only those medical uses for which they were  
3415 authorized on that date are not required to comply with the training requirements  
3416 of 7M1 through 7M4. authorized user identified on a current facility license or permit  
3417 under Appendix 7M for uses listed in Appendix 7M, or under equivalent Agreement State  
3418 or NRC requirements, and has provided written attestation(s), signed by a preceptor  
3419 authorized user, that the individual has achieved a level of competency sufficient to  
3420 function independently as an authorized user for each type of the therapeutic medical unit  
3421 for which the individual is requesting authorized user status for the medical uses  
3422 authorized under 7.48;

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3423 or

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3424 ~~7M3.2~~ An experienced authorized user of the therapeutic medical unit authorized under 7.48  
3425 who:

3426 ~~(1)~~ Was identified before October 25, 2005 (and thus need not comply with the  
3427 requirements of 7M2) either on:

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3428 ~~(a)~~ An NRC or Agreement State license; or

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3429 ~~(b)~~ A permit issued under an NRC or Agreement State broad scope license that  
3430 authorizes medical use or the practice of nuclear pharmacy;

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3431 ~~(2)~~ Performs only those medical uses for which the authorized user identified in accord  
3432 with 7M3.2(1) was authorized on October 25, 2005.

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3433 ~~7M5.2~~ Individuals not required to comply with the training requirements of 7M1 through  
3434 7M4 may serve as preceptors for, and supervisors of, applicants seeking  
3435 authorization on licenses for the same uses for which these individuals are  
3436 authorized.

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3437 ~~7M54~~ Training and experience required by Appendix 7M shall have been obtained:

**Comment [JJ111]:** Additional language added to be compatible with 10 CFR 35.57 (c). This provision effectively allows or clarifies that experienced individuals who are "grandfathered" may serve as preceptors for others.  
  
(NRC RATS 2009-1; Compatibility=B)

3438 ~~7M54.1~~ Within the 7 years preceding the date of license application; or

3439 ~~7M54.2~~ Through documented subsequent continuing education and experience.

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3440 ~~7M5~~ To be recognized by an Agreement State or the U.S. Nuclear Regulatory Commission (posted by  
3441 NRC at <http://www.nrc.gov/materials/miau/med-use/toolkit/spec-board-cert.html>), a specialty  
3442 board shall require that each candidate for certification:

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3443 ~~7M5.1~~ Successfully complete a minimum of 3 years of residency training in a radiation therapy  
3444 program approved by the Residency Review Committee of the Accreditation Council for  
3445 Graduate Medical Education or Royal College of Physicians and Surgeons of Canada, or  
3446 the Committee on Post-Graduate Training of the American Osteopathic Association;

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3447 ~~7M5.2~~ Pass an examination, administered by diplomates of the specialty board, which tests  
3448 knowledge and competence in radiation safety, radionuclide handling, treatment  
3449 planning, quality assurance, and clinical use of stereotactic radiosurgery, remote  
3450 afterloaders and external beam therapy.

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3451 **PART 7, APPENDIX 7N: NUCLEAR MEDICINE TECHNOLOGIST (NMT) ADEQUATE RADIATION**  
3452 **SAFETY TRAINING AND EXPERIENCE**

**Comment [JJ112]:** There is no equivalent section to Appendix N in 10 CFR Part 35. The NRC does not recognize nuclear medicine technologists in regulation or guidance. The CRCPD has not finalized SSRRCR Part Z for training requirements for NMTs, and therefore the current section is not being changed significantly.

3453 **The licensee shall require the nuclear medicine technologist using radioactive materials under the**  
3454 **supervision of an authorized user to be an individual who:**

3455 **7N1** Has provided:

3456 7N1.1 Evidence of:

3457 (1) Current registration with The American Registry of Radiologic Technologists with  
3458 competency in Nuclear Medicine (ARRT(N));

3459 or

3460 (2) Current certification by The Nuclear Medicine Technology Certification Board in  
3461 Nuclear Medicine (CNMT);

3462 or

3463 (3) Being board-eligible to take the CNMT or ARRT(N) examination;

3464 or

3465 (4) Current certification by a recognized specialty board (see 7N5);

3466 and

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3467 7N1.2 Has provided written attestation(s), signed by a preceptor authorized user, that the  
3468 individual has achieved a level of competency sufficient to function independently as a  
3469 nuclear medicine technologist;

3470 (1) Each preceptor authorized user supervising the experiential training required by  
3471 Appendix 7N shall meet the requirements of Appendix 7N, or equivalent  
3472 Agreement State or NRC requirements.

3473 or

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3474 **7N2** Has satisfied the following criteria:

3475 7N2.1 Has provided written attestation(s), signed by a preceptor authorized user, that the  
3476 individual has satisfactorily completed 80 hours in a structured educational program in  
3477 basic radionuclide handling techniques applicable to the medical use of unsealed  
3478 radioactive materials, including:

3479 (1) Classroom and laboratory training in the following areas:

3480 (a) Radiation physics and instrumentation;

3481 (b) Radiation protection;

3482 (c) Mathematics pertaining to the use and measurement of radioactivity;

3483 (d) Chemistry of radioactive material for medical use; and

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- 3484 (e) Radiation biology; and
- 3485 (2) Work experience, involving:
  - 3486 (a) Ordering, receiving, and unpacking radioactive materials safely and
  - 3487 performing the related radiation surveys;
  - 3488 (b) Quality Control checking of instruments used to determine the activity of
  - 3489 dosages and performing checks for proper operation of survey meters;
  - 3490 (c) Calculating, measuring, and safely preparing patient or human research
  - 3491 subject dosages;
  - 3492 (d) Using administrative controls to prevent a misadministration involving the use
  - 3493 of unsealed radioactive material;
  - 3494 (e) Using procedures to contain spilled radioactive material safely and using
  - 3495 proper decontamination procedures; and
  - 3496 (f) Administering dosages to patients or human research subjects;

3497 7N2.2 Has provided written attestation(s), signed by a preceptor authorized user, that the  
3498 individual has achieved a level of competency sufficient to function independently as a  
3499 nuclear medicine technologist;

3500 or

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3501 **7N3** Has demonstrated adequate prior experience as:

3502 7N3.1 A full-time nuclear medicine technologist for a minimum of two years performing during the  
3503 past five-year period under the supervision of an authorized user and has provided  
3504 written attestation(s), signed by a preceptor authorized user, that the individual has  
3505 achieved a level of competency sufficient to function independently as a nuclear medicine  
3506 technologist;

3507 or

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3508 7N3.2 An experienced nuclear medicine technologist working at a facility holding a Department  
3509 license before October 25, 2005 (and thus need not comply with the requirements of  
3510 7N2);

3511 **7N4 Meets the following recency of training requirements:** ~~Training and experience required by~~  
3512 ~~Appendix 7N shall have been obtained.~~

3513 7N4.1 **The training and experience required by Appendix 7N shall have been obtained**  
3514 ~~W~~within the 7 years preceding the date of license application **or amendment request;**

**Comment [JJ113]:** The term "or amendment request" is added for clarity, since many additions of authorized users occur during license amendment requests as well as during license applications.

3515 or

3516 7N4.2 **The individual must have had related,** ~~Through~~ documented, ~~subsequent~~ continuing  
3517 education and experience **since the required training and experience was obtained.**

3518 **7N5** To be recognized by the Department, a specialty board shall require that each candidate for  
3519 certification as a nuclear medicine technologist satisfactorily complete a certification process that  
3520 includes all of the training requirements in 7N2.1.

**\*DRAFT 5 –02/16/2012\***

3521 **PART 7, APPENDIX 70: RADIATION THERAPY TECHNOLOGIST (RTT) ADEQUATE RADIATION**  
3522 **SAFETY TRAINING AND EXPERIENCE**

3523 **The licensee shall require the radiation therapy technologist using radioactive materials under the**  
3524 **supervision of an authorized user to be an individual who:**

3525 **701** Has provided:

3526 701.1 Evidence of:

3527 (1) Current registration with The American Registry of Radiologic Technologists with  
3528 competency in Radiation Therapy;

3529 or

3530 (2) Current certification by a recognized specialty board (see 705);

3531 or

3532 (3) Being board-eligible to take the ARRT(T) examination;

3533 or

3534 (4) Having successfully completed a training program in radiation therapy which has  
3535 resulted in a certificate, associate degree, or baccalaureate degree in a  
3536 radiologic technology program that complies with the requirements of the Joint  
3537 Review Committee on Education in Radiologic Technology (consult the  
3538 *Essentials and Guidelines of an Accredited Educational Program for the*  
3539 *Radiation Therapy Technologist*, Joint Review Committee on Education in  
3540 Radiologic Technology, 1988);

3541 and

3542 701.2 Written attestation(s), signed by a preceptor authorized user, that the individual has  
3543 achieved a level of competency sufficient to function independently as a radiation therapy  
3544 technologist;

3545 (1) Each preceptor authorized user supervising the experiential training required by  
3546 Appendix 70 shall meet the requirements of Appendix 70, or equivalent  
3547 Agreement State or NRC requirements.

3548 or

3549 **702** Has satisfied the following criteria:

3550 702.1 Has provided written attestation(s), signed by a preceptor authorized user, that the  
3551 individual has satisfactorily completed 80 hours in a structured educational program in  
3552 basic radionuclide handling techniques applicable to the medical use of unsealed  
3553 radioactive materials, including:

3554 (1) Classroom and laboratory training in the following areas:

3555 (a) Radiation physics and instrumentation;

3556 (b) Radiation protection;

**Comment [JJ114]:** There is no equivalent section to Appendix O in 10 CFR Part 35. The NRC does not recognize radiation therapy technologists in regulation or guidance. The CRCPD has not finalized SSRCR Part Z for training requirements for Radiation Therapy Technologists, and therefore the current section is not being changed significantly.

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**\*DRAFT 5 –02/16/2012\***

- 3557 (c) Mathematics pertaining to the use and measurement of radioactivity;
- 3558 (d) Radiation biology;
- 3559 and
- 3560 (2) Work experience, involving:
  - 3561 (a) Ordering, receiving, and unpacking radioactive materials safely and
  - 3562 performing the related radiation surveys;
  - 3563 (b) Assisting the authorized user in simulating the patient for treatment;
  - 3564 (c) Preparing the patient for treatment;
  - 3565 (d) Implementing treatment plans as prescribed by the authorized user;
  - 3566 (e) Providing written documentation of treatment setup and patient treatments;
  - 3567 (f) Quality control checks to determine that devices used to deliver the radiation
  - 3568 doses are in compliance with institutional standards and performing
  - 3569 checks for proper operation of survey meters;
  - 3570 (g) Preparing or assisting in the preparation of sources, and implantation and
  - 3571 removal of sealed sources;
  - 3572 (h) Delivering doses to patients or human research subjects under the
  - 3573 supervision of the authorized user;
  - 3574 (i) Maintaining running inventories of radioactive material on hand;
  - 3575 (j) Using administrative controls to prevent a misadministration involving the use
  - 3576 of radioactive material; and,
  - 3577 (k) Properly implementing emergency procedures;
- 3578 702.2 Has provided written attestation(s), signed by a preceptor authorized user, that the
- 3579 individual has achieved a level of competency sufficient to function independently as a
- 3580 radiation therapy technologist;
- 3581 or
- 3582 **703** Has demonstrated adequate prior experience as:
  - 3583 703.1 A full-time radiation therapy technologist for a minimum of two years performing during the
  - 3584 past five-year period under the supervision of an authorized user and has provided
  - 3585 written attestation(s), signed by a preceptor authorized user, that the individual has
  - 3586 achieved a level of competency sufficient to function independently as a radiation therapy
  - 3587 technologist;
  - 3588 or
  - 3589 703.2 An experienced radiation therapy technologist working at a facility holding a Department
  - 3590 license before October 25, 2005 (and thus need not comply with the requirements of
  - 3591 702);

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3592 **704** ~~Meets the following recentness of training requirements: Training and experience required by~~  
3593 ~~Appendix 70 shall have been obtained:~~

3594 704.1 **The training and experience required by Appendix 70 shall have been obtained**  
3595 ~~W~~within the 7 years preceding the date of license application **or amendment request;**

3596 or

3597 704.2 **The individual must have had related,**Through documented, ~~subsequent~~continuing  
3598 education and experience **since the required training and experience was obtained.**

3599 **705** To be recognized by the Department, a specialty board shall require that each candidate for  
3600 certification as a radiation therapy technologist satisfactorily complete a certification process that  
3601 includes all of the training requirements in 702.1.

3602 \_\_\_\_\_

3603 **EDITOR'S NOTES**

3604 6 CCR 1007-1 has been divided into smaller sections for ease of use. Versions prior to 4/1/07 and rule  
3605 history are located in the first section, 6 CCR 1007-1. Prior versions can be accessed from the History link  
3606 that appears above the text in 6 CCR 1007-1. To view versions effective on or after 4/1/07, Select the  
3607 desired part of the rule, for example 6 CCR 1007-1 Part 1 or 6 CCR 1007-1 Parts 8 - 10.

3608 **History**

3609 *[For history of this section, see Editor's Notes in the first section, 6 CCR 1007-1]*

**Comment [JJ115]:** JJ 6/21/2011: The term "or amendment request" is added for clarity, since many additions of authorized users occur during license amendment requests as well as during license applications.



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Colorado Department  
of Public Health  
and Environment

**DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT**

**Hazardous Materials and Waste Management Division**

**6 CCR 1007-1**

**State Board of Health**

**RULES AND REGULATIONS PERTAINING TO RADIATION CONTROL**

**PART 7: Use of Radionuclides in the Healing Arts**

**Last amended 02/15/12, effective 03/30/2012**

**DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT**

**Hazardous Materials and Waste Management Division**

**RADIATION CONTROL - USE OF RADIONUCLIDES IN THE HEALING ARTS**

**6 CCR 1007-1 Part 07**

*[Editor's Notes follow the text of the rules at the end of this CCR Document.]*

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**PART 7: USE OF RADIONUCLIDES IN THE HEALING ARTS**

**USE OF RADIONUCLIDES IN THE HEALING ARTS**

**7.1 Purpose and Scope.**

7.1.1 Authority

Rules and regulations set forth herein are adopted pursuant to the provisions of sections 25-1-108, 25-1.5-101(1)(I), and 25-11-104, CRS.

7.1.2 Basis and Purpose.

A statement of basis and purpose accompanies this part and changes to this part. A copy may be obtained from the Department.

7.1.3 Scope.

This part establishes requirements and provisions for the production, preparation, compounding and use of radionuclides in the healing arts and for issuance of licenses authorizing the medical use of this material. These requirements and provisions provide for the protection of the public health and radiation safety of workers, the general public, patients, and human research subjects. The requirements and provisions of this part are in addition to, and not in substitution for, others in these regulations.

7.1.4 Applicability.

The requirements and provisions of these regulations apply to applicants and licensees subject to this part unless specifically exempted.

7.1.5 Published Material Incorporated by Reference.

Published material incorporated in Part 7 by reference is available in accord with 1.4.

**7.2 Definitions.**

As used in this part, these terms have the definitions set forth as follows:

"Address of use" means the building(s) identified on the license where radioactive material may be produced, prepared, received, used or stored.

"Area of use" means a portion of an address of use that has been set aside for the purpose of producing, preparing, receiving, using, or storing radioactive material.

"Authorized medical physicist" (AMP) means an individual who meets the requirements of Appendix 7B; or

- (1) Is identified as an authorized medical physicist or teletherapy physicist on:
  - a. A specific medical license issued by the Department, NRC, or Agreement State;
  - b. A medical use permit issued by an NRC master material license;
  - c. A permit issued by an NRC or Agreement State broad scope medical use licensee; or
  - d. A permit issued by an NRC master material license broad scope medical use license

"Authorized nuclear pharmacist" (ANP) means a pharmacist who meets the requirements of Appendix 7C ; or

- (1) Is identified as an authorized nuclear pharmacist on:
  - a. A specific license issued by the Department, NRC, or Agreement State that authorizes medical use or the practice of nuclear pharmacy;
  - b. A permit issued by an NRC master material license that authorizes medical use or the practice of nuclear pharmacy;
  - c. A permit issued by an NRC or Agreement State broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or
  - d. A permit issued by an NRC master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or
- (2) Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or
- (3) Is designated as an authorized nuclear pharmacist in accordance with Part 3.

"Authorized user" (AU) means a physician, dentist, or podiatrist who meets the applicable requirements of Appendix 7D through Appendix 7M; or

- (1) Is identified as an authorized user on:
  - a. A Department, NRC, or Agreement State license that authorizes the medical use of radioactive material;
  - b. A permit issued by an NRC master material license that is authorized to permit the medical use of radioactive material;
  - c. A permit issued by an NRC or Agreement State specific licensee of broad scope that is authorized to permit the medical use of radioactive material; or

- d. A permit issued by an NRC master material license broad scope permittee that is authorized to permit the medical use of radioactive material.

"Brachytherapy" means a method of radiation therapy in which plated, embedded, activated, or sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, intraluminal or interstitial application.

"Brachytherapy source" means a radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

"Client" means, for mobile medical service, the person for whom, or in conjunction with whom, medical service is provided.

"Client's address" means the address of use for the purpose of providing mobile medical service in accordance with 7.27.

"Dedicated check source" means a radioactive source that is used to assure the consistent response of a radiation detection or measurement device over several months or years.

"Dentist" means an individual licensed by a State or Territory of the United States, the District of Columbia or the Commonwealth of Puerto Rico to practice dentistry.

"Diagnostic clinical procedures manual" means a collection of written procedures that describes each method (and other instructions and precautions) by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration, or in the case of sealed sources for diagnosis, the procedure.

"HDR", see high dose-rate remote afterloader.

"High dose-rate remote afterloader" (HDR) means a device that remotely delivers a dose rate in excess of 12 gray (1200 rad) per hour at the treatment site.

"LDR", see low dose-rate remote afterloader.

"Low dose-rate remote afterloader" (LDR) means a device that remotely delivers a dose rate of less than or equal to 2 gray (200 rad) per hour at the treatment site (at the specified distance).

"Management" means the chief executive officer, or other individual having the authority to manage, direct, or administer the licensee's activities, or such person's' delegate(s).

"Manual brachytherapy" means a type of therapy in which brachytherapy sources are manually applied or inserted.

"MDR", see medium dose-rate remote afterloader".

"Medical institution" means an organization in which two or more medical disciplines are practiced.

"Medical use" means, for the purposes of Part 7, the intentional internal or external administration of radioactive material or the radiation from radioactive material to patients or human research subjects under the supervision of an authorized user.

"Medium dose-rate remote afterloader" (MDR) means a device that remotely delivers a dose rate of greater than 2 gray (200 rad), but less than, or equal to, 12 gray (1200 rad) per hour at the treatment site (at the specified distance).

"Misadministration" means an event that meets the criteria in 7.21.

"Mobile medical service" means the transportation of radioactive material to, or its medical use at, the client's address and/or a temporary job site.

"Nuclear medicine technologist" (NMT) means an individual who meets the requirements of Appendix 7N and who under the supervision of an authorized user prepares or administers radioactive drugs to patients or human research subjects, or performs *in vivo* or *in vitro* measurements for medical purposes.

"Nuclear medicine technology" means the science and art of *in vivo* and *in vitro* detection and measurement of radioactivity and the administration of radioactive drugs to patients or human research subjects for diagnostic and therapeutic purposes.

"Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates, from a brachytherapy source, or a teletherapy, remote afterloader, or gamma stereotactic radiosurgery unit, for a specified set of exposure conditions.

"Patient intervention" means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

"PDR", see pulsed dose-rate remote afterloader.

"Pharmacist" means an individual licensed by a State or Territory of the United States, the District of Columbia or the Commonwealth of Puerto Rico to practice pharmacy. (See also Authorized nuclear pharmacist)

"Physician" means an individual licensed by a State or Territory of the United States, the District of Columbia or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine.

"Podiatrist" means an individual licensed by a State or Territory of the United States, the District of Columbia or the Commonwealth of Puerto Rico to practice podiatry.

"Preceptor" means an individual who provides, directs or verifies training and experience required for an individual to become a radiation safety officer, an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, a nuclear medicine technologist, or a radiation therapy technologist (see appendices 7A through 7O).

"Prescribed dosage" means the specified activity or range of activity of a radioactive drug as documented in:

- (1) A written directive as specified in 7.11; or
- (2) Accordance with the directions of the authorized user for procedures performed pursuant to 7.30, 7.32, or 7.36.

"Prescribed dose" means:

- (1) For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

- (2) For teletherapy, the total dose and dose per fraction as documented in the written directive;
- (3) For manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or
- (4) For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

"Pulsed dose-rate remote afterloader" (PDR) means a special type of remote afterloading device that uses a single source capable of delivering dose rates (at the specified distance) in the "high dose-rate" range, but:

- (1) Is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and
- (2) Is used to simulate the radiobiology of a low dose rate treatment by inserting the source for a given fraction of each hour.

"Radiation safety officer" (RSO) means, for the purposes of Part 7, an individual who has demonstrated sufficient knowledge to apply radiation protection regulations appropriately, who in accord with 7.7 has been assigned such responsibility by the licensee, and who meets the requirements in Appendix 7A; or

- (1) Is identified as a Radiation Safety Officer on:
  - a. A specific medical use license issued by the Department, NRC, or Agreement State; or
  - b. A medical use permit issued by an NRC master material licensee.

"Radiation therapy technologist" (RTT) means an individual who meets the requirements of Appendix 7O and is under the supervision of an authorized user to perform procedures and apply radiation emitted from sealed radioactive sources to human beings for therapeutic purposes.

"Radiation therapy technology" means the science and art of applying radiation emitted from sealed radioactive sources to patients or human research subjects for therapeutic purposes.

"Radioactive drug" means any chemical compound containing radioactive material that may be used on or administered to patients or human research subjects as an aid in the diagnosis, treatment, or prevention of disease or other abnormal condition.

"Sealed source" means radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material under the most severe conditions which are likely to be encountered in normal use and handling.

"Sealed Source and Device Registry" means the national registry that contains the registration certificates maintained by the Nuclear Regulatory Commission, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

"Stereotactic radiosurgery" means the use of external radiation in conjunction with a stereotactic guidance device to precisely deliver a dose to a treatment site.

"Structured educational program" means an accredited educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

"Teletherapy", as used in this part, means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.

"Temporary job site", as used in Part 7, means a location where mobile medical services are confined to the mobile unit not at a licensed address of use. "Therapeutic dosage" means a dosage of unsealed radioactive material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

"Therapeutic dose" means a radiation dose delivered from a sealed source containing radioactive material to a patient or human research subject for palliative or curative treatment.

"Treatment site" means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

"Trunnion" means a support bar sometimes used as a bearing instead of a socket.

"Type of use" means use of radioactive material as specified under 7.30, 7.32, 7.36, 7.40, 7.42, 7.48 or 7.62.

"Unit dosage" means a dosage that:

- (1) Is obtained or prepared in accordance with the regulations for uses described in 7.30, 7.32, or 7.36; and
- (2) Is to be administered as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

"Written directive" means an authorized user's written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in 7.11.

## **GENERAL REGULATORY REQUIREMENTS**

### **7.3 License Required.**

7.3.1 A person shall manufacture, produce, prepare, acquire, receive, possess, use, or transfer radioactive material for medical use only in accordance with a specific license issued by the Department, an Agreement State or NRC, or as allowed in 7.3.1.1 or 7.3.1.2.

7.3.1.1 Unless prohibited by license condition, an individual may receive, possess, use, or transfer radioactive material in accordance with the regulations in this part under the supervision of an authorized user as provided in 7.10.

7.3.1.2 Unless prohibited by license condition, an individual may prepare unsealed radioactive material for medical use in accordance with the regulations in this part under the supervision of an authorized nuclear pharmacist or authorized user as provided in 7.10.

7.3.2 Provisions for the protection of Human Research Subjects.

A licensee may conduct research involving human subjects using radioactive material under the following conditions:

- 7.3.2.1 For research conducted, funded, supported, or regulated by a federal agency which has implemented The Federal Policy for the Protection of Human Subjects (Federal Policy), the licensee shall:
- (1) Obtain prior informed consent from the human research subjects; and
  - (2) Obtain prior review and approval of the research activities by an "Institutional Review Board" in accordance with the meaning of these terms as defined and described in the Federal Policy; or
- 7.3.2.2 For research not conducted, funded, supported, or regulated by a federal agency which has implemented the Federal Policy, then:
- (1) The licensee shall apply for and receive a specific amendment to its Department license before conducting such research. The amendment request shall include a written commitment that the licensee will, before conducting research:
    - a. Obtain prior informed consent from the human research subjects; and
    - b. Obtain prior review and approval of the research activities by an "Institutional Review Board" in accordance with the meaning of these terms as defined and described in the Federal Policy;
- 7.3.2.3 A licensee not authorized pursuant to 3.11 shall apply for and receive approval of a specific amendment to its Department license before conducting research involving human subjects;
- 7.3.2.4 The research involving human subjects authorized in 7.3.2 shall be conducted using radioactive material authorized for medical use in the license; and
- 7.3.2.5 Nothing in 7.3.2 relieves licensees from complying with the other requirements in Part 7.
- 7.3.3 Nothing in this part relieves the licensee from complying with applicable FDA, other federal, and state requirements governing radioactive drugs or devices.
- 7.3.4 Application for License, Amendment, or Renewal.
- 7.3.4.1 An application shall be signed by the applicant's or licensee's management.
- 7.3.4.2 An application for a new or renewal license for medical use of radioactive material as described in 7.30, 7.32, 7.36, 7.40, 7.42, 7.48 or 7.62 must be made by:
- (1) Filing a completed Department Form R-12 (7C), and
  - (2) Submitting procedures required by Form R-12 (7C), and 7.12, 7.15, 7.51, 7.58, 7.59, and 7.61, as applicable, and other procedures as requested by the Department.
- 7.3.4.3 A request for a license amendment must be made by:
- (1) Submitting an original amendment request in letter format.
  - (2) Submitting procedures required by 7.12, 7.15, 7.51, 7.58, 7.59, and 7.61, as applicable, and other procedures as requested by the Department.

7.3.4.4 In addition to the requirements in 7.3.4.2 and 7.3.4.3, an application for a new license, renewal license, or amendment for medical use of radioactive material as described in 7.62 must also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in 7.1 through 7.29, as well as any specific information on:

- (1) Radiation safety precautions and instructions;
- (2) Training and experience of proposed users;
- (3) Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and
- (4) Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.

7.3.4.5 The applicant or licensee shall also provide any other information requested by the Department in its review of the application.

7.3.4.6 An applicant that satisfies the requirements specified in 3.11 may apply for a Type A specific license of broad scope.

#### 7.3.5 Mobile Medical Service Administrative Requirements.

7.3.5.1 The Department shall license mobile medical services or clients of such services. The mobile medical service shall be licensed if the service receives, uses or possesses radioactive material. The client of the mobile medical service shall be licensed if the client receives or possesses radioactive material to be used by a mobile medical service.

7.3.5.2 Mobile medical service licensees shall obtain a letter signed by the management of each location where services are rendered that authorizes use of radioactive material at the client's address of use. This letter shall clearly delineate the authority and responsibility of both the client and the mobile medical service. If the client is licensed, the letter shall document procedures for notification, receipt, storage and documentation of transfer of radioactive material delivered to the client's address for use by the mobile medical service.

7.3.5.3 A mobile medical service shall not have radioactive material delivered directly from the manufacturer or the distributor to the client, unless the client has a license allowing possession of the radioactive material. Radioactive material delivered to the client shall be received and handled in conformance with the client's license.

7.3.5.4 A mobile medical service shall inform the client's management who is on site at each client's address of use at the time that radioactive material is being administered.

7.3.5.5 A licensee providing mobile medical services shall retain the letter required in 7.3.5.2 for 3 years after the last provision of service.

7.3.5.6 A mobile medical service licensee shall, at a minimum, maintain the following documents on each mobile unit:

- (1) The current operating and emergency procedures;
- (2) A copy of the license;

- (3) Copies of the letter required by 7.3.5.2;
- (4) Current calibration records for each survey instrument and diagnostic equipment or dose delivery device in use; and
- (5) Survey records covering uses associated with the mobile unit during, at a minimum, the preceding 30 calendar days.

7.3.5.7 The mobile medical service shall designate and manage each area of use in the client's facility as a restricted area while radioactive material is present. For each location where radioactive materials will be routinely used, the licensee shall provide to the Department:

- (1) A diagram of the location of use, including information about the placement of required postings; and
- (2) Calculation(s) or survey(s) results that demonstrate compliance with applicable dose limits in 4.14 and 4.15 at the location of use.

7.3.5.8 The mobile medical service shall ensure that:

- (1) Supervision by an authorized user is in accordance with 7.10.1;
- (2) Radiation exposures to the client's personnel working in the client facility are:
  - (a) Below the dose limits to members of the public listed in 4.14; or
  - (b) The client's personnel are instructed as described in 10.3 and monitored for exposure in accordance with 4.18 unless the licensee can demonstrate that 4.18 does not apply.

7.3.5.9 A mobile medical service licensee shall maintain all records required by Parts 4 and 7 of these regulations at a location within the Department's jurisdiction that is:

- (1) A single address of use:
  - (a) Identified as the records retention location; and
  - (b) Staffed at all reasonable hours by individual(s) authorized to provide the Department with access for purposes of inspection; or
- (2) When no address of use is identified on the license for records retention, the mobile unit:
  - (a) Identified in the license; and
  - (b) Whose current client's address of use and area of use schedule is reported to the Department.

7.3.6 A licensee possessing a Type A specific license of broad scope for medical use is exempt from:

7.3.6.1 The provisions of 7.3.4.4 regarding the need to file an amendment to the license for medical uses of radioactive material as described in 7.62;

- 7.3.6.2 The provisions of 7.4.2 regarding the need to file an amendment before permitting anyone to work as an authorized user, an authorized nuclear pharmacist or an authorized medical physicist under the license;
  - 7.3.6.3 The provisions of 7.4.5 regarding additions to or changes in the areas of use at the addresses specified in the license;
  - 7.3.6.4 The provisions of 7.5.1 regarding notification to the Department for new authorized users, new authorized nuclear pharmacists and new authorized medical physicists;
  - 7.3.6.5 The provisions of 7.14 regarding suppliers for sealed sources.
- 7.3.7 The Department may, upon application of any interested person or upon its own initiative, grant such exemptions from the regulations in Part 7 as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

#### **7.4 License Amendments.**

A licensee shall apply for and shall have received a license amendment before the licensee:

- 7.4.1 Receives, prepares, or uses radioactive material for a type of use that is permitted under this part but that is not authorized on the licensee's current license issued pursuant to this part;
- 7.4.2 Permits anyone to work as an authorized user, authorized medical physicist, or an authorized nuclear pharmacist under the license in accordance with the training and experience requirements specified in:
  - 7.4.2.1 Appendix 7D through Appendix 7M for an authorized user for a specific type of use of radioactive material;
  - 7.4.2.2 Appendix 7B for an authorized medical physicist;
  - 7.4.2.3 Appendix 7C for an authorized nuclear pharmacist; and
- 7.4.3 Changes a Radiation Safety Officer, except as provided in 7.7.6;
- 7.4.4 Receives radioactive material in excess of the amount or in a different physical or chemical form than is authorized on the license;
- 7.4.5 Adds to or changes the area(s) of use or address(es) of use identified in the application or on the license, except as specified in 7.5.2.4; and
- 7.4.6 Changes statements, representations, and procedures which are incorporated into the license; or
- 7.4.7 Releases licensed facilities for unrestricted use.

#### **7.5 Notifications; Maintenance of Records.**

- 7.5.1 A licensee shall provide to the Department required documentation of adequate radiation safety training and experience under Appendix 7B for each authorized medical physicist pursuant to 7.4.2, under Appendix 7C for each authorized nuclear pharmacist, and under the applicable appendix of Appendix 7D through Appendix 7M for each individual authorized user.
- 7.5.2 A licensee shall notify the Department in writing within 30 days after:

- 7.5.2.1 An authorized user, authorized medical physicist, authorized nuclear pharmacist, or Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change;
- 7.5.2.2 The licensee's mailing address changes;
- 7.5.2.3 The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in 3.15.2 of these regulations; or
- 7.5.2.4 The licensee has added to or changed the areas where radioactive material is used in accordance with 7.30 and 7.32.

### 7.5.3 Maintenance of Records.

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

## 7.6 License Issuance.

7.6.1 The Department shall issue a license for the medical use of radioactive material if:

- 7.6.1.1 The applicant has filed Department Form R-12 in accordance with the instructions in 7.3.4;
- 7.6.1.2 The applicant has paid any applicable fee;
- 7.6.1.3 The applicant meets the requirements of Part 3 of these regulations; and
- 7.6.1.4 The Department finds the applicant equipped and committed to observe the safety standards established by the Department in these regulations for the protection of the public health and safety.

7.6.2 The Department shall issue a license for mobile services if the applicant:

- 7.6.2.1 Meets the requirements in 7.6.1, and in particular 7.3.5; and
- 7.6.2.2 Assures that individuals to whom radioactive drugs or radiation from implants containing radioactive material will be administered may be released following treatment in accordance with 7.26.

## ADDITIONAL OVERALL REQUIREMENTS

### 7.7 Authority and Responsibilities for the Radiation Protection Program

7.7.1 In addition to the radiation protection program requirements of 4.5 of these regulations, a licensee's management must approve in writing:

- 7.7.1.1 Requests for license application, renewal, or amendments before submittal to the Department;

- 7.7.1.2 Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist or authorized medical physicist; and
- 7.7.1.3 Radiation protection program changes that do not require a license amendment and are permitted under 7.7.
- 7.7.2 A licensee's management shall appoint a Radiation Safety Officer (RSO), who agrees in writing to be responsible for implementing the radiation safety program. The licensee, through the RSO, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements.
- 7.7.3 A licensee shall establish in writing the authority, duties, and responsibilities of the Radiation Safety Officer, and of the Alternate RSO, if required.
- 7.7.4 A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative, to:
  - 7.7.4.1 Identify radiation safety problems;
  - 7.7.4.2 Initiate, recommend, or provide corrective actions;
  - 7.7.4.3 Stop unsafe operations; and
  - 7.7.4.4 Verify implementation of corrective actions.
- 7.7.5 A licensee shall retain a record of actions taken pursuant to 7.7.1, 7.7.2 and 7.7.3 for 5 years, including:
  - 7.7.5.1 A summary of the actions taken (and a signature of licensee management) in accordance with 7.7.1;
  - 7.7.5.2 A signed copy of the RSO's agreement (including the signature of the RSO and licensee management) to be responsible for implementing the radiation safety program, as required by 7.7.2; and
  - 7.7.5.3 A current copy of the authorities, duties and responsibilities of the RSO as required by 7.7.3.
- 7.7.6 For up to sixty days each year, a licensee may permit an authorized user or an individual qualified to be a radiation safety officer to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in 7.7.4, provided the licensee takes the actions required in 7.7.2, 7.7.3, 7.7.4 and 7.7.5. A licensee may simultaneously appoint more than one temporary RSO, if needed, to ensure that the licensee has a temporary RSO that satisfies the requirements to be an RSO for each of the different uses of radioactive material permitted by the license.

## **7.8 Radiation Safety Committee.**

- 7.8.1 Licensees that are authorized for one or more different types of radioactive material use under 7.36, 7.42, 7.48, or 7.62 shall establish a Radiation Safety Committee to oversee all uses of radioactive material permitted by the license.
- 7.8.2 The Committee shall:
  - 7.8.2.1 Include:

- (1) An authorized user of each type of use permitted by the license;
- (2) The Radiation Safety Officer
- (3) A representative of the nursing service
- (4) A representative of management who is neither an authorized user nor a Radiation Safety Officer; and
- (5) Other members as the licensee deems appropriate.

7.8.2.2 Meet as necessary, but at a minimum shall meet at intervals not to exceed 6 months.

7.8.2.3 Maintain minutes of each meeting, including:

- (1) The date of the meeting;
- (2) Members present;
- (3) Members absent; and
- (4) Summary of deliberations and discussions.

## **7.9 Radiation Protection Program Changes.**

7.9.1 A licensee may revise its radiation protection program without Department approval if:

- 7.9.1.1 The revision does not require an amendment under 7.4;
- 7.9.1.2 The revision is in compliance with the regulations and the license;
- 7.9.1.3 The revision has been reviewed and approved by the Radiation Safety Officer, licensee management and licensee's Radiation Safety Committee (if applicable); and
- 7.9.1.4 The affected individuals are instructed on the revised program before the changes are implemented.

7.9.2 A licensee shall retain a record of each change for 5 years, including

- 7.9.2.1 A copy of the old and new procedures;
- 7.9.2.2 The effective date of the change; and
- 7.9.2.2 The signature of the licensee management that reviewed and approved the change.

## **7.10 Supervision.**

7.10.1 A licensee that permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by 7.3.2 shall:

- 7.10.1.1 In addition to the requirements of 10.3 of these regulations, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of Part 7, and license conditions with respect to the use of radioactive material; and;

- 7.10.1.2 Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures, written directive procedures, regulations of Part 7, and license conditions with respect to the medical use of radioactive material.
- 7.10.2 A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by 7.3.3, shall:
- 7.10.2.1 In addition to the requirements of 10.3, instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's use of radioactive material; and
- 7.10.2.2 Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, the written radiation protection procedures, the regulations of Part 7, and license conditions.
- 7.10.3 Unless physical presence as described in other sections of Part 7 is required, a licensee who permits supervised activities under 7.10.1 and 7.10.2 shall require an authorized user to be immediately available by telephone within ten minutes to communicate with the supervised individual, unless otherwise authorized by the Department with prior written approval.
- 7.10.4 A licensee who permits supervised activities under 7.10.1 and 7.10.2 is responsible for the acts and omissions of the supervising authorized user and supervised individual(s).

#### **7.11 Written Directives.**

- 7.11.1 A written directive must be dated and signed by an authorized user, including the signatory's printed or typed name, prior to administration of:
- 7.11.1.1 I-131 sodium iodide greater than 1.11 MBq (30  $\mu$ Ci), or
- 7.11.1.2 Any therapeutic dosage of radioactive material, or
- 7.11.1.3 Any therapeutic dose of radiation from radioactive material.
- 7.11.2 The written directive must contain the patient or human research subject's name and the following:
- 7.11.2.1 For an administration of a dosage of radioactive drug containing radioactive material, the name of the radioactive drug containing radioactive material, dosage, and route of administration;
- 7.11.2.2 For gamma stereotactic radiosurgery, the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;
- 7.11.2.3 For teletherapy, the total dose, dose per fraction, number of fractions, and treatment site;
- 7.11.2.4 For high dose rate remote afterloading brachytherapy, the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or
- 7.11.2.5 For all other brachytherapy, including LDR, MDR, and PDR:

- (1) Prior to implantation: treatment site, the radionuclide, and dose; and
- (2) After implantation but prior to completion of the procedure: the radioisotope, treatment site, number of sources, and total source strength and exposure time (or the total dose).

7.11.3 If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented as soon as possible in writing in the patient's record and a written directive is prepared within 48 hours of the oral directive.

7.11.4 A written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to the administration of the dosage of radioactive drug containing radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

7.11.5 If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented as soon as possible in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision.

7.11.6 The licensee shall retain a copy of each written directive and/or written revision to an existing written directive for 3 years.

#### **7.12 Procedures for Administrations Requiring a Written Directive.**

7.12.1 For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:

7.12.1.1 The patient's or human research subject's identity is verified before each administration;  
and

7.12.1.2 Each administration is in accordance with the written directive.

7.12.2 The procedures required by 7.12.1 must, at a minimum, address the following items that are applicable for the licensee's use of radioactive material:

7.12.2.1 Verifying the identity of the patient or human research subject;

7.12.2.2 Verifying that the specific details of the administration are in accordance with the treatment plan, if applicable, and the written directive;

7.12.2.3 Checking both manual and computer-generated dose calculations; and

7.12.2.4 Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by 7.48

#### **7.13 Duties of Authorized User and Authorized Medical Physicist.**

7.13.1 A licensee shall assure that only authorized users for the type of radioactive material used:

7.13.1.1 Prescribe the radiopharmaceutical dosage and/or dose to be administered through the issuance of a written directive or reference to the diagnostic clinical procedures manual;  
and

7.13.1.2 Direct, as specified in 7.10 and 7.12, or in license conditions, the administration of radioactive material for medical use to patients or human research subjects;

7.13.1.3 Prepare and administer, or supervise the preparation and administration of radioactive material for medical use, in accordance with 7.3.2, 7.3.3 and 7.10;

7.13.2 A licensee shall assure that only authorized medical physicists perform, as applicable:

7.13.2.1 Measurements and calculations as described in 7.41;

7.13.2.2 Full calibration measurements as described in 7.54, 7.55, and 7.56;

7.13.2.3 Periodic spot checks as described in 7.58, 7.59 and 7.61; and

7.13.2.4 Radiation surveys as described in 7.57.

#### **7.14 Suppliers for Sealed Sources or Devices for Medical Use.**

7.14.1 Sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to Part 3 of these regulations or the equivalent regulations of another Agreement State, a Licensing State or the NRC;

7.14.2 Sealed source or devices non-commercially transferred from a Part 7 licensee or an Agreement State medical use licensee; or

7.14.3 Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to Part 3 of these regulations, or the equivalent regulations of another Agreement State, a Licensing State, or the NRC.

### **SPECIFIC REQUIREMENTS**

#### **7.15 Quality Control of Diagnostic Equipment.**

7.15.1 Each licensee shall establish written quality control procedures for all diagnostic equipment used for radionuclide studies.

7.15.2 As a minimum, quality control procedures and frequencies shall be:

7.15.2.1 Those recommended by equipment manufacturers; or

7.15.2.2 Procedures which have been approved by the Department.

7.15.3 The licensee shall conduct quality control of diagnostic equipment in accordance with written procedures.

7.15.4 A licensee shall retain a record of each quality control test required by the written quality control procedures for 3 years.

#### **7.16 Possession, Use, and Testing of Instruments to Measure the Activity of Unsealed Radioactive Materials.**

7.16.1 For direct measurements performed in accordance with 7.18, a licensee shall possess and use instrumentation to measure the activity of unsealed radioactive materials prior to administration to each patient or human research subject.

- 7.16.2 A licensee shall calibrate the instrumentation required in 7.16.1 in accordance with nationally recognized standards or the manufacturer's instructions.
- 7.16.3 In addition to the calibration required in 7.16.2, the licensee shall at a minimum also perform tests for constancy, linearity, and geometry dependence, as appropriate to demonstrate proper operation of the instrument.
- 7.16.4 A licensee shall retain a record of each instrument calibration and test required by 7.16 for 3 years. The record shall include the:
- 7.16.4.1 Model and serial number of the instrument;
  - 7.16.4.2 Date of the calibration and other tests;
  - 7.16.4.3 Results of the calibration and other tests; and
  - 7.16.4.4 Name of the individual who performed the calibration and other tests.

### **7.17 Calibration of Survey Instruments.**

- 7.17.1 A licensee shall ensure that the survey instruments used to show compliance with Part 4 and Part 7 have been calibrated before first use, annually, and following any repair that will affect the calibration.
- 7.17.2 To satisfy the requirements of 7.17.1 the licensee shall:
- 7.17.2.1 Calibrate all required scale readings up to 10 mSv (1 rem) per hour with a radiation source;
  - 7.17.2.2 Have each radiation survey instrument calibrated as follows, or by acceptable equivalent methods:
    - (1) At energies appropriate for use and at intervals not to exceed 12 months or after instrument servicing, except for battery changes;
    - (2) For linear scale instruments, at 2 points located approximately one-third and two-thirds of full-scale on each scale;
    - (3) For logarithmic scale instruments, at mid-range of each decade and at 2 points of at least one decade;
    - (4) For digital instruments, at 3 points between 0.02 and 10 mSv (2 and 1000 mrem) per hour; and
    - (5) For dose rate instruments, so that an accuracy within plus or minus 20 percent of the true radiation dose rate can be demonstrated at each point checked.
  - 7.17.2.3 Conspicuously note on the instrument the date of calibration.
- 7.17.3 The licensee shall not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is greater than 20 percent.
- 7.17.4 The licensee shall retain a record of each survey instrument calibration required by 7.17 for 3 years. The record shall include the:

- 7.17.4.1 Model and serial number of the instrument;
- 7.17.4.2 Date of the calibration;
- 7.17.4.3 Results of the calibration; and
- 7.17.4.4 Name of the individual who performed the calibration.

**7.18 Determination of Dosages of Radioactive Material for Medical Use.**

- 7.18.1 A licensee shall determine and record the activity of each dosage prior to medical use.
  - 7.18.1.1 For photon-emitting radioactive material, this determination shall be within 30 minutes prior to medical use.
  - 7.18.1.2 For all other radioactive material, this determination shall be within the period before medical use that is no greater than 10 percent of the physical half-life of the radioactive material.
- 7.18.2 For a unit dosage, the determination required by 7.18.1 shall be made by:
  - 7.18.2.1 direct measurement of radioactivity; or
  - 7.18.2.2 a decay correction, based on the measurement made by:
    - (1) a manufacturer or preparer licensed pursuant to Part 3 of these regulations or equivalent provisions of another Agreement State, or NRC; or
    - (2) an NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA.
- 7.18.3 For other than a unit dosage, the determination by 7.18.1 shall be made by:
  - 7.18.3.1 direct measurement of radioactivity; or
  - 7.18.3.2 by a combination of measurements of radioactivity and mathematical calculations; or
  - 7.18.3.3 by a combination of volumetric measurements and mathematical calculations, based on the measurement made by:
    - (1) a manufacturer or preparer licensed pursuant to Part 3 of these regulations or equivalent provisions of another Agreement State, or NRC.
- 7.18.4 Unless otherwise directed by the authorized user, a licensee shall not use a dosage if the dosage differs from the prescribed dosage by more than 20 percent.
- 7.18.5 A license shall retain a record of the each dosage determination required by 7.18.1 for 3 years. The record shall contain the:
  - 7.18.5.1 Name of the radioactive drug;
  - 7.18.5.2 Patient's or human research subject's name, and identification number if one has been assigned;

- 7.18.3.3 Prescribed dosage;
- 7.18.3.4 Determined dosage; or a notation that the total activity is less than 1.1 MBq (30  $\mu$ Ci);
- 7.18.3.5 Date and time of the dosage determination; and
- 7.18.3.6 Name of the individual who determined the dosage.

#### **7.19 Authorization for Calibration, Transmission and Reference Sources.**

Any person authorized by 7.3 for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration and reference use:

- 7.19.1 Sealed sources manufactured and distributed by persons specifically licensed pursuant to Part 3 of these regulations or equivalent provisions of the another Agreement State, a Licensing State, or NRC, and that do not exceed 1.1 GBq (30 mCi) each;
- 7.19.2 Any radioactive material with a half-life not longer than 120 days or less in individual amounts not to exceed 0.55 GBq (15 mCi);
- 7.19.3 Any radioactive material with a half life greater than 120 days in individual amounts not to exceed the smaller of:
  - 7.19.3.1 7.4 MBq (200  $\mu$ Ci);
  - 7.19.3.2 1000 times the quantities in Part 3 Schedule 3B; and
- 7.19.4 Technetium-99m in amounts as needed.

#### **7.20 Requirements for Possession of Sealed Sources and Brachytherapy Sources.**

- 7.20.1 A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer or equivalent instructions approved by the Department and shall maintain the instructions for the duration of source use in a legible form convenient to users.
- 7.20.2 A licensee in possession of a sealed source shall test the source for leakage:
  - 7.20.2.1 In accordance with Part 4 of these regulations; and
  - 7.20.2.2 At intervals not to exceed 6 months or at intervals approved by the Department, another Agreement State, a Licensing State or the NRC in the Sealed Source and Device Registry.
- 7.20.3 To satisfy the leak test requirements of 7.20, the licensee shall measure the sample so that the leak test can detect the presence of 185 Bq (0.005  $\mu$ Ci) of radioactive material in the sample.
- 7.20.4 If the leak test reveals the presence of 0.005 microcurie (185 Bq) or more of removable contamination, the licensee shall:
  - 7.20.4.1 Immediately withdraw the sealed source from use and store, dispose or cause it to be repaired in accordance with the requirements of these regulations; and
  - 7.20.4.2 File a written report with the Department within 5 days of receiving the leak test result, including the model number and serial number, if assigned, of the leaking source, the

radionuclide and its estimated activity, the date and results of the test, and the action taken.

7.20.5 A licensee in possession of a sealed source or brachytherapy source, except for a gamma stereotactic radiosurgery source, shall conduct a semi-annual physical inventory of all such sources. The licensee shall retain each inventory record for 3 years. The inventory records shall contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its estimated activity, the location of each source, and the name of the individual who performed the inventory.

## **7.21 Reports and Notifications of Misadministrations.**

7.21.1 Other than events that result from intervention by a patient or human research subject, a licensee shall report any event in which the administration of radioactive material or radiation from radioactive material results in:

7.21.1.1 A dose that differs from the prescribed dose by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and either

- (1) The total dose delivered differs from the prescribed dose by 20 percent or more;
- (2) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or
- (3) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

7.21.1.2 A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following:

- (1) An administration of a wrong radioactive drug;
- (2) An administration of a radioactive drug containing radioactive material by the wrong route of administration;
- (3) An administration of a dose or dosage to the wrong individual or human research subject;
- (4) An administration of a dose or dosage delivered by the wrong mode of treatment; or
- (5) A leaking sealed source.

7.21.1.3 A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sievert (50 rem) to an organ or tissue and 50 percent of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

7.21.2 A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results, or will result in, unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

7.21.3 The licensee shall notify the Agency by telephone no later than the next calendar day after discovery of the misadministration.

7.21.4 The licensee shall submit a written report to the Agency within 15 days after discovery of the misadministration.

7.21.4.1 The written report must include:

- (1) The licensee's name;
- (2) The name of the prescribing physician;
- (3) A brief description of the event;
- (4) Why the event occurred;
- (5) The effect, if any, on the individual(s) who received the administration;
- (6) Actions, if any, that have been taken, or are planned, to prevent recurrence;
- (7) Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

7.21.4.2 The report may not contain the individual's name or any other information that could lead to identification of the individual.

7.21.5 The licensee shall provide notification of the misadministration to the referring physician and also notify the individual who is the subject of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the misadministration may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

7.21.6 Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the misadministration, or to that individual's responsible relatives or guardians.

7.21.7 A licensee shall retain a record of a misadministration for 3 years. The record must contain:

7.21.7.1 The licensee's name;

7.21.7.1 Names of the individuals involved;

7.21.7.1 The social security number or other identification number if one has been assigned, of the individual who is the subject of the misadministration;

7.21.7.1 A brief description of the event and why it occurred;

7.21.7.1 The effect, if any, on the individual;

7.21.7.1 The actions, if any, taken, or planned, to prevent recurrence; and

7.21.7.1 Whether the licensee notified the individual (or the individual's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

7.21.8 A copy of the record required under 7.21.7 shall be provided to the referring physician if other than the licensee, within 15 days after discovery of the misadministration.

## **7.22 Notification to the Department of Deceased Patients or Human Research Subjects Containing Radioactive Material.**

7.22.1 The licensee shall notify the Department by telephone immediately upon discovery that a patient or human research subject containing radioactive material has died, and it is possible that any individual could receive exposures in excess of 4.14 as a result of the deceased's body.

7.22.2 The licensee shall submit a written report to the Department within 30 days after discovery that the patient or human research subject referenced in 7.22.1 has died. The written report must include the:

7.22.2.1 Licensee's name;

7.22.2.2 Date of death;

7.22.2.3 Radionuclide, chemical and physical form and calculated activity at time of death; and

7.22.2.4 Names (or titles) and address(es) of known individuals who might have received exposures exceeding 5 mSv (500 mrem).

7.22.3 The licensee shall retain a record of each written report required by 7.22 for 3 years.

## **7.23 Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child.**

7.23.1 A licensee shall report any dose to an embryo/fetus that is greater than 5 mSv (500 mrem) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

7.23.2 A licensee shall report any dose to a nursing child, that was not specifically approved, in advance, by the authorized user, that is a result of an administration of radioactive material to a breast feeding individual that:

7.23.2.1 Is greater than 5 millisievert (500 mrem) total effective dose equivalent; or

7.23.2.2 Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

7.23.3 The licensee shall notify by telephone the Agency no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in 7.23.1 or 7.23.2.

7.23.4 The licensee shall submit a written report to the Agency within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in 7.23.1 or 7.23.2.

7.23.4.1 The written report must include:

- (1) The licensee's name;
- (2) The name of the prescribing physician;
- (3) A brief description of the event;
- (4) Why the event occurred;
- (5) The effect on the embryo/fetus or the nursing child;
- (6) What actions, if any, have been taken, or are planned, to prevent recurrence; and
- (7) Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

7.23.4.2 The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

7.23.5 The licensee shall notify the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under 7.23.1 or 7.23.2, unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother, when appropriate. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

7.23.6 A licensee shall retain a record of a dose to an embryo/fetus or a nursing child for 3 years. The record must contain:

7.23.6.1 The licensee's name;

7.23.6.2 Names of all the individuals involved;

7.23.6.3 Social security number or other identification number if one has been assigned to the pregnant individual or nursing child who is the subject of the event;

7.23.6.4 A brief description of the event and why it occurred;

7.23.6.5 The effect, if any, on the embryo/fetus or nursing child;

7.23.6.6 The actions, if any, taken, or planned, to prevent recurrence; and

7.23.6.7 Whether the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

7.23.7 A copy of the record required under 7.23.6 shall be provided to the referring physician, if other than the licensee, within 15 days after discovery of the event.

#### **7.24 Vial Shields and Labels.**

7.24.1 A licensee shall require each individual preparing or handling a vial that contains a radiopharmaceutical to keep the vial in a vial radiation shield.

7.24.2 Each syringe and vial that contains a radioactive drug shall be labeled to identify the radioactive drug, to include the isotope and amount of radioactivity. Each syringe shield and vial shield shall also be labeled unless the label on the syringe or vial is visible when shielded.

#### **7.25 Surveys for Contamination and Ambient Exposure Rate.**

7.25.1 Surveys required by 7.25.2 and 7.25.3 are in addition to surveys required by Part 4.

##### **7.25.2 Daily Survey Requirements**

7.25.2.1 At the end of each day of use, a licensee shall survey with an exposure rate instrument, all areas where radioactive drugs containing radioactive material requiring a written directive were prepared for use or administered.

(1) A licensee does not need to perform the surveys required by 7.25.2.1 in an area where patients or human research subjects are confined when they cannot be released pursuant to 7.26.

7.25.2.2 At the end of each day of use, a licensee shall survey for removable contamination all areas where generators and bulk radioactive drugs are prepared for use. An instrument capable of detecting 33.3 becquerels (2000 dpm) of contamination on each wipe sample shall be used.

##### **7.25.3 Weekly Survey Requirements**

7.25.3.1 At least once each week, a licensee shall survey, with an exposure rate instrument, all areas where radioactive drugs or radioactive wastes are stored.

7.25.3.2 At least once each week, a licensee shall survey for removable contamination in all areas where radioactive materials other than sealed sources as defined in Part 7 are stored. An instrument capable of detecting 33.3 becquerels (2000 dpm) of contamination on each wipe sample shall be used.

7.25.4 A licensee shall establish action levels for the surveys required by 7.25.2 and 7.25.3 and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if action levels are exceeded.

7.25.5 A licensee shall retain a record of each survey required by 7.25.1, 7.25.2 and 7.25.3 for 3 years. The record must include:

7.25.5.1 The date of the survey;

7.25.5.2 The results of the survey;

7.25.5.3 The instrument used to make the survey (including, if applicable, that the instrument was checked for consistent response with a dedicated check source prior to each daily use); and

7.25.5.4 The name of the individual who performed the survey.

## **7.26 Release of Individuals Containing Radioactive Drugs or Implants.**

7.26.1 A licensee may authorize the release from the licensee's control of any individual who has been administered radioactive drugs or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).<sup>1</sup>

<sup>1</sup> Appendix U of U.S. Nuclear Regulatory Commission NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program Specific Guidance About Medical Licenses" describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem).

7.26.2 A licensee shall provide the released individual or the individual's parent or guardian with instructions, including written instructions on the actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem).

7.26.2.1 If the total effective dose equivalent to a nursing infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption in breast-feeding, the instructions shall also include:

- (1) Guidance on the interruption or discontinuation of breast-feeding; and
- (2) Information on the potential consequences, if any, of failure to follow the guidance.

7.26.3 If the total effective dose equivalent to a nursing infant or child could exceed 5 mSv (0.5 rem) from continued breast-feeding, the licensee shall maintain a record that the instructions required by 7.26.2 were provided to a breast-feeding woman.

7.26.4 The licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with 7.26, if the total effective dose equivalent is calculated by:

7.26.4.1 Using the retained activity rather than the administered activity;

7.26.4.2 Using an occupancy factor less than 0.25 at 1 meter;

7.26.4.3 Using the biological or effective half-life; and

7.26.4.4 Considering the shielding by tissue.

7.26.5 The records required by 7.26.3 and 7.26.4 must be retained for 3 years after the date of release of the individual.

7.26.6 Reports of Patient Departure Prior to Authorized Release.

7.26.6.1 The licensee shall notify the Department by telephone immediately upon discovery that a patient or human research subject has departed from the licensee's facility without authorization under 7.26.

7.26.6.2 The licensee shall submit a written report to the Department within 30 days after discovery of the unauthorized departure. The written report must include:

- (1) The licensee's name;
- (2) The date and time of the unauthorized departure;

- (3) The projected date and time when release would have occurred;
- (4) The address of the patient's or human research subject's home or anticipated destination following departure;
- (5) The radionuclide, chemical and physical form and calculated activity at time of release;
- (6) The apparent reason(s) for the departure prior to authorized release; and
- (7) A description of any changes in the licensee's patient release criteria or patient instructions that are designed to avoid a recurrence of such an event.

#### **7.27 Mobile Nuclear Medicine Service Technical Requirements.**

A licensee providing mobile nuclear medicine service shall:

- 7.27.1 Transport to each client's address of use only syringes or vials containing prepared drugs or radioactive materials that are intended for reconstitution of radioactive drug kits;
- 7.27.2 Bring into each client's address of use all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;
- 7.27.3 Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at a client's address of use;
- 7.27.4 Check instruments used to measure the activity of unsealed radioactive material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function shall include a constancy check;
- 7.27.5 Check survey instruments for consistent response with a dedicated check source before use at each client's address;
- 7.27.6 Prior to leaving a client's address of use, perform area surveys and survey for removable contamination in all areas of use, to ensure compliance with Part 4 of these regulations; and
- 7.27.7 Retain a record of each survey required by 7.27.6 for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

#### **7.28 Storage of Volatiles and Gases.**

- 7.28.1 A licensee shall store volatile radioactive materials and radioactive gases in a radiation shield and container.
- 7.28.2 A licensee shall store and use a multi-dose container in a properly functioning fume hood.
- 7.28.3 A licensee who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed in Part 4 of these regulations.
  - 7.28.3.1 The system shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.
  - 7.28.3.2 A licensee shall check the operation of collection systems monthly. Records of these checks shall be maintained for 3 years.

## **7.29 Decay-In-Storage.**

7.29.1 A licensee may hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard for its radioactivity if the licensee:

7.29.1.1 Monitors radioactive material at the container surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding;

7.29.1.3 Removes or obliterates all radiation labels, except for material that will be handled as biomedical waste after release; and

7.29.1.4 Separates and monitors each generator column individually with all radiation shielding removed to ensure that its contents have decayed to background radiation level before disposal.

7.29.2 Records of Decay-in-Storage.

For radioactive material disposed in accordance with 7.29.1, the licensee shall retain a record of each disposal for 3 years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.

## **SPECIFIC REQUIREMENTS FOR THE USE OF RADIOACTIVE MATERIAL FOR UPTAKE, DILUTION, AND EXCRETION STUDIES**

### **7.30 Use of Unsealed Radioactive Material for Uptake, Dilution, and Excretion Studies for which a Written Directive is Not Required.**

7.30.1 A licensee may use any unsealed radioactive material, in quantities that do not require a written directive, as described in 7.11, for a diagnostic use involving measurements of uptake, dilution, or excretion that:

7.30.1.1 Is obtained from a manufacturer or preparer licensed pursuant to 3.12.10 or equivalent regulations of another Agreement State, a Licensing State, or NRC; or;

7.30.1.2 Excluding production of PET radioactive material, is prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in Appendix 7E, Appendix 7F, or Appendix 7E3.1(2)(g), or an individual under the supervision of either as specified in 7.10;

7.30.1.3 Is obtained from and prepared by a Department, Agreement State, Licensing State or NRC licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

7.30.1.4 Is prepared by the licensee in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA for use in research.

7.30.2 Authorized User Training For Uptake, Dilution, And Excretion Studies.

The licensee shall require an authorized user of an unsealed radioactive material for the uses authorized under 7.30 to meet the requirements of Appendix 7D.

### 7.31 Possession of Survey Instrument.

A licensee authorized to use radioactive material for uptake, dilution, and excretion studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range 1.0  $\mu\text{Sv}$  (0.1 mrem) per hour to 500  $\mu\text{Sv}$  (50 mrem) per hour. The instrument shall be operable and calibrated in accordance with 7.17.

### SPECIFIC REQUIREMENTS FOR THE USE OF UNSEALED RADIOACTIVE MATERIAL - WRITTEN DIRECTIVE NOT REQUIRED

#### 7.32 Use of Unsealed Radioactive Material for Imaging and Localization Studies for which a Written Directive is Not Required.

7.32.1 A licensee may use, for imaging and localization studies, any radioactive material prepared for medical use, in quantities that do not require a written directive, as described in 7.11, that:

7.32.1.1 Is obtained from a manufacturer or preparer licensed pursuant to 3.12.10 or equivalent regulations of another Agreement State, a Licensing State, or NRC; or;

7.32.1.2 Excluding production of PET radioactive material, is prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in Appendix 7E, or Appendix 7F and Appendix 7E3.1(2)(g), or an individual under the supervision of either as specified in 7.10.

7.32.1.3 Is obtained from and prepared by a Department, Agreement State, Licensing State or NRC licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

7.32.1.4 Is prepared by the licensee in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA for use in research.

7.32.2 Authorized User Training for Imaging and Localization Studies for which a Written Directive is Not Required.

The licensee shall require an authorized user of an unsealed radioactive material for the uses authorized under 7.32 to meet the requirements of Appendix 7E.

#### 7.33 Radionuclide Contaminants.

7.33.1 A licensee shall not administer to humans a radioactive drug containing:

7.33.1.1 More than 0.15 kBq of molybdenum-99 per MBq of technetium-99m (0.15  $\mu\text{Ci}$  of  $^{99}\text{Mo}$  per mCi of  $^{99\text{m}}\text{Tc}$ ).

7.33.1.2 More than 0.02 kBq of strontium-82 per MBq of rubidium-82 chloride injection (0.02  $\mu\text{Ci}$  of  $^{82}\text{Sr}$  per mCi of  $^{82}\text{Rb}$  chloride);

7.33.1.3 More than 0.2 kBq of strontium-85 per MBq of rubidium-82 chloride injection (0.2  $\mu\text{Ci}$  of  $^{85}\text{Sr}$  per mCi of  $^{82}\text{Rb}$ ).

7.33.2 To demonstrate compliance with 7.33.1, the licensee preparing radioactive drugs from radionuclide generators shall measure the concentration of radionuclide contaminant in:

7.33.2.1 Each eluate after receipt of a molybdenum-99/technetium-99m generator;

7.33.2.2 Each eluate or extract, before the first patient use of the day, as appropriate for other than molybdenum-99/technetium-99m generator systems.

**7.33.3 Records of Radionuclide Purity.**

A licensee who must measure radionuclide contaminant concentration shall retain a record of each radionuclide contaminant test for 3 years. The record shall include, for each measured elution of radionuclide used to prepare a radioactive drug, the ratio of the measures expressed as kBq of contaminant per MBq of desired radionuclide ( $\mu\text{Ci}/\text{mCi}$ ), the time and date of the test, and the name of the individual who made the measurement.

**7.33.4 Immediate Report.**

A licensee shall report immediately to the Department each occurrence of radionuclide contaminant concentration exceeding a limit specified in 7.33.1.

**7.34 Aerosols and Gases.**

Provided the conditions of 7.28 are met, a licensee shall use radioactive aerosols or gases only if specific application is made to and approved by the Department.

**7.35 Radiation Detection Capability.**

A licensee authorized to use radioactive material pursuant to 7.32, 7.36, or 7.42 shall possess portable radiation detection survey instrumentation capable of detecting dose rates over the range 1.0  $\mu\text{Sv}$  (0.1 mrem) per hour to 500  $\mu\text{Sv}$  (50 mrem) per hour and over the range of 10  $\mu\text{Sv}$  (1 mrem) per hour to 10 mSv (1 rem) per hour. Each instrument shall be operable and calibrated in accordance with 7.17.

**SPECIFIC REQUIREMENTS FOR THE USE OF UNSEALED RADIOACTIVE MATERIAL - WRITTEN DIRECTIVE REQUIRED**

**7.36 Use of Unsealed Radioactive Material for Which A Written Directive Is Required.**

7.36.1 A licensee may use any unsealed radioactive material for diagnostic or therapeutic medical use for which a written directive is required that:

7.36.1.1 Is obtained from a manufacturer or preparer licensed pursuant to 3.12.10 or equivalent regulations of another Agreement State, a Licensing State, or NRC; or

7.36.1.2 Excluding production of PET radioactive material, is prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in Appendix 7E, or Appendix 7F, or an individual under the supervision of either as specified in 7.10;

7.36.1.3 Is obtained from and prepared by a Department, Agreement State, Licensing State or NRC licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

7.36.1.4 Is prepared by the licensee in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA for use in research.

7.36.2 Authorized User Training For Use Of Any Unsealed Radioactive Material For Diagnostic Or Therapeutic Medical Use For Which A Written Directive Is Required.

The licensee shall require an authorized user of an unsealed radioactive material for diagnostic or therapeutic medical use for which a written directive is required under 7.36 to meet the requirements of Appendix 7F.

7.36.3 Authorized User Training For Oral Administration of  $< / = 1.22 \text{ GBq } ^{131} \text{ I}$  (33 mCi) Sodium Iodide Requiring A Written Directive.

The licensee shall require an authorized user of an unsealed radioactive material for oral administration of  $< / = 1.22 \text{ GBq } ^{131} \text{ I}$  (33 mCi) sodium iodide requiring a written directive under 7.36 to meet the requirements of Appendix 7G.

7.36.4 Authorized User Training For Oral Administration Of  $> 1.22 \text{ GBq } ^{131} \text{ I}$  (33 mCi) Sodium Iodide Requiring A Written Directive.

The licensee shall require an authorized user of an unsealed radioactive material for oral administration of  $> 1.22 \text{ GBq } ^{131} \text{ I}$  (33 mCi) sodium iodide requiring a written directive under 7.36 to meet the requirements of Appendix 7H.

7.36.5 Authorized User Training For Parenteral Administration Requiring A Written Directive.

The licensee shall require an authorized user of an unsealed radioactive material for parenteral administration requiring a written directive under 7.36 to meet the requirements of Appendix 7I.

**7.37 Safety Instruction.**

In addition to the requirements of Part 10 of these regulations:

7.37.1 The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects that have received therapy with a radioactive drug, and cannot be released in accordance with 7.26.

7.37.2 The instruction required by 7.37.1 shall be appropriate for the duties of the personnel and include:

7.37.2.1 Patient or human research subject control;

7.37.2.2 Visitor control, to include the following;

(1) Routine visitation to hospitalized individuals in accordance with Part 4 of these regulations;

(2) Contamination control;

(3) Waste control; and

(4) Notification of the RSO, or his or her designee, and the authorized user if the patient or the human research subject dies or has a medical emergency.

7.37.3 A licensee shall keep a record of individuals receiving instruction required by 7.37.1 and maintain such records for 3 years. The record shall include a list of the topics covered, the date of instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who gave the instruction.

### **7.38 Safety Precautions.**

7.38.1 For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with 7.26, a licensee shall:

7.38.1.1 Quarter the patient or the human research subject either in:

- (1) A private room with a private sanitary facility; or
- (2) A room, with a private sanitary facility, with another individual who also has received similar radiopharmaceutical therapy and who cannot be released in accordance with 7.26; and

7.38.1.2 Visibly post the patient's or the human research subject's door with a "Caution: Radioactive Material" sign and note on the door or on the patient's or the human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room;

7.38.1.3 Either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle such materials and items as radioactive waste.

7.38.2 A licensee shall notify the RSO , or his or her designee, and the authorized user immediately if the hospitalized patient dies or has a medical emergency and notify the Department as required by 7.39.

### **7.39 Emergency Notification.**

The licensee shall notify the Department in accordance with 7.22 if it is possible that any individual could receive exposures in excess of 4.14 as a result of a deceased's body.

## **SPECIFIC REQUIREMENTS FOR THE USE OF SEALED SOURCES FOR DIAGNOSIS**

### **7.40 Use of Sealed Sources for Diagnosis.**

7.40.1 A licensee shall use for diagnostic medical uses only sealed sources:

7.40.1.1 Approved in the Sealed Source and Device Registry; and

7.40.1.2 Handled in accordance with the manufacturer's radiation safety and handling instructions:

7.40.2 Authorized User Training For Use Of Sealed Sources For Diagnosis.

The licensee shall require an authorized user under 7.40 to meet the requirements of Appendix 7J.

## **SPECIFIC REQUIREMENTS FOR THE USE OF SEALED SOURCES FOR MANUAL BRACHYTHERAPY**

### **7.41 Calibration Measurements of Brachytherapy Sealed Sources.**

- 7.41.1 Prior to the first medical use of a brachytherapy sealed source on or after October 25, 2005, a licensee shall perform the following:
- 7.41.1.1 Determine the source output or activity using a dosimetry system that meets the requirements of 7.53;
  - 7.41.1.2 Determine source positioning accuracy within applicators; and
  - 7.41.1.3 Use published protocols accepted by nationally recognized bodies to meet the requirements of 7.41.1.1 and 7.41.1.2.
- 7.41.2 A licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with 7.41.1.
- 7.41.3 A licensee shall mathematically correct the outputs or activities determined in 7.41.1 for physical decay at intervals consistent with 1.0 percent physical decay.
- 7.41.4 An authorized medical physicist shall perform or review the measurements and calculations made pursuant to 7.41.1, 7.41.2, or 7.41.3.
- 7.41.5 Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The actual source output shall consider decay based on the activity determined in accordance with paragraphs 7.41.1, 7.41.2, or 7.41.3.
- 7.41.6 A licensee shall retain a record of each calibration on brachytherapy sources required by 7.41.1 for 3 years after the last use of the source. The record must include the date of the calibration; the manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source; the source output or activity; source positioning accuracy within applicators; and the signature of the authorized medical physicist.
- 7.41.7 A licensee shall retain a record of decay calculations required by 7.41.5 for the life of the source. The record must include the date and initial activity of the source as determined under 7.41, and for each decay calculation, the date, the source activity and the signature of the authorized medical physicist.

#### **7.42 Use of Sealed Sources For Manual Brachytherapy.**

- 7.42.1 A licensee shall use for manual brachytherapy only sealed sources:
- 7.42.1.1 Approved in the Sealed Source and Device Registry; or
  - 7.42.1.2 In research in accordance with an effective Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of 7.14.1 are met.
- 7.42.2 Authorized User Training For Use Of Sealed Sources For Manual Brachytherapy.
- The licensee shall require an authorized user under 7.42 to meet the requirements of Appendix 7K.
- 7.42.3 Authorized User Training For Use Of Strontium-90 Sealed Sources For Ophthalmic Uses.
- The licensee shall require an authorized user of strontium-90 sealed sources for ophthalmic uses under 7.42 to meet the requirements of Appendix 7L.

### **7.43 Safety Instruction.**

- 7.43.1 The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects that are undergoing implant therapy and cannot be released in accordance with 7.26.
- 7.43.2 The instruction required by 7.43.1 shall be commensurate with the duties of the personnel and include:
- 7.43.2.1 Size and appearance of the brachytherapy sources;
  - 7.43.2.2 Safe handling and shielding instructions in case of a dislodged source;
  - 7.43.2.3 Patient or human research subject control;
  - 7.43.2.4 Visitor control, including both;
    - (1) Routine visitation to hospitalized individuals in accordance with 4.14.1.1; and
    - (2) Visitation authorized in accordance with 4.14.3; and
  - 7.43.2.5 Notification of the RSO, or his or her designee, and the authorized user if the patient or the human research subject dies or has a medical emergency .
- 7.43.3 A licensee shall keep a record of individuals receiving instruction required by 7.43.1 and maintain such records for 3 years. The record shall include a list of the topics covered, the date of instruction, the names(s) of the attendee(s), and the name(s) of the individual(s) who gave the instruction.

### **7.44 Safety Precautions.**

- 7.44.1 For each patient or the human research subject that is receiving brachytherapy and cannot be released in accordance with 7.26, a licensee shall:
- 7.44.1.1 Not place the patient or the human research subject in the same room with a patient who is not receiving radiation therapy;
  - 7.44.1.2 Visibly post the patient's or human research subject's door with a "Caution: Radioactive Material" sign and note on the door or on the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room.
- 7.44.2 A licensee shall have emergency response equipment available near each treatment room to respond to a source that inadvertently becomes:
- 7.44.2.1 Dislodged from the patient; or
  - 7.44.2.2 Lodged within the patient following removal of the source applicators.
- 7.44.3 A licensee shall notify the RSO , or his or her designee, and the authorized user immediately if the hospitalized patient dies or has a medical emergency and notify the Department as required by 7.39.

### **7.45 Brachytherapy Sources Inventory.**

7.45.1 A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use.

7.45.2 Promptly after removing brachytherapy sources from a patient, a licensee shall return brachytherapy sources to a secure storage area and count or otherwise verify the number returned to ensure that all sources taken from the storage area have been returned.

7.45.3 A licensee shall maintain a record of brachytherapy source accountability for 3 years.

7.45.3.1 For temporary implants, the record must include the number and activity of sources:

- (1) Removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use; and
- (2) Not implanted, the time and date they were returned to storage, and the name of the individual who returned them to storage.

7.45.3.2 For permanent implants, the record must include the number and activity of sources:

- (1) Removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;
- (2) Returned to storage, the date they were returned to storage, and the name of the individual who returned them to storage; and
- (3) Permanently implanted in the patient or human research subject.

#### **7.46 Surveys After Source Implant and Removal.**

7.46.1 Immediately after implanting sources in a patient or a human research subject, the licensee shall perform a survey to locate and account for all sources that have not been implanted.

7.46.2 Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall perform a radiation survey of the patient with a radiation detection survey instrument to confirm that all sources have been removed. The licensee shall not release from confinement for medical care a patient treated by temporary implant until all sources have been removed.

7.46.3 A licensee shall maintain a record of patient surveys which demonstrate compliance with 7.46.1 and 7.6.2 for 3 years. Each record shall include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

#### **7.47 Therapy-related Computer Systems.**

7.47.1 The licensee shall perform acceptance testing on the treatment planning system in accordance with published protocols accepted by nationally recognized bodies.

7.47.2 At a minimum, the acceptance testing required by 7.47.1 shall include, as applicable, verification of:

7.47.2.1 The source-specific input parameters required by the dose calculation algorithm;

7.47.2.1 The accuracy of dose, dwell time, and treatment time calculations at representative points;

7.47.2.1 The accuracy of isodose plots and graphic displays; and

7.47.2.1 The accuracy of the software used to determine radioactive source positions from radiographic images.

#### **SPECIFIC REQUIREMENTS FOR PHOTON-EMITTING REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS**

##### **7.48 Use of a Sealed Source in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit.**

7.48.1 A licensee shall use sealed sources in remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses:

7.48.1.1 Approved in the Sealed Source and Device Registry; and

7.48.1.2 In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of 7.14.1 are met.

7.48.2 Authorized User Training For Use of a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit.

The licensee shall require an authorized user under 7.48 to meet the requirements of Appendix 7M.

##### **7.49 Installation, Maintenance, Adjustment, and Repair.**

7.49.1 Only a person specifically licensed by the Department, another Agreement State, or the NRC shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

7.49.2 Except for low dose-rate remote afterloader units, only a person specifically licensed by the Department, another Agreement State, a Licensing State, or the NRC shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

7.49.3 For a low dose-rate remote afterloader unit, only a person specifically licensed by the Department, another Agreement State, a Licensing State, or the NRC, or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.

7.49.4 A licensee shall retain a record of the installation, maintenance, adjustment and repair done on remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units for 3 years. The record shall include the date, description of the service, and name(s) of the individual(s) who performed the work.

##### **7.50 Surveys of Patients and Human Research Subjects Treated with a Remote Afterloader Unit.**

7.50.1 Before releasing a patient or a human research subject from licensee control, a licensee shall make a survey of the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe, shielded position.

7.50.2 A licensee shall maintain a record of patient surveys which demonstrate compliance with 7.50.1 for 3 years. Each record shall include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

**7.51 Safety Procedures and Instructions for a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit.**

7.51.1 A licensee shall:

7.51.1.1 Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;

7.51.1.2 Permit only individuals approved by the authorized user, RSO, or authorized medical physicist to be present in the treatment room during treatment with the source(s), if such presence is necessary and justified;

7.51.1.3 Prevent dual operation of more than one radiation producing device in a treatment room, if applicable; and

7.51.1.4 Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. This procedure must include:

- (1) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;
- (2) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and
- (3) The names and telephone numbers of the authorized users, the authorized medical physicist, and the RSO to be contacted if the unit or console operates abnormally.

7.51.2 A copy of the procedures required by 7.51.1.4 shall be physically located at the unit console.

7.51.3 A licensee shall conspicuously post instructions at the unit console to inform the operator of the names and telephone numbers of the authorized users, the authorized medical physicist, and the RSO to be contacted if the unit or console operates abnormally.

7.51.4 A licensee shall provide instruction, initially and at least annually, to all individuals who operate a unit, as appropriate to the individual's assigned duties, in:

7.51.4.1 The procedures identified in 7.51.1.4; and

7.51.4.2 The operating procedures for the unit.

7.51.5 A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

7.51.6 A licensee shall keep a record of individuals receiving instruction required by 7.51.4 and maintain such records for 3 years. The record shall include a list of the topics covered, the date of instruction, the names(s) of the attendee(s), and the name(s) of the individual(s) who gave the instruction.

## **7.52 Doors, Interlocks, and Warning Systems.**

- 7.52.1 A licensee shall control access to the treatment room by a door at each entrance.
- 7.52.2 A licensee shall equip each entrance to the treatment room with an electrical interlock system that shall:
- 7.52.2.1 Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;
  - 7.52.2.2 Cause the source(s) to be shielded promptly when an entrance door is opened; and
  - 7.52.2.3 Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s)' on/off control is reset at the console.
- 7.52.3 A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.
- 7.52.4 Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.
- 7.52.5 For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.
- 7.52.6 In addition to the requirements specified in 7.52.1 through 7.52.5, a licensee shall:
- 7.52.6.1 For low dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units, require:
    - (1) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during the initiation of all patient treatments involving the unit; and
    - (2) An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.
  - 7.52.6.2 For high dose-rate remote afterloader units, require:
    - (1) An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and
    - (2) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.

7.52.6.3 For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.

7.52.6.4 If a patient or research subject suffers a medical emergency during radiation therapy:

- (1) Cease the therapy immediately;
- (2) Remove the source(s); and
- (3) Provide appropriate care to the patient or research subject.

7.52.6.5 If the patient expires during treatment, remove the source(s) before further actions are taken.

7.52.6.6 Notify the RSO, or his or her designee, and an authorized user as soon as possible, if the patient or human research subject has a medical emergency and, immediately, if the patient dies.

7.52.7 A licensee shall have emergency response equipment available near each treatment room, to respond to a situation in which a source inadvertently:

7.52.7.1 Remains in the unshielded position; or

7.52.7.2 Lodges within the patient following completion of the treatment.

### **7.53 Dosimetry Equipment.**

7.53.1 Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions shall be met:

7.53.1.1 The system shall have been calibrated using a system or source traceable to the National Institute of Standards and Technology and published protocols accepted by nationally recognized bodies, or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The calibration shall have been performed within the previous 2 years and after any servicing that may have affected system calibration; or

7.53.1.2 The system shall have been calibrated within the previous 4 years; 18 to 30 months after that calibration, the system shall have been intercompared with another dosimetry system that was calibrated within the past 24 months by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The results of the intercomparison must have indicated that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee shall not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.

7.53.2 The licensee shall have available for use a dosimetry system for spot-check output measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with 7.53.1. This comparison shall have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in 7.53.1.

7.53.3 The licensee shall maintain a record of each calibration, intercomparison, and comparison for the duration of the license. For each calibration, intercomparison, or comparison, the record shall include:

7.53.3.1 The date;

7.53.3.2 The manufacturer's name, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by 7.53.1 and 7.53.2;

7.53.3.3 The correction factor that were determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison;

7.53.3.4 The names of the individuals who performed the calibration, intercomparison, or comparison.

#### **7.54 Full Calibration Measurements on Teletherapy Units.**

7.54.1 A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:

7.54.1.1 Before the first medical use of the unit;

7.54.1.2 Before medical use under the following conditions:

(1) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(2) Following replacement of the source or following reinstallation of the teletherapy unit in a new location; and

(3) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

7.54.1.3 At intervals not exceeding 1 year.

7.54.2 To satisfy the requirement of 7.54.1, full calibration measurements shall include determination of:

7.54.2.1 The output within +/- 3 percent for the range of field sizes and for the distance or range of distances used for medical use;

7.54.2.2 The coincidence of the radiation field and the field indicated by the light beam localizing device;

7.54.2.3 The uniformity of the radiation field and its dependence on the orientation of the useful beam;

7.54.2.4 Timer accuracy, constancy, and linearity;

7.54.2.5 "On off" error; and

7.54.2.6 The accuracy of all distance measuring and localization devices in medical use.

- 7.54.3 A licensee shall use the dosimetry system described in 7.53 to measure the output for one set of exposure conditions. The remaining radiation measurements required in 7.54.2.1 may then be made using a dosimetry system that indicates relative dose rates.
- 7.54.4 A licensee shall make full calibration measurements required by 7.54.1 in accordance with published protocols accepted by nationally recognized bodies.
- 7.54.5 A licensee shall correct mathematically the outputs determined in 7.54.2.1 for physical decay for intervals not exceeding 1 month for cobalt 60, 6 months for cesium 137, or at intervals consistent with 1 percent decay for all other nuclides.
- 7.54.6 Full calibration measurements required by 7.54.1 and physical decay corrections required by 7.54.5 shall be performed by the authorized medical physicist.
- 7.54.7 A licensee shall maintain a record of each calibration for the duration of the license. The record shall include:
- 7.54.7.1 The date of the calibration;
  - 7.54.7.2 The manufacturer's name, model number, and serial number for the teletherapy unit, source(s), and instruments used to calibrate the teletherapy unit;
  - 7.54.7.3 The results and assessments of the full calibrations; and
  - 7.54.7.4 The signature of the authorized medical physicist who performed the full calibration.

#### **7.55 Full Calibration Measurements on Remote Afterloader Units.**

- 7.55.1 A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit:
- 7.55.1.1 Before the first medical use of the unit;
  - 7.55.1.2 Before medical use under the following conditions:
    - (1) Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and
    - (2) Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and
  - 7.55.1.3 At intervals not exceeding one (1) calendar quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and
  - 7.55.1.4 At intervals not exceeding 1 year for low dose-rate remote afterloader units.
- 7.55.2 To satisfy the requirement of 7.55.1, full calibration measurements must include, as applicable, determination of:
- 7.55.2.1 The output within +/- 5 percent;
  - 7.55.2.2 Source positioning accuracy to within +/- 1 millimeter;
  - 7.55.2.3 Source retraction with backup battery upon power failure;

- 7.55.2.4 Length of the source transfer tubes;
  - 7.55.2.5 Timer accuracy and linearity over the typical range of use;
  - 7.55.2.6 Length of the applicators; and
  - 7.55.2.7 Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.
- 7.55.3 In addition to the requirements for full calibrations for low dose-rate remote afterloader units in 7.55.2, a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding one quarter.
- 7.55.4 A licensee shall use the dosimetry system described in 7.53 to measure the output.
- 7.55.5 A licensee shall make full calibration measurements required by 7.55.1 of this section in accordance with published protocols accepted by nationally recognized bodies.
- 7.55.6 For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with 7.55.1 through 7.55.5.
- 7.55.7 A licensee shall mathematically correct the outputs determined in 7.55.2.1 for physical decay at intervals consistent with 1 percent physical decay.
- 7.55.8 Full calibration measurements required by 7.55.1 and physical decay corrections required by 7.55.7 must be performed by the authorized medical physicist.
- 7.55.9 A licensee shall retain a record of each calibration for the duration of the license. The record shall include:
- 7. 55.9.1 The date of the calibration;
  - 7. 55.9.2 The manufacturer's name, model number, and serial number for the remote afterloader unit, source(s), and instruments used to calibrate the remote afterloader unit;
  - 7. 55.9.3 The results and assessments of the full calibrations;
  - 7. 55.9.4 The results of the autoradiograph required for low dose-rate remote afterloader units; and
  - 7. 55.9.5 The signature of the authorized medical physicist who performed the full calibration.

#### **7.56 Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units.**

- 7.56.1 A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit:
- 7.56.1.1 Before the first medical use of the unit;
  - 7.56.1.2 Before medical use under the following conditions:
    - (1) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

- (2) Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and
- (3) Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and

7.56.1.3 At intervals not exceeding 1 year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

7.56.2 To satisfy the requirement of 7.56.1, full calibration measurements must include determination of:

7.56.2.1 The output within +/-3 percent;

7.56.2.2 Relative helmet factors;

7.56.2.3 Isocenter coincidence;

7.56.2.4 Timer accuracy and linearity over the range of use;

7.56.2.5 On-off error;

7.56.2.6 Trunnion centricity;

7.56.2.7 Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

7.56.2.8 Helmet microswitches;

7.56.2.9 Emergency timing circuits; and

7.56.2.10 Stereotactic frames and localizing devices (trunnions).

7.56.3 A licensee shall use the dosimetry system described in 7.53 to measure the output for one set of exposure conditions. The remaining radiation measurements required in 7.56.2.1 may be made using a dosimetry system that indicates relative dose rates.

7.56.4 A licensee shall make full calibration measurements required by 7.56.1 in accordance with published protocols accepted by nationally recognized bodies.

7.56.5 A licensee shall mathematically correct the outputs determined in 7.56.2.1 at intervals not exceeding 1 month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.

7.56.6 Full calibration measurements required by 7.56.1 and physical decay corrections required by 7.56.5 must be performed by the authorized medical physicist.

7.56.7 A licensee shall retain a record of each calibration for the duration of the license. The record shall include:

7.56.7.1 The date of the calibration;

- 7. 56.7.2 The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit, source(s), and instruments used to calibrate the gamma stereotactic radiosurgery unit;
- 7. 56.7.3 The results and assessments of the full calibrations;
- 7. 56.7.4 The signature of the authorized medical physicist who performed the full calibration.

#### **7.57 Radiation Surveys of Therapeutic Treatment Units.**

- 7.57.1 A licensee authorized to use radioactive material in remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1  $\mu$ Sv (0.1 mrem) per hour to 500  $\mu$ Sv (50 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 10  $\mu$ Sv (1 mrem) per hour to 10 mSv (1 rem) per hour. The instruments shall be operable and calibrated in accordance with 7.17.
- 7.57.2 In addition to the survey requirements in Part 4 of these regulations, a person licensed pursuant to Part 7 shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position does not exceed the levels stated in the Sealed Source and Device Registry.
- 7.57.3 The licensee shall make the survey required by 7.57.2 at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).
- 7.57.4 A licensee shall retain a record of the radiation surveys required by 7.57.2 for the duration of use of the unit. The record must include:
  - 7.57.4.1 The date of the measurements;
  - 7.57.4.2 The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;
  - 7.57.4.3 Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and
  - 7.57.4.4 The signature of the authorized medical physicist who performed the test.

#### **7.58 Periodic Spot Checks for Teletherapy Units.**

- 7.58.1 A licensee authorized to use teletherapy units for medical use shall perform output spot checks on each teletherapy unit once in each calendar month, including determination of:
  - 7.58.1.1 Timer accuracy and timer linearity over the range of use;
  - 7.58.1.2 "On off" error;
  - 7.58.1.3 The coincidence of the radiation field and the field indicated by the light beam localizing device;
  - 7.58.1.4 The accuracy of all distance measuring and localization devices used for medical use;

- 7.58.1.5 The output for one typical set of operating conditions measured with the dosimetry system described in 7.53; and
- 7.58.1.6 The difference between the measurement made in 7.58.1.5 and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).
- 7.58.2 A licensee shall perform spot checks required by 7.58.1 in accordance with procedures established by the authorized medical physicist. That individual need not actually perform the output spot-check measurements.
- 7.58.3 A licensee shall have the authorized medical physicist review the results of each spot check within 15 days. The authorized medical physicist shall promptly notify the licensee in writing of the results of each spot check.
- 7.58.4 A licensee authorized to use a teletherapy unit for medical use shall perform safety spot checks of each teletherapy facility once in each calendar month and after each source installation to assure proper operation of:
  - 7.58.4.1 Electrical interlocks at each teletherapy room entrance;
  - 7.58.4.2 Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation restriction of source housing angulation or elevation, carriage or stand travel, and operation of the beam "on off" mechanism;
  - 7.58.4.3 Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;
  - 7.58.4.4 Viewing and intercom systems;
  - 7.58.4.5 Treatment room doors from inside and outside the treatment room; and
  - 7.58.4.6 Electrically assisted treatment room doors with the teletherapy unit electrical power turned "off".
- 7.58.5 If the results of the checks required in 7.58.4 indicate the malfunction of any system, a licensee shall lock the control console in the "off" position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.
- 7.58.6 A licensee shall maintain a record of each spot check required by 7.58.1 and 7.58.5 for 3 years. The record shall include:
  - 7.58.6.1 The date of the spot check;
  - 7.58.6.2 The manufacturer's name, model number, and serial number for the teletherapy unit, source, and instrument used to measure the output of the teletherapy unit;
  - 7.58.6.3 An assessment of timer linearity and constancy;
  - 7.58.6.4 The calculated "on off" error;
  - 7.58.6.5 A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device
  - 7.58.6.6 The determined accuracy of each distance measuring or localization device;

- 7.58.6.7 The difference between the anticipated output and the measured output;
- 7.58.6.8 Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and
- 7.58.6.9 The name of the individual who performed the periodic spot check and the signature of the authorized medical physicist who reviewed the record of the spot check.

### **7.59 Periodic Spot Checks for Remote Afterloader Units.**

- 7.59.1 A licensee authorized to use remote afterloader units for medical use shall perform spot checks of each remote afterloader facility and on each unit:
  - 7.59.1.1 At the beginning of each day of use of a high dose-rate, medium dose-rate or pulsed dose-rate remote afterloader unit;
  - 7.59.1.2 Prior to each patient treatment with a low dose-rate remote afterloader unit; and
  - 7.59.1.3 After each source installation.
- 7.59.2 The licensee shall have the authorized medical physicist establish written procedures for performing the spot checks required in 7.59.1. The authorized medical physicist need not actually perform the spot-check measurements.
- 7.59.3 A licensee shall have the authorized medical physicist review the results of each spot check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot check.
- 7.59.4 To satisfy the requirements of 7.59.1, spot checks must, at a minimum, assure proper operation of:
  - 7.59.4.1 Emergency response equipment;
  - 7.59.4.2 Viewing and intercom systems in each high dose-rate, medium dose-rate and pulsed dose-rate remote afterloader facility;
  - 7.59.4.3 Radiation monitors used to indicate the source position;
  - 7.59.4.4 Electrical interlocks at each remote afterloader unit room entrance;
  - 7.59.4.5 Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
  - 7.59.4.6 Timer accuracy;
  - 7.59.4.7 Clock (date and time) in the unit's computer; and
  - 7.59.4.8 Decayed source(s) activity in the unit's computer.
- 7.59.5 If the results of the checks required in 7.59.4 indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

7.59.6 A licensee shall retain a record of each check required by 7.59.4 for 3 years. The record must include, as applicable:

7.59.6.1 The date of the spot check;

7.59.6.2 The manufacturer's name, model number, and serial number for the remote afterloader unit and source;

7.59.6.3 An assessment of timer accuracy;

7.59.6.4 Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and

7.59.6.5 The name of the individual who performed the periodic spot check and the signature of the authorized medical physicist who reviewed the record of the spot check.

## **7.60 Additional Technical Requirements for Mobile Remote Afterloader Units.**

7.60.1 A licensee providing mobile remote afterloader service shall:

7.60.1.1 Check survey instruments for consistent response before medical use at each address of use or on each day of use, whichever is more frequent; and

7.60.1.2 Account for all sources before departure from a client's address of use.

7.60.2 In addition to the periodic spot checks required by 7.59, a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the operation of:

7.60.2.1 Electrical interlocks on treatment area access points;

7.60.2.2 Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

7.60.2.3 Viewing and intercom systems;

7.60.2.4 Applicators, source transfer tubes, and transfer tube-applicator interfaces;

7.60.2.5 Radiation monitors used to indicate room exposures;

7.60.2.6 Source positioning (accuracy); and

7.60.2.7 Radiation monitors used to indicate whether the source has returned to a safe shielded position.

7.60.3 In addition to the requirements for checks in 7.60.2, a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

7.60.4 If the results of the checks required in 7.60.2 indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

7.60.5 A licensee shall retain a record of each check required by 7.60.2 for 3 years. The record must include:

7.60.5.1 The date of the check;

7.60.5.2 The manufacturer's name, model number, and serial number of the remote afterloader unit;

7.60.5.3 Notations accounting for all sources before the licensee departs from a facility;

7.60.5.4 Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators and source transfer tubes, and source positioning accuracy; and

7.60.5.5 The signature of the individual who performed the check.

### **7.61 Periodic Spot Checks for Gamma Stereotactic Radiosurgery Units.**

7.61.1 A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot checks of each gamma stereotactic radiosurgery facility and on each unit:

7.61.1.1 Monthly;

7.61.1.2 At the beginning of each day of use; and

7.61.1.3 After each source installation.

7.61.2 The licensee shall have the authorized medical physicist:

7.61.2.1 Establish written procedures for performing the spot checks required in 7.61.1; and

7.61.2.2 Review the results of each spot check required by 7.61.1.1 within 15 days of the check. The authorized medical physicist need not actually perform the spot-check measurements. The authorized medical physicist shall notify the licensee as soon as possible, in writing, of the results of the spot check.

7.61.3 To satisfy the requirements of 7.61.1.1 spot checks must, at a minimum:

7.61.3.1 Assure proper operation of:

(1) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(2) Helmet microswitches;

(3) Emergency timing circuits; and

(4) Stereotactic frames and localizing devices (trunnions).

7.61.3.2 Determine:

(1) The output for one typical set of operating conditions measured with the dosimetry system described in 7.53.2;

- (2) The difference between the measurement made in 7.61.3.2(1) and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay);
- (3) Source output against computer calculation;
- (4) Timer accuracy and linearity over the range of use;
- (5) On-off error; and
- (6) Trunnion centricity.

7.61.4 To satisfy the requirements of 7.61.1.2 and 7.61.1.3, spot checks must assure proper operation of:

7.61.4.1 Electrical interlocks at each gamma stereotactic radiosurgery room entrance;

7.61.4.2 Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;

7.61.4.3 Viewing and intercom systems;

7.61.4.4 Timer termination;

7.61.4.5 Radiation monitors used to indicate room exposures; and

7.61.4.6 Emergency off buttons.

7.61.5 A licensee shall arrange for prompt repair of any system identified in 7.61.3 that is not operating properly.

7.61.6 If the results of the checks required in 7.61.4 indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

7.61.7 A licensee shall retain a record of each check required by 7.61.3 and 7.61.4 for 3 years. The record must include:

7.61.7.1 The date of the spot check;

7.61.7.2 The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;

7.61.7.3 An assessment of timer linearity and accuracy;

7.61.7.4 The calculated on-off error;

7.61.7.5 A determination of trunnion centricity;

7.61.7.6 The difference between the anticipated output and the measured output;

7.61.7.7 An assessment of source output against computer calculations;

7.61.7.8 Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure

indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and

7.61.7.9 The name of the individual who performed the periodic spot check and the signature of the authorized medical physicist who reviewed the record of the spot check.

#### **7.62 Other Medical Uses of Radioactive Material or Radiation From Radioactive Material.**

7.62.1 A licensee may use radioactive material or a radiation source approved for medical use that is not specifically addressed in Part 7 if:

7.62.1.1 The applicant or licensee has submitted the information required by 7.3.4.2, 7.3.4.3, and 7.3.4.4; and

7.62.1.2 The applicant or licensee has received written approval from the an Agreement State, Licensing State, or NRC in a license and uses the material in accordance with the regulations and specific conditions that the Agreement State, Licensing State, or NRC considers necessary for the medical use of the material.

#### **7.63 Five Year Inspection.**

7.63.1 A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at intervals not to exceed 5 years, whichever comes first, to assure proper functioning of the source exposure mechanism.

7.63.2 This inspection and servicing shall only be performed by persons specifically licensed to do so by the Department, another Agreement State, a Licensing State, or the NRC.

7.63.3 A licensee shall keep a record of the inspection and servicing for the duration of the license. The record shall contain:

7.63.3.1 The inspector's radioactive materials license number;

7.63.3.2 The date of inspection;

7.63.3.3 The manufacturer's name and model number and serial number of both the treatment unit and source;

7.63.3.4 A list of components inspected and serviced;

7.63.3.5 A list of components inspected and serviced, and the type of service;

7.63.3.6 A list of components replaced; and

7.63.3.7 The signature of the inspector.

**PART 7, APPENDIX 7A: TRAINING FOR RADIATION SAFETY OFFICER (RSO)**

**The licensee shall require the individual fulfilling the responsibilities of the Radiation Safety Officer (RSO) as provided in 7.7 to be an individual who:**

**7A1** Is certified by a specialty board whose certification process has been recognized by NRC or an Agreement State and who meets the requirements in paragraphs 7A4 and 7A5 of this Appendix. NRC recognized specialty boards are posted on the NRC website at <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>. To have its certification process recognized, a specialty board shall require all candidates for certification to:

7A1.1 (1) Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

and

(2) Have 5 or more years of professional experience in health physics, provided:

(a) At least 3 years are in applied health physics;

and

(b) Graduate training may substitute for no more than 2 years of the required 5 years of experience;

and

(3) Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry;

or

7A1.2 (1) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

and

(2) Have 2 years of full-time practical training and/or supervised experience in medical physics that is:

(a) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by an Agreement State or NRC;

or

(b) In clinical nuclear medicine facilities providing diagnostic and / or therapeutic services under the general supervision of physicians who meet the requirements for Authorized Users in 7A7, Appendix 7E or Appendix 7F;

and

- (3) Pass an examination administered by diplomates of the specialty board that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety.

or

**7A2** Has satisfied the following criteria:

7A2.1 Has completed a structured educational program consisting of:

- (1) 200 hours of classroom and laboratory training in the following areas:
  - (a) Radiation physics and instrumentation;
  - (b) Radiation protection;
  - (c) Mathematics pertaining to the use and measurement of radioactivity;
  - (d) Radiation biology; and
  - (e) Radiation dosimetry;

and

- (2) 1 year of full-time radiation safety experience, under the supervision of the individual identified as an RSO or Alternate RSO, on an Agreement State or NRC license or permit issued by a NRC master material licensee that authorizes similar type(s) of use of radioactive material, involving the following:
  - (a) Shipping, receiving, and performing related radiation surveys;
  - (b) Using and performing checks for proper operation of dose calibrators, survey meters, and, if appropriate, instruments used to measure radionuclides;
  - (c) Securing and controlling radioactive material;
  - (d) Using administrative controls to avoid mistakes in the administration of radioactive material;
  - (e) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;
  - (f) Using emergency procedures to control radioactive material; and
  - (g) Disposing of radioactive material;

or

**7A3** Meets the following requirements:

7A3.1 Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State under Appendix 7B1

and has experience in radiation safety for similar types of use of radioactive material for which the licensee is seeking the approval of the individual as Radiation Safety Officer and who meets the requirements in 7A4 and 7A5.

or

7A3.2 Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of radioactive materials for which the individual has RSO responsibilities;

and

**7A4** Has provided written attestation(s), signed by a preceptor RSO, that the individual has satisfactorily completed the requirements in 7A5 and in 7A1.1(1) and 7A1.1(2) or 7A1.2(1) and 7A1.2(2) or 7A2.1 or 7A3.1 or 7A3.2, and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO for a medical use licensee;

and

**7A5** Has training in the radiation safety, regulatory issues, and emergency procedures for the type(s) of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by an RSO, Alternate RSO, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized on an Agreement State or NRC license for the type(s) of use of radioactive material for which the licensee is seeking approval.

and

**7A6** Meets the following recentness of training requirements:

7A6.1 The training and experience required by Appendix 7A shall have been obtained within the 7 years preceding the date of license application or amendment request;

or

7A6.2 The individual must have had related, documented continuing education and experience since the required training and experience was obtained.

or

**7A7** Meets the following requirements for an experienced Radiation Safety Officer:

7A7.1 An individual identified as a Radiation Safety Officer on a license issued by the NRC or Agreement State, a permit issued under an NRC or Agreement State broad scope license before October 25, 2005, are not required to comply with the training requirements of 7A1 through 7A6. 7A7.2 Individuals not required to comply with the training requirements of 7A1 through 7A6 may serve as preceptors for, and supervisors of, applicants seeking authorization on licenses for the same uses for which these individuals are authorized.

**PART 7, APPENDIX 7B: TRAINING FOR AUTHORIZED MEDICAL PHYSICIST (AMP)**

**The licensee shall require each authorized medical physicist to be an individual who:**

**7B1** Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in paragraph 7B2.3 and 7B3 of this Appendix. NRC recognized specialty boards are posted on the NRC website at <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>.

7B1.1 To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

and

(2) Have 2 years of full-time practical training and/or supervised experience in medical physics:

(a) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by an Agreement State or NRC;

or

(b) In clinical radiation facilities providing high energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in 7B5, Appendix 7K or Appendix 7M;

and

(3) Pass an examination administered by diplomates of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery;

or

**7B2** Has satisfied the following criteria:

7B2.1 Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

and

7B2.2 Has completed 1 year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization.

(1) The training and work experience of 7B2.2 must be: Conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons or electrons with energies greater than or equal to 1 MeV) and brachytherapy services and must include:

(a) Performing sealed source leak tests and inventories;

(b) Performing decay corrections;

(c) Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable;

and

(d) Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable;

and

7B2.3 Has obtained written attestation that the individual has satisfactorily completed the requirements in:

(1) 7B3 and 7B1.1(1) and 7B1.1(2);

or

(2) 7B2 and 7B3;

and

(3) Has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in this Appendix (7B), 7B5, or equivalent NRC or Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status;

and

**7B3** Has met the following requirements:

7B3.1 Has training for the type(s) of use for which authorization is sought that includes:

(1) Hands-on device operation,

(2) Safety procedures,

(3) Clinical use,

and

(4) The operation of a treatment planning system.

7B3.2 The training required by 7B3.1 may be satisfied by:

(1) Satisfactorily completing a training program provided by the vendor;

or

Through training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

**and**

**7B4** Meets the following recentness of training requirements:

7B4.1 Training and experience required by Appendix 7B shall have been obtained within the 7 years preceding the date of license application or amendment request;

or

7B4.2 The individual must have had related, documented, continuing education and experience since the required training and experience was obtained.

or

**7B5** Meets the following requirements for an experienced authorized medical physicist:

7B5.1 An individual identified as an authorized medical physicist on a license issued by the NRC or Agreement State, a permit issued under an NRC or Agreement State broad scope license before October 25, 2005, are not required to comply with the training requirements of 7B1 through 7B4.

or

7B5.2 An experienced medical physicist who has demonstrated to the Department experience in the type(s) of use for which the individual is requesting authorized medical physicist status (and thus need not comply with the specific training and experience requirements of 7B1 through 7B4):

(1) Having been certified before October 25, 2005 by the American Board of Radiology in:

(a) Therapeutic radiological physics;

(b) Roentgen ray and gamma ray physics;

(c) X-ray and radium physics;

or

(d) Radiological physics;

or

(2) Having been certified before October 25, 2005 by the American Board of Medical Physics in radiation oncology physics;

and

(3) Has sufficient work experience that includes the tasks listed in 7.13.2 and/or other sections of these regulations related to medical physics, as applicable (having also satisfied 7B2.1 and being trained in therapeutic radiological physics).

7B5.3 Individuals not required to comply with the training requirements of 7B1 through 7B4 may serve as preceptors for, and supervisors of, applicants seeking authorization on licenses for the same uses for which these individuals are authorized.

**PART 7, APPENDIX 7C: TRAINING FOR AUTHORIZED NUCLEAR PHARMACIST (ANP)**

**The licensee shall require each authorized nuclear pharmacist to be a pharmacist who has a current active Colorado State Board of Pharmacy license and who:**

**7C1** Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in paragraph 7C2.2 of this Appendix. NRC recognized specialty boards are posted on the NRC website at <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>.

7C1.1 To have its certification process recognized, a specialty board shall require all candidates for certification to:

- (1) Have graduated from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;
- (2) Hold a current, active license to practice pharmacy;
- (3) Provide evidence of having acquired at least 4000 hours of training/experience in nuclear pharmacy practice (academic training may be substituted for no more than 2000 hours of the required training and experience);

and

- (4) Pass an examination, in nuclear pharmacy administered by diplomates of the specialty board, which assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, and research and development.

or

**7C2** Has satisfied the following criteria:

7C2.1 Has completed 700 hours in a structured educational program that includes:

- (1) 200 hours of classroom and laboratory training in the following areas:
  - (a) Radiation physics and instrumentation;
  - (b) Radiation protection;
  - (c) Mathematics pertaining to the use and measurement of radioactivity;
  - (d) Chemistry of radioactive material for medical use; and
  - (e) Radiation biology;

and

- (2) Supervised practical experience in nuclear pharmacy involving:
  - (a) Shipping, receiving, and performing related radiation surveys;

- (b) Using and performing checks for proper operation of instruments to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;
- (c) Calculating, assaying, and safely preparing dosages for patients or human research subjects;
- (d) Using administrative controls to avoid misadministrations in the administration of radioactive material;

and

- (e) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

and

7C2.2 Has provided written attestation(s), signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in 7C1.1(1), 7C1.1(2), and 7C1.1(3) or 7C2, and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

and

**7C3** Meets the following recentness of training requirements:

7C3.1 The training and experience required by Appendix 7C shall have been obtained within the 7 years preceding the date of license application or amendment request;

or

7C3.2 The individual must have had related, documented, continuing education and experience since the required training and experience was obtained.

or

**7C4** Meets the following requirements for an experienced authorized nuclear pharmacist.

7C4.1 An individual identified as an authorized nuclear pharmacist on a license issued by the NRC or Agreement State, a permit issued under an NRC or Agreement State broad scope license before October 25, 2005, are not required to comply with the training requirements of 7C1 through 7C3.

7C4.2 Individuals not required to comply with the training requirements of 7C1 through 7C3 may serve as preceptors for, and supervisors of, applicants seeking authorization on licenses for the same uses for which these individuals are authorized.

**PART 7, APPENDIX 7D: AUTHORIZED USER TRAINING FOR UPTAKE, DILUTION AND EXCRETION STUDIES (7.30 USES)**

**The licensee shall require an authorized user of an unsealed radioactive material for the uses authorized under 7.30 to be a physician who has a current active State of Colorado license and:**

**7D1** Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in paragraph 7D3.2 of this Appendix. NRC recognized specialty boards are posted on the NRC website at <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>.

7D1.1 To have its certification process recognized, a specialty board shall require that all candidates for certification to:

(1) Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive materials for uptake, dilution, and excretion studies as described in 7D3.1(1) through 7D3.1(2)(f);

and

(2) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control.

or

**7D2** Is an authorized user under Appendix 7E, Appendix 7F, or equivalent Agreement State or NRC requirements; or 7D3

or

**7D3** Has satisfied the following criteria:

7D3.1 Has satisfactorily completed 60 hours of training and experience including a minimum of 8 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive materials for uptake, dilution, and excretion studies. The training and experience must include:

(1) Classroom and laboratory training in the following areas:

- (a) Radiation physics and instrumentation;
- (b) Radiation protection;
- (c) Mathematics pertaining to the use and measurement of radioactivity;
- (d) Chemistry of radioactive material for medical use; and
- (e) Radiation biology;

and

- (2) Work experience under the supervision of an authorized user who meets the requirements of 7D5, 7D, 7E, 7F, or equivalent Agreement State or NRC requirements, involving:
- (a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
  - (b) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
  - (c) Calculating, measuring, and safely preparing patient or human research subject dosages;
  - (d) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;
  - (e) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
  - (f) Administering dosages to patients or human research subjects;

and

7D3.2 Has provided written attestation(s), signed by a preceptor authorized user who meets the requirements of 7D5, Appendix 7D, Appendix 7E, or Appendix 7F, or equivalent Agreement State or NRC requirements, that the individual has satisfactorily completed the requirements in 7D1.1(1) or 7D3.1, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 7.30.

and

**7D4** Meets the following recentness of training requirements:

- 7D4.1 The training and experience required by Appendix 7D shall have been obtained within the 7 years preceding the date of license application or amendment request; or
- 7D4.2 The individual must have had related, documented, continuing education and experience since the required training and experience was obtained.

or

**7D5** Meets the following requirements for an experienced authorized user for 7.30 uses:

- 7D5.1 An individual identified as an authorized user for the medical use of radioactive material on a license issued by the NRC or Agreement State, a permit issued under an NRC or Agreement State broad scope license that authorizes medical use before October 25, 2005, who perform only those medical uses for which they were authorized on that date are not required to comply with the training requirements of 7D1 through 7D4.
- 7D5.2 Individuals not required to comply with the training requirements of 7D1 through 7D4 may serve as preceptors for, and supervisors of, applicants seeking authorization on licenses for the same uses for which these individuals are authorized.

**PART 7, APPENDIX 7E: AUTHORIZED USER TRAINING FOR IMAGING AND LOCALIZATION STUDIES (7.32 USES)**

**The licensee shall require an authorized user of an unsealed radioactive material for the uses authorized under 7.32 to be a physician who has a current active State of Colorado license and:**

7E1 Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in paragraph 7E3.2 of this Appendix. NRC recognized specialty boards are posted on the NRC website at <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>.

7E1.1 To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive materials for imaging and localization studies as described in 7E3.1(1) through 7E3.1(2)(g);

and

(2) Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control;

or

7E2 Is an authorized user under Appendix 7F and meets the requirements in 7E3.1(2)(g), or equivalent Agreement State or NRC requirements;

or

7E3 Has satisfied the following criteria:

7E3.1 Has satisfactorily completed 700 hours, including a minimum of 80 hours of classroom and laboratory training in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive materials for imaging and localization studies. The training must include at a minimum:

(1) Classroom and laboratory training in the following areas:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity;

(d) Chemistry of radioactive material for medical use; and

(e) Radiation biology;

and

- (2) Work experience under the supervision of an authorized user who meets the requirements of 7E5, 7E, or 7F and 7E3.1(2)(g), or equivalent Agreement State or NRC requirements, involving:
- (a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
  - (b) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
  - (c) Calculating, measuring, and safely preparing patient or human research subject dosages;
  - (d) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;
  - (e) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
  - (f) Administering dosages to patients or human research subjects;
  - (g) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radiochemical purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs;

and

7E3.2 Has provided written attestation(s), signed by a preceptor authorized user who meets the requirements of 7E5, Appendix 7E, or Appendix 7F and 7E3.1(2)(g), or equivalent Agreement State or NRC requirements, that the individual has satisfactorily completed the requirements in 7E1.1(1) or 7E3, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 7.30 and 7.32.

and

**7E4** Meets the following recentness of training requirements:

7E4.1 The training and experience required by Appendix 7E shall have been obtained within the 7 years preceding the date of license application or amendment request;

or

7E4.2 The individual must have had related, documented, continuing education and experience since the required training and experience was obtained.

or

**7E5** Meets the following requirements for an experienced authorized user for 7.32 uses:

**7E5.1** An individual identified as an authorized user for the medical use of radioactive material on a license issued by the NRC or Agreement State, a permit issued under an NRC or Agreement State broad scope license that authorizes medical use before October 25,

2005, who perform only those medical uses for which they were authorized on that date are not required to comply with the training requirements of 7E1 through 7E4.7E5.2  
Individuals not required to comply with the training requirements of 7E1 through 7E4 may serve as preceptors for, and supervisors of, applicants seeking authorization on licenses for the same uses for which these individuals are authorized.

**PART 7, APPENDIX 7F: AUTHORIZED USER TRAINING FOR DIAGNOSTIC OR THERAPEUTIC USE OF UNSEALED RADIOACTIVE MATERIAL REQUIRING A WRITTEN DIRECTIVE (7.36.2 USES)**

**The licensee shall require an authorized user of an unsealed radioactive material for the uses authorized under 7.36.2 to be a physician who has a current active State of Colorado license and:**

**7F1** Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in paragraph 7F2.1(2)(f) and 7F2.2 of this Appendix. NRC recognized specialty boards are posted on the NRC website at <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>.

7F1.1 To have its certification process recognized, a specialty board shall require all candidates for certification to:

- (1) Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in 7F2.1(1) through 7F2.1(2)(e). Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association;

and

- (2) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed radioactive material for which a written directive is required;

or

**7F2** Has satisfied the following criteria:

7F2.1 Has satisfactorily completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training must include:

(1) Classroom and laboratory training in the following areas:

- (a) Radiation physics and instrumentation;
- (b) Radiation protection;
- (c) Mathematics pertaining to the use and measurement of radioactivity;
- (d) Chemistry of radioactive material for medical use; and
- (e) Radiation biology;

and

(2) Work experience, under the supervision of an authorized user who meets the requirements of 7F4, or 7F, or equivalent Agreement State or NRC requirements. A supervising authorized user, who meets the requirements in 7F2.1, must also have experience in administering dosages in the same dosage category or categories (i.e., 7F2.1(2)(f)) as the individual requesting authorized user status. The work experience must involve:

- (a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- (b) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
- (c) Calculating, measuring, and safely preparing patient or human research subject dosages;
- (d) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;
- (e) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

and

- (f) Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of 3 cases in each of the following categories for which the individual is requesting authorized user status:
  - (i) Oral administration of less than or equal to 1.22 GBq (33 mCi) of Na I-131 for which a written directive is required;
  - (ii) Oral administration of greater than 1.22 GBq (33 mCi) of Na I-131 for which a written directive is required [experience with at least 3 cases in 7F2.1(2)(f)(ii) also satisfies the requirement in category 7F2.1(2)(f)(i)];
  - (iii) Parenteral administration of any beta emitter, or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required;

and/or

- (iv) Parenteral administration of any other radionuclide for which a written directive is required;

and

7F2.2 Has provided written attestation(s), that the individual has satisfactorily completed the requirements in 7F1.1(1) and 7F2.1(2)(f) or 7F2.1, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 7.36. The written attestation must be signed by a preceptor authorized user who:

(1) Meets the requirements in 7F4, Appendix 7F, or equivalent NRC or Agreement State requirements; and

(2) The preceptor authorized user, who meets the requirements in 7F2.1 must have experience in administering dosages in the same dosage category or categories (i.e., 7F2.1(2)(f)) as the individual requesting authorized user status.

and

**7F3** Meets the following recentness of training requirements:

7F3.1 The training and experience required by Appendix 7F shall have been obtained: within the 7 years preceding the date of license application or amendment request;

or

7F3.2 The individual must have had related, documented, continuing education and experience since the required training and experience was obtained.

or

**7F4** Meets the following requirements for an experienced authorized user for 7.36.2 uses:

7F4.1 An individual identified as an authorized user for the medical use of radioactive material on a license issued by the NRC or Agreement State, a permit issued under an NRC or Agreement State broad scope license that authorizes medical use before October 25, 2005, who perform only those medical uses for which they were authorized on that date are not required to comply with the training requirements of 7F1 through 7F3.

7F4.2 Individuals not required to comply with the training requirements of 7F1 through 7F3 may serve as preceptors for, and supervisors of, applicants seeking authorization on licenses for the same uses for which these individuals are authorized.

**PART 7, APPENDIX 7G: AUTHORIZED USER TRAINING FOR THE ORAL ADMINISTRATION OF SODIUM IODIDE I-131 REQUIRING A WRITTEN DIRECTIVE IN QUANTITIES LESS THAN OR EQUAL TO 1.22 Gbq I (33 mCi) (7.36.3 USES)**

**The licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 GBq (33 mCi), to be a physician who has a current active State of Colorado license and:**

**7G1** Is certified by a medical specialty board whose certification process includes all of the requirements in 7G3.1 and 7G3.1(2) of this Appendix and whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in paragraph 7G3.1(3) of this Appendix. NRC recognized specialty boards are posted on the NRC website at <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>.

or

**7G2** Is an authorized user under Appendix 7F for uses listed in 7F2.1(2)(f)(i) or 7F2.1(2)(f)(ii), Appendix 7H, or equivalent NRC or Agreement State requirements;

or

**7G3** Has satisfied the following criteria:

7G3.1 Has satisfactorily completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive.:

(1) The 80 hours of classroom and laboratory training must include:

- (a) Radiation physics and instrumentation;
- (b) Radiation protection;
- (c) Mathematics pertaining to the use and measurement of radioactivity;
- (d) Chemistry of radioactive material for medical use; and
- (e) Radiation biology;

and

(2) Has work experience under the supervision of an authorized user who meets the requirements of 7G5, or Appendix 7F, Appendix 7G, Appendix 7H or equivalent Agreement State or NRC requirements. A supervising authorized user, who meets the requirements in 7F2.1, must also have experience in administering dosages as specified in 7F2.1(2)(f)(i) or 7F2.1(2)(f)(ii) as the individual requesting authorized user status. The work experience must involve:

- (a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- (b) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

- (c) Calculating, measuring, and safely preparing patient or human research subject dosages;
- (d) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;
- (e) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

and

- (f) Administering dosages to patients or human research subjects that includes at least 3 cases involving the oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131;

and

- (3) Has provided written attestation(s), that the individual has completed the requirements of 7G3.1(1) and 7G3.1(2), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses of unsealed radioactive materials using Na I-131 authorized under 7.36. The written attestation must be signed by a preceptor authorized user who:

- (a) Meets the requirements in 7G5, Appendix 7F, Appendix 7G, or Appendix 7H, or equivalent NRC or Agreement State requirements;

and

- (b) The preceptor authorized user, who meets the requirements in 7F2.1 must have experience in administering dosages as specified in 7F2.1(2)(f)(i) or 7F2.1(2)(f)(ii).

and

**7G4** Meets the following recentness of training requirements:

7G4.1 The training and experience required by Appendix 7G shall have been obtained within the 7 years preceding the date of license application or amendment request;

or

7G4.2 The individual must have had related, documented, continuing education and experience since the required training and experience was obtained.

or

**7G5** Meets the following requirements for an experienced authorized user for 7.36.3 uses:

7G5.1 An individual identified as an authorized user for the medical use of radioactive material on a license issued by the NRC or Agreement State, a permit issued under an NRC or Agreement State broad scope license that authorizes medical use before October 25, 2005, who perform only those medical uses for which they were authorized on that date are not required to comply with the training requirements of 7G1 through 7G4.

7G5.2 Individuals not required to comply with the training requirements of 7G1 through 7G4 may serve as preceptors for, and supervisors of, applicants seeking authorization on licenses for the same uses for which these individuals are authorized.

**PART 7, APPENDIX 7H: AUTHORIZED USER TRAINING FOR THE ORAL ADMINISTRATION OF SODIUM IODIDE I-131 REQUIRING A WRITTEN DIRECTIVE IN QUANTITIES GREATER THAN 1.22 GBq (33 mCi) (7.36.4 USES)**

**The licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 GBq (33 mCi), to be a physician who has a current active State of Colorado license and:**

**7H1** Is certified by a medical specialty board whose certification process includes all of the requirements in 7H3.1, and 7H3.1(2) and whose certification has been recognized by the NRC or an Agreement State, and who meets the requirements in paragraph 7H3.2 of this Appendix. NRC recognized specialty boards are posted on the NRC website at <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>.

or

**7H2** Is an authorized user under Appendix 7F for uses listed in 7F2.1(2)(f)(ii), or equivalent NRC or Agreement State requirements;

or

**7H3** Has satisfied the following criteria:

7H3.1 Has satisfactorily completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive.

(1) The 80 hours of classroom and laboratory training must include:

- (a) Radiation physics and instrumentation;
- (b) Radiation protection;
- (c) Mathematics pertaining to the use and measurement of radioactivity;
- (d) Chemistry of radioactive material for medical use; and
- (e) Radiation biology;

and

(2) Has work experience, under the supervision of an authorized user who meets the requirements of 7H5, Appendix 7F, Appendix 7H or equivalent Agreement State or NRC requirements. A supervising authorized user, who meets the requirements in 7F2.1, must also have experience in administering dosages as specified in 7F2.1(2)(f)(ii). The work experience must involve:

- (a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- (b) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

- (c) Calculating, measuring, and safely preparing patient or human research subject dosages;
  - (d) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;
  - (e) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
- and
- (f) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131;

and

- (3) Has provided written attestation(s), that the individual has completed the requirements of 7H3.1(1) and 7H3.1(2), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses of unsealed radioactive materials using Na I-131 in activities greater than 1.22 GBq (33 mCi) authorized under 7.36. The written attestation must be signed by a preceptor authorized user who:

- (1) Meets the requirements in 7H5, Appendix 7F, or Appendix 7H, or equivalent NRC or Agreement State requirements;

and

- (2) The preceptor authorized user, who meets the requirements in 7F2.1 must have experience in administering dosages as specified in 7F2.1(2)(f)(ii).

and

**7H4** Meets the following recentness of training requirements:

7H4.1 The training and experience required by Appendix 7H shall have been obtained within the 7 years preceding the date of license application or amendment request;

or

7H4.2 The individual must have had related, documented, continuing education and experience since the required training and experience was obtained.

or

**7H5** Meets the following requirements for an experienced authorized user for 7.36.4 uses:

7H5.1 An individual identified as an authorized user for the medical use of radioactive material on a license issued by the NRC or Agreement State, a permit issued under an NRC or Agreement State broad scope license that authorizes medical use before October 25, 2005, who perform only those medical uses for which they were authorized on that date are not required to comply with the training requirements of 7H1 through 7H4.

7H5.2 Individuals not required to comply with the training requirements of 7H1 through 7H4 may serve as preceptors for, and supervisors of, applicants seeking authorization on licenses for the same uses for which these individuals are authorized.

**PART 7, APPENDIX 7I: AUTHORIZED USER TRAINING FOR THE PARENTERAL ADMINISTRATION OF UNSEALED RADIOACTIVE MATERIAL REQUIRING A WRITTEN DIRECTIVE (7.36.5 USES)**

**The licensee shall require an authorized user for parenteral administration of unsealed radioactive material for which a written directive is required to be a physician who has a current active State of Colorado license and:**

**711** Is an authorized user under Appendix 7F for uses listed in 7F2.1(2)(f)(iii) or 7F2.1(2)(f)(iv), or equivalent NRC or Agreement State requirements;

or

**712** Is an authorized user under Appendix 7K, Appendix 7M, or equivalent NRC or Agreement State requirements and who meets the requirements in 714;

or

**713** Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State under Appendix 7K or Appendix 7M, and who meets the requirements in paragraph 714 of this section.

or

**714** Has satisfied the following criteria:

714.1 Has satisfactorily completed 80 hours of classroom and laboratory training applicable to parenteral administrations, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required.

(1) The training must include:

- (a) Radiation physics and instrumentation;
- (b) Radiation protection;
- (c) Mathematics pertaining to the use and measurement of radioactivity;
- (d) Chemistry of radioactive material for medical use;

and

- (e) Radiation biology;

and

(2) Has work experience under the supervision of an authorized user who meets the requirements of 716, Appendix 7F, Appendix 7I, or equivalent Agreement State or NRC requirements, in the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized

user, who meets the requirements in 7F, must have experience in administering dosages as specified in 7F2.1(2)(f)(iii) and/or 7F2.1(2)(f)(iv). The work experience must involve:

- (a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- (b) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
- (c) Calculating, measuring, and safely preparing patient or human research subject dosages;
- (d) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;
- (e) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

and

- (f) Administering dosages to patients or human research subjects that include:
  - (i) At least 3 cases involving the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV;

and/or

- (ii) At least 3 cases involving the parenteral administration of any other radionuclide, for which a written directive is required;

and

- (3) Has provided written attestation(s) that the individual has completed the requirements in 7I2 or 7I3, and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed radioactive materials requiring a written directive. The written attestation must be signed by a preceptor authorized user who:

- (a) Meets the requirements in 7I6, Appendix F, or Appendix I, or equivalent NRC or Agreement State requirements;

and

- (b) Meets the requirements in Appendix 7F must have experience in administering dosages as specified in 7F2.1(2)(f)(iii) and/or 7F2.1(2)(f)(iv).

and

**7I5** Meets the following recentness of training requirements:

715.1 The training and experience required by Appendix 7I shall have been obtained within the 7 years preceding the date of license application or amendment request;

or

715.2 The individual must have had related, documented, continuing education and experience since the required training and experience was obtained.

or

**716** Meets the following requirements for an experienced authorized user for 7.36.5 uses:

716.1 An individual identified as an authorized user for the medical use of radioactive material on a license issued by the NRC or Agreement State, a permit issued under an NRC or Agreement State broad scope license that authorizes medical use before October 25, 2005, who perform only those medical uses for which they were authorized on that date are not required to comply with the training requirements of 711 through 715.

716.2 Individuals not required to comply with the training requirements of 711 through 715 may serve as preceptors for, and supervisors of, applicants seeking authorization on licenses for the same uses for which these individuals are authorized.

**PART 7, APPENDIX 7J: AUTHORIZED USER TRAINING FOR USE OF SEALED SOURCES FOR DIAGNOSIS (7.40 USES)**

**The licensee shall require an authorized user of a diagnostic sealed source for use in a device authorized under 7.40 to be a physician, dentist or podiatrist who has a current active State of Colorado license and:**

**7J1** Is certified by a specialty board whose certification process includes all of the requirements in 7J2 and 7J3, and whose certification process has been recognized by the NRC or an Agreement State. ; NRC recognized specialty boards are posted on the NRC website at <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>. or

**7J2** Has satisfied the following criteria:

7J2.1 Has completed 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device.

(1) The training must include:

- (a) Radiation physics and instrumentation;
- (b) Radiation protection;
- (c) Mathematics pertaining to the use and measurement of radioactivity;
- (d) Radiation biology;

and

**7J3** Has completed training in the use of the device for the uses requested.

and

**7J4** Meets the following recentness of training requirements:

7J4.1 The training and experience required by Appendix 7J shall have been obtained within the 7 years preceding the date of license application or amendment request;

or

7J4.2 The individual must have had related, documented, continuing education and experience since the required training and experience was obtained.

or

**7J5** Meets the following requirements for an experienced authorized user for 7.40 uses:

7J5.1 An individual identified as an authorized user for the medical use of radioactive material on a license issued by the NRC or Agreement State, a permit issued under an NRC or Agreement State broad scope license that authorizes medical use before October 25, 2005, who perform only those medical uses for which they were authorized on that date are not required to comply with the training requirements of 7J1 through 7J4.;

7J5.2 Individuals not required to comply with the training requirements of 7J1 through 7J4 may serve as preceptors for, and supervisors of, applicants seeking authorization on licenses for the same uses for which these individuals are authorized.

**PART 7, APPENDIX 7K: AUTHORIZED USER TRAINING FOR THE USE OF MANUAL BRACHYTHERAPY SOURCES (7.42 USES)**

**The licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under 7.42 to be a physician who has a current active State of Colorado license and:**

**7K1** Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State, and who meets the requirements in paragraph 7K2.3 of this Appendix. NRC recognized specialty boards are posted on the NRC website at <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>.

7K1.1 To have its certification process recognized, a specialty board shall require all candidates for certification to:

- (1) Successfully complete a minimum of 3 years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and
- (2) Pass an examination, administered by diplomats of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy;

or

**7K2** Has satisfied the following criteria:

7K2.1 Has satisfactorily completed a structured educational program in basic radionuclide handling techniques applicable to the medical use of manual brachytherapy sources, that includes:

- (1) 200 hours of classroom and laboratory training in the following areas:
  - (a) Radiation physics and instrumentation;
  - (b) Radiation protection;
  - (c) Mathematics pertaining to the use and measurement of radioactivity;
  - (d) Radiation biology;

and

- (2) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in 7K4, Appendix 7K, or equivalent NRC or Agreement State requirements at a medical institution, involving:
  - (a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
  - (b) Checking survey meters for proper operation;
  - (c) Preparing, implanting, and removing brachytherapy sources;

- (d) Maintaining running inventories of material on hand;
- (e) Using administrative controls to prevent a misadministration involving the use of radioactive material;
- (f) Using emergency procedures to control radioactive material;

and

7K2.2 Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in 7K4, Appendix 7K, or equivalent Agreement State or NRC requirements, provided that the experience:

- (a) Is part of a formal training program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association;

and

- (b) May be obtained concurrently with the supervised work experience required by 7K2.1(2).

and

7K2.3 Has provided written attestation(s), signed by a preceptor authorized user who meets the requirements in 7K4, Appendix 7K, or equivalent Agreement State or NRC requirements, that the individual has satisfactorily completed the requirements in 7K1.1(1), or paragraphs 7K2.1 and 7K2.2, and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under 7.42.

and

**7K3** Meets the following recentness of training requirements:

7K3.1 The training and experience required by Appendix 7K shall have been obtained: within the 7 years preceding the date of license application or amendment request;

or

7K3.2 The individual must have had related, documented, continuing education and experience since the required training and experience was obtained.

or

**7K4** Meets the following requirements for an experienced authorized user for 7.42 uses:

7K4.1 An individual identified as an authorized user for the medical use of radioactive material on a license issued by the NRC or Agreement State, a permit issued under an NRC or Agreement State broad scope license that authorizes medical use before October 25, 2005, who perform only those medical uses for which they were authorized on that date are not required to comply with the training requirements of 7K1 through 7K3.

7K4.2 Individuals not required to comply with the training requirements of 7K1 through 7K3 may serve as preceptors for, and supervisors of, applicants seeking authorization on licenses for the same uses for which these individuals are authorized.

**PART 7, APPENDIX 7L: AUTHORIZED USER TRAINING FOR OPHTHALMIC USE OF STRONTIUM-90 (7.42 USES)**

**The licensee shall require an authorized user of a Strontium-90 source for ophthalmic radiotherapy authorized under 7.42 to be a physician who has a current active State of Colorado license and:**

**7L1** Is an authorized user under Appendix 7K or equivalent NRC or Agreement State requirements;

or

**7L2** Has satisfied the following criteria:

7L2.1 Has satisfactorily completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy.

(1) The training must include:

- (a) Radiation physics and instrumentation;
- (b) Radiation protection;
- (c) Mathematics pertaining to the use and measurement of radioactivity;
- (d) Radiation biology;

and

(2) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals, This supervised clinical training must involve:

- (a) Examination of each individual to be treated;
- (b) Calculation of the dose to be administered;
- (c) Administration of the dose; and
- (d) Follow-up and review of each individual's case history;

and

(3) Has provided written attestation(s), signed by a preceptor authorized user who meets the requirements in 7L4, Appendix 7K, Appendix 7L, or equivalent NRC or Agreement State requirements, that the individual has satisfactorily completed the requirements of 7L2 and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic radiotherapy uses authorized under 7.42.

and

**7L3** Meets the following recentness of training requirements:

7L3.1 The training and experience required by Appendix 7L shall have been obtained within the 7 years preceding the date of license application or amendment request;

or

7L3.2 The individual must have had related, documented, continuing education and experience since the required training and experience was obtained.

or

**7L4** Meets the following requirements for an experienced authorized user for 7.42 ophthalmic radiotherapy uses:

7L4.1 An individual identified as an authorized user for the medical use of radioactive material on a license issued by the NRC or Agreement State, a permit issued under an NRC or Agreement State broad scope license that authorizes medical use before October 25, 2005, who perform only those medical uses for which they were authorized on that date are not required to comply with the training requirements of 7L1 through 7L3.

7L4.2 Individuals not required to comply with the training requirements of 7L1 through 7L3 may serve as preceptors for, and supervisors of, applicants seeking authorization on licenses for the same uses for which these individuals are authorized.

**PART 7, APPENDIX 7M: AUTHORIZED USER TRAINING FOR USE OF SEALED SOURCES IN REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS (7.48 USES)**

**The licensee shall require an authorized user of a sealed source for use in a device authorized under 7.48 to be a physician who has a current active State of Colorado license and:**

**7M1** Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in paragraph 7M2.3 and 7M3 of this Appendix. NRC recognized specialty boards are posted on the NRC website at <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>.

7M1.1 To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete a minimum of 3 years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association;

and

(1) Pass an examination, administered by diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy;

or

**7M2** Has satisfied the following criteria:

7M2.1 Has satisfactorily completed a structured educational program in basic radionuclide handling techniques applicable to the use of sealed sources in a therapeutic medical unit that includes:

(1) 200 hours of classroom and laboratory training in the following areas:

- (a) Radiation physics and instrumentation;
- (b) Radiation protection;
- (c) Mathematics pertaining to the use and measurement of radioactivity;
- (d) Radiation biology;

and

(2) 500 hours of supervised work experience, under the supervision of an authorized user who meets the requirements in 7M5, Appendix 7M, or equivalent Agreement State or NRC requirements at a medical institution, involving:

- (a) Reviewing full calibration measurements and periodic spot checks;

- (b) Preparing treatment plans and calculating treatment doses and times;
- (c) Using administrative controls to prevent a misadministration involving the use of radioactive material;
- (d) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;
- (e) Checking and using survey meters; and
- (f) Selecting the proper dose and how it is to be administered;

and

**7M2.2** Has completed 3 years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in 7M5, Appendix 7M, or equivalent Agreement State or NRC requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph 7M2.1(2) of this section; and

**7M2.3** Has provided written attestation(s) that the individual has satisfactorily completed the requirements of 7M1 or 7M2.1 and 7M2.2, and 7M3, and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user who meets the requirements in 7M5, Appendix 7M, or equivalent Agreement State or NRC requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status;

and

**7M3** Has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by:

**7M3.1** Satisfactorily completing a vendor training program;

or

**7M3.2** By receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization;

and

**7M4** Meets the following recentness of training requirements:

**7M4.1** The training and experience required by Appendix 7M shall have been obtained within the 7 years preceding the date of license application or amendment request;

or

7M4.2 The individual must have had related, documented, continuing education and experience since the required training and experience was obtained.

or

**7M5** Meets the following requirements for an experienced authorized user for 7.48 uses.

7M5.1 An individual identified as an authorized user for the medical use of radioactive material on a license issued by the NRC or Agreement State, a permit issued under an NRC or Agreement State broad scope license that authorizes medical use before October 25, 2005, who perform only those medical uses for which they were authorized on that date are not required to comply with the training requirements of 7M1 through 7M4.

7M5.2 Individuals not required to comply with the training requirements of 7M1 through 7M4 may serve as preceptors for, and supervisors of, applicants seeking authorization on licenses for the same uses for which these individuals are authorized.

**PART 7, APPENDIX 7N: NUCLEAR MEDICINE TECHNOLOGIST (NMT) ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE**

**The licensee shall require the nuclear medicine technologist using radioactive materials under the supervision of an authorized user to be an individual who:**

**7N1** Has provided:

7N1.1 Evidence of:

(1) Current registration with The American Registry of Radiologic Technologists with competency in Nuclear Medicine (ARRT(N));

or

(2) Current certification by The Nuclear Medicine Technology Certification Board in Nuclear Medicine (CNMT);

or

(3) Being board-eligible to take the CNMT or ARRT(N) examination;

or

(4) Current certification by a recognized specialty board (see 7N5);

and

7N1.2 Has provided written attestation(s), signed by a preceptor authorized user, that the individual has achieved a level of competency sufficient to function independently as a nuclear medicine technologist;

(1) Each preceptor authorized user supervising the experiential training required by Appendix 7N shall meet the requirements of Appendix 7N, or equivalent Agreement State or NRC requirements.

or

**7N2** Has satisfied the following criteria:

7N2.1 Has provided written attestation(s), signed by a preceptor authorized user, that the individual has satisfactorily completed 80 hours in a structured educational program in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive materials, including:

(1) Classroom and laboratory training in the following areas:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity;

(d) Chemistry of radioactive material for medical use; and

(e) Radiation biology; and

(2) Work experience, involving:

(a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(b) Quality Control checking of instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(c) Calculating, measuring, and safely preparing patient or human research subject dosages;

(d) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;

(e) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(f) Administering dosages to patients or human research subjects;

7N2.2 Has provided written attestation(s), signed by a preceptor authorized user, that the individual has achieved a level of competency sufficient to function independently as a nuclear medicine technologist;

or

**7N3** Has demonstrated adequate prior experience as:

7N3.1 A full-time nuclear medicine technologist for a minimum of two years performing during the past five-year period under the supervision of an authorized user and has provided written attestation(s), signed by a preceptor authorized user, that the individual has achieved a level of competency sufficient to function independently as a nuclear medicine technologist;

or

7N3.2 An experienced nuclear medicine technologist working at a facility holding a Department license before October 25, 2005 (and thus need not comply with the requirements of 7N2);

**7N4** Meets the following recentness of training requirements:

7N4.1 The training and experience required by Appendix 7N shall have been obtained within the 7 years preceding the date of license application or amendment request;

or

7N4.2 The individual must have had related, documented, continuing education and experience since the required training and experience was obtained.

**7N5** To be recognized by the Department, a specialty board shall require that each candidate for certification as a nuclear medicine technologist satisfactorily complete a certification process that includes all of the training requirements in 7N2.1.

**PART 7, APPENDIX 70: RADIATION THERAPY TECHNOLOGIST (RTT) ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE**

The licensee shall require the radiation therapy technologist using radioactive materials under the supervision of an authorized user to be an individual who:

**701** Has provided:

701.1 Evidence of:

(1) Current registration with The American Registry of Radiologic Technologists with competency in Radiation Therapy;

or

(2) Current certification by a recognized specialty board (see 705);

or

(3) Being board-eligible to take the ARRT(T) examination;

or

(4) Having successfully completed a training program in radiation therapy which has resulted in a certificate, associate degree, or baccalaureate degree in a radiologic technology program that complies with the requirements of the Joint Review Committee on Education in Radiologic Technology (consult the Essentials and Guidelines of an Accredited Educational Program for the Radiation Therapy Technologist, Joint Review Committee on Education in Radiologic Technology, 1988);

and

701.2 Written attestation(s), signed by a preceptor authorized user, that the individual has achieved a level of competency sufficient to function independently as a radiation therapy technologist;

(1) Each preceptor authorized user supervising the experiential training required by Appendix 70 shall meet the requirements of Appendix 70, or equivalent Agreement State or NRC requirements.

or

**702** Has satisfied the following criteria:

702.1 Has provided written attestation(s), signed by a preceptor authorized user, that the individual has satisfactorily completed 80 hours in a structured educational program in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive materials, including:

(1) Classroom and laboratory training in the following areas:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

- (c) Mathematics pertaining to the use and measurement of radioactivity;
- (d) Radiation biology;

and

(2) Work experience, involving:

- (a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- (b) Assisting the authorized user in simulating the patient for treatment;
- (c) Preparing the patient for treatment;
- (d) Implementing treatment plans as prescribed by the authorized user;
- (e) Providing written documentation of treatment setup and patient treatments;
- (f) Quality control checks to determine that devices used to deliver the radiation doses are in compliance with institutional standards and performing checks for proper operation of survey meters;
- (g) Preparing or assisting in the preparation of sources, and implantation and removal of sealed sources;
- (h) Delivering doses to patients or human research subjects under the supervision of the authorized user;
- (i) Maintaining running inventories of radioactive material on hand;
- (j) Using administrative controls to prevent a misadministration involving the use of radioactive material; and,
- (k) Properly implementing emergency procedures;

702.2 Has provided written attestation(s), signed by a preceptor authorized user, that the individual has achieved a level of competency sufficient to function independently as a radiation therapy technologist;

or

**703** Has demonstrated adequate prior experience as:

703.1 A full-time radiation therapy technologist for a minimum of two years performing during the past five-year period under the supervision of an authorized user and has provided written attestation(s), signed by a preceptor authorized user, that the individual has achieved a level of competency sufficient to function independently as a radiation therapy technologist;

or

703.2 An experienced radiation therapy technologist working at a facility holding a Department license before October 25, 2005 (and thus need not comply with the requirements of 702);

**704** Meets the following recentness of training requirements:

704.1 The training and experience required by Appendix 7O shall have been obtained within the 7 years preceding the date of license application or amendment request;

or

704.2 The individual must have had related, documented, continuing education and experience since the required training and experience was obtained.

**705** To be recognized by the Department, a specialty board shall require that each candidate for certification as a radiation therapy technologist satisfactorily complete a certification process that includes all of the training requirements in 7O2.1.

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## **EDITOR'S NOTES**

6 CCR 1007-1 has been divided into smaller sections for ease of use. Versions prior to 4/1/07 and rule history are located in the first section, 6 CCR 1007-1. Prior versions can be accessed from the History link that appears above the text in 6 CCR 1007-1. To view versions effective on or after 4/1/07, Select the desired part of the rule, for example 6 CCR 1007-1 Part 1 or 6 CCR 1007-1 Parts 8 - 10.

## **History**

*[For history of this section, see Editor's Notes in the first section, 6 CCR 1007-1]*