STATE OF COLORADO

John W. Hickenlooper, Governor
Christopher E. Urbina, MD, MPH
Executive Director and Chief Medical Officer

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

4300 Cherry Creek Dr. S.
Denver, Colorado 80246-1530
Phone (303) 692-2000
Located in Glendale, Colorado

http://www.cdphe.state.co.us

Laboratory Services Division
8100 Lowry Blvd.
Denver, Colorado 80230-6928
(303) 692-3090

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.

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.

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)

Attachment 1
James G. Luehman, Deputy Director
U.S. Nuclear Regulatory Commission
April 23, 2012

RATs ID	CFR Title	State Section
	ITEMS FOR RATS 2006-1	
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 ***NOTE: Definitions for AMP, ANP, AU, and RSO were modified to parallel the requirements of Part 35.2 following the initial review by NRC.***
2006-1 §35.49	Suppliers for sealed sources or devices for medical use.	Section 7.14 ***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]***
2006-1 §35.50	Training for Radiation Safety Officer.	Appendix 7A (See 7A1.2(2)(b)) ***NOTE: This provision was modified in Part 7 based on NRC comment.*** ***[Ref: Item 3 of 12/05/11 NRC Letter]***
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 ***NOTE: Training references modified following initial review by NRC.*** ***[Ref: Item 6 of 12/05/11 NRC Letter]***
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. ***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]***

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). ***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]***
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.
	ITEMS FOR RATS 2007-1	
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. ***NOTE: Footnote language modified following initial review by NRC.***
2007-1 §35.92	Decay-in-storage.	Section 7.29. ***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]***

2007-1 §35.190	Training for uptake, dilution, and excretion studies.	Appendix 7D. ***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).*** ***[Ref: Item 7 of 12/05/11 NRC Letter]***
2007-1 §35.290	Training for imaging and localization studies.	Appendix 7E. ***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.*** ***[Ref: Item 9 of 12/05/11 NRC Letter]***
	ITEMS FOR RATS 2007-3	
2007-3 §35.11	License required.	7.3.1 ***NOTE: Language modified to correct references following initial review by NRC.*** ***[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. ***NOTE: Slight formatting (renumbering) of section 7.18.3 following NRC review.***
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. ***NOTE: Modifications made due to 2006-1 RATS item following NRC review.***
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. ***NOTE: Modifications made due to 2006-1 RATS item following NRC review.***
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 ***NOTE: Modifications made due to 2006-1 RATS item following NRC review.***
	ITEMS FOR RATS 2009-1	
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. ***NOTE: Reference in Appendix 7I6.2 corrected per NRC review.*** ***[Ref: Item 4 of 12/05/11 NRC Letter]***
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 ***NOTE: Reference in Appendix 7F corrected per NRC review.*** ***[Ref: Item 11 of 12/05/11 NRC Letter]***
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. ***NOTE: Reference in Appendix 7G corrected per NRC review.*** ***[Ref: Item 12 of 12/05/11 NRC Letter]***
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. ***NOTE: Reference in Appendix 7H corrected per NRC review.*** ***[Ref: Item 13 of 12/05/11 NRC Letter]***
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. ***NOTE: Reference in Appendix 7K corrected per NRC review.*** ***[Ref: Item 14 of 12/05/11 NRC Letter]***
2009-1 § 35.690	Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.	Appendix 7M.
	NON-RATS (OTHER) CHANGES	
§ 35.11	License required	7.3.2 Language modified for consistency and clarification. ***NOTE: Slight wording modifications made following initial NRC review.***
§ 35.13	License amendments	7.4.2.1 Language modified for consistency and clarification. ***NOTE: Modification made following initial NRC review.***
§ 35.24	Radiation safety committee	7.8.1 Clarifying language added. ***NOTE: Modification made following initial NRC review.***

§ 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. ***NOTE: Formatting changes made following initial review by NRC.***
§ 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. ***NOTE: SI unit changes in 7.25.2.2 and 7.25.3.2 were made following initial review by NRC.***
§35.490(b)(1)(ii)(E)	Authorized user training for the use of manual brachytherapy sources	Appendix 7K, Section 7K2.1(2)(e) ***NOTE: Deleted the word "unsealed" as it is not appropriate for this section.***

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.~~

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.

"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 permitee 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 ~~training and experience requirements for a use of radioactive material specified in the~~ applicable ~~appendix~~ **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

Formatted: Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0.75" + Indent at: 1"

Formatted: Numbered + Level: 1 + Numbering Style: a, b, c, … + Start at: 1 + Alignment: Left + Aligned at: 1" + Indent at: 1.25"

Formatted: Indent: Hanging: 0.5", Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 1" + Indent at: 1.25"

Formatted: Indent: Left: 1", Numbered + Level: 1 + Numbering Style: a, b, c, … + Start at: 1 + Alignment: Left + Aligned at: 1.5" + Indent at: 1.75"

Formatted: Indent: Hanging: 0.5", Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 1" + Indent at: 1.25"

Formatted: Not Highlight

Formatted: Indent: Hanging: 0.5", Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 1" + Indent at: 1.25"

Formatted: Indent: Left: 1", Hanging: 0.19", Numbered + Level: 1 + Numbering Style: a, b, c, … + Start at: 1 + Alignment: Left + Aligned at: 1.5" + Indent at: 1.75"

d. A permit issued by an NRC master material license broad scope permitee 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.

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

"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 ~~an~~ 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.

Formatted: Indent: Left: 0.81", Hanging: 0.44", Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 1.5" + Indent at: 1.75"

Formatted: Numbered + Level: 1 + Numbering Style: a, b, c, … + Start at: 1 + Alignment: Left + Aligned at: 1" + Indent at: 1.25"

"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**~~2~~ or 7.3.**1.2**~~3~~.

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

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 ~~Involving Human~~ Subjects.

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

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

7.3.2.1 ~~The~~**For** research ~~is~~ conducted, funded, supported, or regulated by a federal agency which has implemented **The** ~~f~~**F**ederal ~~p~~**P**olicy for the **P**~~p~~rotection of ~~h~~**H**uman ~~s~~**S**ubjects **(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.~~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 ~~such~~ research **involving human subjects**;

~~7.3.2.3 At a minimum, the licensee shall obtain prior informed consent from the human subjects and 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 federal policy for the protection of human subjects;~~

7.3.2.4 The research involving human subjects authorized in 7.3.2~~.1~~ 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 ~~an original and one copy of~~ **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**.

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.

Formatted: Indent: Left: 1"

Comment [JJ6]: Paragraph reworded for clarification.

Formatted: Font: 10 pt

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.

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

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

Formatted: Font: 10 pt

7.3.4.3 A request for a license amendment ~~or renewal~~ must be made by:

(1) Submitting an original **amendment request** ~~and one copy~~ 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.

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.

Formatted: Font: 10 pt

Formatted: Font: 10 pt

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 ~~The applicable appendix of~~ Appendix 7D through Appendix 7M for an authorized user for a **specific** type of use of radioactive material;

Formatted: Font: 10 pt

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 license 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 ~~two~~**one** or more different types of radioactive material use under 7.36, 7.42, 7.48, **or** 7.62 ~~or two or more types of units under 7.48~~ 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.

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.)

Formatted: Font: 10 pt

Formatted: Font: 10 pt

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,** ~~I~~instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's use of radioactive material; and

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

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, ~~and able to be physically present within one hour,~~ unless otherwise authorized by the Department with prior written approval.~~; and~~

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.

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 µCi), 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** ~~number of~~ 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;

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

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;

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

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**~~1~~ Full calibration measurements as described in 7.54, 7.55, and 7.56;

7.13.2.**3**~~2~~ Periodic spot checks as described in 7.58, 7.59 and 7.61; and

7.13.2.**4**~~3~~ Radiation surveys as described in 7.57.

7.14 Suppliers for Sealed Sources or Devices for Medical Use.

For medical use, a licensee shall use only:

7.14.1 Sealed sources or devices ~~initially~~ 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; ~~and~~

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**:**

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.

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

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

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

Formatted: Font: 10 pt

Formatted: Font: 10 pt

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

7.15.2.1 ~~t~~Those recommended by equipment manufacturers~~;~~ or

7.15.2.2 ~~p~~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 ~~test~~ **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** ~~The tests~~ required in 7.16.2**, the licensee** shall at a minimum ~~include~~ **also perform** tests for constancy, linearity, ~~accuracy~~ and geometry dependence, as appropriate to demonstrate proper operation of the instrument.

7.16.4 A licensee shall retain a record of each instrument ~~test~~**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;

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)

(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 ~~either~~ by**:**

7.18.2.1 direct measurement **of radioactivity**~~s~~; or

7.18.2.2 ~~by~~ 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, ~~a Licensing 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

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

Formatted: Font: 10 pt

Formatted: Font: 10 pt

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, ~~a Licensing State~~ or NRC.

Formatted: Font: 10 pt

Formatted: Font: 10 pt

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 µCi);

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 µCi);

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.

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 uCi) of radioactive material in the sample.

7.20.~~4~~3 If the leak test reveals the presence of 0.005 microcurie (185 Bq) or more of removable contamination, the licensee shall:

7.20.~~4~~3.1 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~~3.2 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~~4 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;

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)

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

(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 ~~Radiation Dose~~ 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~~1~~ **Daily Survey Requirements**

7.25.2.1 ~~Except as provided in 7.25.2, a~~**A**t the end of each day of use, a licensee shall survey~~,~~ with a**n exposure rate** ~~radiation detection~~ 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~~2~~ **Weekly Survey Requirements**

7.25.3.1 At least once each week, a licensee shall survey, with a**n** ~~radiation detection~~**exposure 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.

Formatted: Indent: Left: 0.5"

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.

Formatted: Indent: Left: 1", Tab stops: 1.88", Left + Not at 1.5"

Formatted: Indent: Left: 0.5"

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

Formatted: Font: 10 pt

Comment [JJ40]: Subsection header added for clarity.

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: 10 pt, Not Highlight

Formatted: Not Highlight

Formatted: Indent: Left: 0.5"

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.

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

7.25.4 A licensee shall establish ~~dose rate~~ action levels for the surveys required by 7.25.2~~1~~ and 7.25.2~~3~~ and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if ~~a dose rate exceeds an~~ action level**s are exceeded**.

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

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

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

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

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

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

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

7.25.~~5~~9 A licensee shall retain a record of each survey required by 7.25.1, 7.25.2 and 7.25.~~3~~5 for 3 years. The record must include**:**

7.25.5.1 ~~t~~**T**he date of the survey**;**~~,~~

7.25.5.2 ~~t~~**T**he results of the survey**;**~~,~~

7.25.5.3 ~~t~~**T**he 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 ~~t~~**T**he 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).[1]

[1] **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).**

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

Formatted: Font: 10 pt

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

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: 10 pt, Not Highlight

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

Formatted: par2, Indent: Left: 0", Hanging: 0.69", Tab stops: 0.69", Left

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

7.26.2 ~~Instructions to Individuals:~~ **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 A licensee shall provide the released individual, or the individual's parent or guardian, with oral and written safety instructions on actions recommended to maintain doses to other individuals as low as is reasonably achievable.~~

7.26.2.1~~2~~ If **the total effective dose equivalent to** a ~~breast-feeding~~ **nursing** infant or child could **exceed 1 mSv (0.1 rem) assuming there were no interruption in breast-feeding**~~receive a radiation dose as a result of the release of the patient~~, 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.

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

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:** ~~signed by the authorized user, for 3 years after the date of release, of:~~

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

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-live; and

7.26.4.4 Considering the shielding by tissue.~~; and~~

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

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

7.26.6~~5~~.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~~5~~.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:

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

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.

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.

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.

Formatted: Font: 10 pt, Not Highlight

Formatted: par1, Indent: Left: 0", Tab stops: Not at 1.44"

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).

Formatted: Indent: Left: 0", First line: 0"

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.

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).

Formatted: Font: 10 pt, Not Highlight

Formatted: par1

Formatted: par2, Indent: Left: 0", Hanging: 0.69", Tab stops: 0.69", Left

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

(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 Use radioactive gases only in areas of use and under conditions which have been evaluated and approved by the Department for compliance with airborne release standards; and~~

7.27.7~~8~~ 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.

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

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 ~~is~~:

7.30.1.1 **Is** ~~O~~**o**btained 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** P**p**repared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in ~~7.30.2~~**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** ~~O~~**o**btained 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

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

Formatted: Font: 10 pt

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]

Formatted: Font: 10 pt

Formatted: Font: 10 pt

7.30.1.4 Is Pprepared 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 µSv (0.1 mrem) per hour to 500 µSv (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 is:

7.32.1.1 Is Oobtained 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 Pprepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in 7.32.2**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 Oobtained 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 Pprepared 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 µCi of ^{99} Mo per mCi of ^{99m} 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]

Formatted: Font: 10 pt

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: 10 pt

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]

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

7.33.1.2 More than 0.02 kBq of strontium-82 per MBq of rubidium-82 chloride injection (0.02 µCi of ^{82}Sr per mCi of ^{82}Rb chloride);

7.33.1.3 More than 0.2 kBq of strontium-85 per MBq of rubidium-82 chloride injection (0.2 µCi of ^{85}Sr per mCi of ^{82}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 ~~The first~~**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 (µCi/ 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 µSv (0.1 mrem) per hour to 500 µSv (50 mrem) per hour and over the range of 10 µSv (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 ~~has been~~:

7.36.1.1 **Is** ~~O~~**o**btained 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** ~~P~~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**~~7.36.2, 7.36.3 or 7.36.4~~, ~~—~~or an 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]

Formatted: Font: 10 pt

7.36.1.3 Is ~~O~~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 ~~P~~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 GBq ^{131}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 GBq ^{131}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 GBq ^{131}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 GBq ^{131}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 names(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 ~~effective~~ **active** Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of 7.14.1 are met.

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

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~~1 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.

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

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 µSv (0.1 mrem) per hour to 500 µSv (50 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 10 µSv (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~~1 Electrical interlocks at each remote afterloader unit room entrance;

7.59.4.~~5~~2 Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

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

~~7.59.4.4 Emergency response equipment;~~

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

7.59.4.6 Timer accuracy;

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.

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) ~~ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE~~

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 ~~Has provided:~~**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)**~~Evidence of current certification in health physics or medical physics by a recognized specialty board (see 7A5); and~~ **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

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.

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.

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: 10 pt

Formatted: par2

Formatted: Indent: Hanging: 1"

Formatted: par2

Formatted: Font: 10 pt, Not Italic

(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;

Formatted: Font: 10 pt

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]

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Indent: Hanging: 1"

Formatted: par3

Formatted: Font: 10 pt, Not Italic

Formatted: Indent: Hanging: 0.5"

Formatted: Indent: Hanging: 1"

(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; ~~and~~

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 ~~7A2.2~~ Has ~~experiential~~ training in the radiation safety, regulatory issues, and emergency procedures for the type(s) of use for which ~~the~~ **a** licensee ~~is~~ seek~~s~~**ing** approval**.**~~,~~ **This training requirement may be satisfied by completing** ~~for example,~~ 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 ~~that authorizes similar~~**for the** type(s) of use of radioactive material **for which the licensee is seeking approval.**~~; and~~

~~7A2.3 Has provided 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;~~

~~or~~

Formatted: Indent: Left: 0", First line: 0"

Formatted: Indent: Left: 0.5"

Formatted: Font: 10 pt

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt, Not Highlight

Formatted: Indent: Left: 0", First line: 0"

Formatted: Indent: Left: 0.5"

Formatted: Indent: Left: 0", First line: 0"

Formatted: Indent: Left: 0"

Formatted: Font: 10 pt

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: 10 pt

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: 10 pt

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Indent: Hanging: 1"

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

~~7A3.1 An experienced medical physicist who has provided written attestation(s), signed by a preceptor RSO, that the medical physicist:~~

~~(1) Is certified by a specialty board whose certification process has been recognized under 7A5.2; and~~

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

~~or~~

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

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

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

~~or~~

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~~3.3~~ 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.**~~experienced RSO who was identified before October 25, 2005 (and thus need not comply with 7A1, 7A2.1 or 7A2.2) either on:~~

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

~~(2) A permit issued by an Agreement State or NRC broad scope licensee that authorizes medical use; or on~~

~~(3) An equivalent permit or license recognized by the Department for similar types and uses of radioactive material.~~

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.

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.

Formatted: par3, Indent: Left: 0.5"

Formatted: Font: 10 pt, Not Highlight

Formatted: par3, Indent: Left: 1", Tab stops: 0.88", Left

Formatted: Font: 10 pt, Not Highlight

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)

Formatted: Not Highlight

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: Not Bold

~~**7A4** Training and experience required by Appendix 7A shall have been obtained:~~

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

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

~~**7A5** 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) a specialty board shall require that each candidate for certification:~~

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

~~(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 be substituted 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 that 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;~~

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

~~(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 nuclear medicine facilities providing diagnostic and / or therapeutic services under the general supervision of physicians who meet the requirements of Appendix 7F or Appendix 7G; 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.~~

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

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

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

Formatted: par3

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;~~

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt, Not Highlight

Formatted: Indent: Left: 1.5", Hanging: 0.5", Numbered + Level: 1 + Numbering Style: a, b, c, … + Start at: 1 + Alignment: Left + Aligned at: 1" + Indent at: 1.25", Tab stops: 2", Left

Formatted: Indent: Left: 1.5"

Formatted: Indent: Left: 1.5", Hanging: 0.5", Numbered + Level: 1 + Numbering Style: a, b, c, … + Start at: 1 + Alignment: Left + Aligned at: 1" + Indent at: 1.25"

Formatted: Indent: Left: 0.5"

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

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

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

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

~~(1) Including:~~

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

~~(b) Safety procedures;~~

~~(c) Clinical use, and~~

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

~~(2) Provided by either:~~

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

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

Formatted: Indent: Hanging: 0.5"

or

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

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;

Formatted: Tab stops: 4.82", Left + Not at 1" + 1.5"

and

7B2.2 Has ~~satisfactorily~~ completed ~~2~~1 year~~s~~ 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.**

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

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

Formatted: par2

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

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

~~(3) Are c~~**C**onducted in clinical radiation facilities that provide high~~-~~-energy, external beam **therapy** (photons or electrons **with energies greater than or equal to**~~=/ >~~ 1 MeV) ~~therapy~~ and brachytherapy services **and must include:**~~;~~

~~(4) And 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

~~Has also satisfied 7B1.1 and 7B1.2.~~

~~or~~

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.

Formatted: Indent: Hanging: 1.5"

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: 10 pt, Not Highlight

Formatted: Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 1" + Indent at: 1.25", Tab stops: 1.25", Left + Not at 1.5"

Formatted: Indent: Left: 1", Hanging: 0.25", Tab stops: 1.25", Left + Not at 1.5"

Formatted: Font: 10 pt, Not Highlight

Formatted: Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 1" + Indent at: 1.25", Tab stops: 1.25", Left + Not at 1.5"

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Indent: Left: 1", Hanging: 0.25", Tab stops: 1.25", Left + Not at 1.5"

Formatted: Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 1" + Indent at: 1.25", Tab stops: 1.25", Left + Not at 1.5"

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: 10 pt

Formatted: Indent: Hanging: 1"

Formatted: par2

Formatted: Indent: Left: 0"

Formatted: Indent: Left: 1"

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~~3~~ Meets the following requirements for an experienced authorized medical physicist:~~Has demonstrated adequate prior experience as:~~

7B3~~5~~.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

7B3~~5.23~~ 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

Formatted: Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 1" + Indent at: 1.25"

Formatted: Indent: Left: 1"

Formatted: Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 1" + Indent at: 1.25"

Formatted: par1, Indent: Left: 0"

Formatted: Indent: Left: 0", Hanging: 0.5"

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.

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: par2

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Indent: Hanging: 1"

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: par2

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

status (and thus need not comply with the specific training and experience requirements of 7B1 **through**~~or~~ 7B~~4~~2):

(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) ~~And having~~**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.

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

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

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

~~**7B5** 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), a specialty board shall require that each candidate for certification:~~

~~7B5.1 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~~

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

~~(1) 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~~

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

Formatted: Font: 10 pt

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.

Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: Indent: Hanging: 1"
Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: Font: 10 pt

Formatted: Font: 10 pt
Formatted: Font: 10 pt, Not Highlight
Formatted: par3, Indent: Left: 1", Tab stops: 0.31", Left

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)

Formatted: Not Highlight
Formatted: Font: 10 pt, Not Highlight
Formatted: Font: Not Bold
Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: Font: 10 pt

~~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.~~

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

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 ~~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 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.

~~Evidence of:~~

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

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

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

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

or

7C2 Has satisfied the following criteria:

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

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

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 1" + Indent at: 1.25", Tab stops: 1.25", Left + Not at 1.5"

Formatted: Indent: Left: 1", Hanging: 0.25"

Formatted: Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 1" + Indent at: 1.25", Tab stops: 1.25", Left + Not at 1.5"

Formatted: par2

Formatted: par2

(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 a**n 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~~3~~ Meets the following requirements for an experienced authorized nuclear pharmacist. ~~Has demonstrated adequate prior experience as:~~

Formatted: Indent: Left: 0", First line: 0"

Formatted: Indent: Hanging: 1.5"

Formatted: Indent: Hanging: 0.5"

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.

Formatted: Indent: Hanging: 0.5"

Formatted: Indent: Left: 0", First line: 0"

Formatted: Font: 10 pt

7C43.1 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.~~authorized nuclear pharmacist identified on a current facility license or permit, either on:~~

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

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

~~or~~

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

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.

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

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

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

~~**7C5** 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), a specialty board shall require that each candidate for certification:~~

~~7C5.1 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;~~

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

~~7C5.3 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~~

~~7C5.4 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.~~

Formatted: Font: 10 pt
Formatted: Font: 10 pt, Not Highlight
Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: par2
Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: par2
Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: Indent: Left: 0.5"
Formatted: Font: 10 pt, Not Highlight

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.

(NRC RATS 2009-1; Compatibility=B)

Formatted: Not Highlight
Formatted: Font: 10 pt, Not Highlight
Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: Font: 10 pt

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

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 ~~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 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.

~~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.~~

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:

7D~~2~~3.1 Has ~~provided written attestation(s), signed by a preceptor authorized user, that the individual 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~~ing~~:

(1) ~~8 hours of c~~**C**lassroom and laboratory training in the following areas:

(a) Radiation physics and instrumentation;

Comment [O79]: Words "and experience" added consistent with 10 CFR 35.190 per NRC review of Draft 2.

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

Formatted: Font: 10 pt

Formatted: Indent: Hanging: 0.5"

Formatted: Indent: Left: 0", First line: 0", Tab stops: 0", Left + Not at 0.5"

(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 7D54, 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

7D~~2~~3.2 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.

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

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

Formatted: Indent: Left: 1", First line: 0"

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]

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: 10 pt

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]

Formatted: Font: 10 pt

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.

Formatted: par2

Formatted: Indent: Hanging: 0.5"

7D~~3~~5 Meets the following requirements for an experienced authorized user for 7.30 uses:~~Has demonstrated adequate prior experience as:~~

7D~~3~~5.1 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.** ~~authorized user identified on a current facility license or permit under Appendix 7E or Appendix 7F (and also meets the requirements specified in 7E3.1.7), or under equivalent Agreement State or NRC requirements, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 7.30;~~

~~or~~

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

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

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

~~or~~

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

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

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.

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

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

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

~~**7D5** 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), a specialty board shall require that each candidate for certification:~~

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

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

Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: Font: 10 pt, Not Highlight
Formatted: Font: 10 pt, Not Highlight
Formatted: Font: 10 pt, Not Highlight
Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: Indent: Left: 1"
Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: Indent: Left: 0.5"
Formatted: Font: 10 pt, Not Highlight
Formatted: Font: 10 pt
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)
Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: par1

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

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 ~~Has provided:~~**Is certified by a medical specialty board who ~~se~~ 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;

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

~~7E1.2 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 and 7.32;~~

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

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:

7E~~2~~**3**.1 Has ~~provided written attestation(s), signed by a preceptor authorized user, that the individual 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~~ing~~ **at a minimum**:

(1) ~~At least 80 hours of c~~**C**lassroom and laboratory training in the following areas:

(a) Radiation physics and instrumentation;

Formatted: Font: 10 pt
Formatted: Font: 10 pt, Not Highlight
Formatted: Font: 10 pt
Formatted: par2
Formatted: Font: 10 pt
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]
Formatted: par2, Indent: Left: 1", First line: 0", Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0.5" + Indent at: 0.75", Tab stops: 1.25", Left
Formatted: Font: 10 pt
Formatted: par2, Tab stops: 1.25", Left
Formatted: Font: Not Italic
Formatted: Indent: Left: 1", First line: 0", Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0.5" + Indent at: 0.75", Tab stops: 1.25", Left + Not at 1.5"
Formatted: Font: 10 pt
Formatted: Indent: Hanging: 0.5"
Formatted: Font: 10 pt
Formatted: Indent: Left: 0", First line: 0", Tab stops: 0", Left + Not at 0.5"

(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

7E~~2~~3.2 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

Formatted: Indent: Left: 0", First line: 0"

Formatted: Font: 10 pt, Not Highlight

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]

Formatted: Font: 10 pt

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.

7E4.2 The individual must have had related, documented, continuing education and experience since the required training and experience was obtained.

or

7E~~3~~5 Meets the following requirements for an experienced authorized user for 7.32 uses:~~Has demonstrated adequate prior experience as:~~

7E~~5~~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 7E1 through 7E4.**~~authorized user identified on a current facility license or permit under Appendix 7F (and also meets the requirements specified in 7E2.1(2)(g)), 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 authorized under 7.30 and 7.32; or~~

~~7E3.2 An experienced authorized user for imaging and localization studies who:~~

~~(1) Was identified before October 25, 2005 (and thus need not comply with the requirements of 7E2) either on:~~

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

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

~~(2) Performs only those medical uses for which the authorized user identified in accord with 7E3.2(1) was authorized on October 25, 2005.~~

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.

~~**7E4** Training and experience required by Appendix 7E shall have been obtained:~~

~~7E4.1 Within the 7 years preceding the date of license application; or~~

~~7E4.2 Through documented subsequent continuing education and experience.~~

~~**7E5** 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), a specialty board shall require that each candidate for certification:~~

~~7E5.1 Complete 700 hours in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive materials for imaging and localization studies (including the topics specified in 7E2.1); and~~

~~7E5.2 Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control.~~

Formatted: par2
Formatted: Indent: Hanging: 0.5"
Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: Font: 10 pt, Not Highlight
Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: Indent: Left: 1"
Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: Indent: Left: 0.5"
Formatted: Font: 10 pt, Not Highlight
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.

(NRC RATS 2009-1; Compatibility=B)
Formatted: Not Highlight
Formatted: Font: 10 pt, Not Highlight
Formatted: Font: Not Bold
Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: Font: 10 pt

PART 7, APPENDIX 7F: AUTHORIZED USER TRAINING FOR DIAGNOSTIC OR THERAPEUTIC USE OF UNSEALED RADIOACTIVE MATERIAL REQUIRING A WRITTEN DIRECTIVE (7.36.2 USES) ~~ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE~~

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 ~~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 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;

~~Evidence of current certification by a recognized specialty board (see 7F5); and~~

~~7F1.2 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 7.36;~~

~~(1) Each preceptor authorized user supervising the experiential training required by Appendix 7F shall meet the requirements of this Appendix 7F, including experience in administering dosages in the same dosage category or categories listed in 7F2.1(3), or equivalent Agreement State or NRC requirements.~~

or

7F2 Has satisfied the following criteria:

7F2.1 Has ~~provided written attestation(s), signed by a preceptor authorized user, that the individual 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 ~~medical~~ **written** directive.~~,~~ **The training must** include~~ing~~:

(1) ~~At least 200 hours of c~~**C**lassroom and laboratory training in the following areas:

Formatted: Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 1" + Indent at: 1.25", Tab stops: 1.25", Left + Not at 0.5" + 1.5"

Formatted: Font: 10 pt, Not Highlight

Formatted: Indent: Left: 1", Hanging: 0.25", Tab stops: 1.25", Left + Not at 0.5" + 1.5"

Formatted: Indent: Hanging: 0.5"

(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~~ing~~:

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: 10 pt

(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:

~~(3) Has administered dosages of radioactive drugs to patients or human research subjects:~~

~~(a) That include 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; ~~and~~

(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~~3~~)(f~~a~~)(ii) also satisfies the requirement in category 7F2.1(2~~3~~)(f~~a~~)(i)]; ~~and~~

(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

~~(b) Provided that the experience required by 7F2.1(3) may be obtained concurrently with the supervised work experience required by 7F2.1(2);~~

7F2.2 Has provided written attestation(s), ~~signed by a preceptor authorized user,~~ 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

~~(1)~~(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

7F~~4~~3 Meets the following requirements for an experienced authorized user for 7.36.2 uses: ~~Has demonstrated adequate prior experience as:~~

7F~~4~~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 7F1 through 7F3.**~~authorized user identified on a current facility license or permit under Appendix 7F for uses listed in Appendix 7F, 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 authorized under 7.36;~~

Formatted: Tab stops: 4.12", Left

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]

Formatted: Font: 10 pt

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.

Formatted: Indent: Hanging: 0.5"

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: 10 pt

~~or~~

~~7F3.2 An experienced authorized user for use of unsealed radioactive material who:~~

~~(1) Was identified before October 25, 2005 (and thus need not comply with the requirements of 7F2) either on:~~

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

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

~~(2) Performs only those medical uses for which the authorized user identified in accord with 7F3.2(1) was authorized on October 25, 2005.~~

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.

~~**7F4** Training and experience required by Appendix 7F shall have been obtained:~~

~~7F4.1 Within the 7 years preceding the date of license application; or~~

~~7F4.2 Through documented subsequent continuing education and experience.~~

~~**7F5** 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), a specialty board shall require that each candidate for certification:~~

~~7F5.1 Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty that includes 700 hours of training and experience as described in 7F2.1. Eligible training programs must be 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 Committee on Post-Graduate Training of the American Osteopathic Association; and~~

~~7F5.2 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 byproduct material.~~

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: par2

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt, Not Highlight

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)

Formatted: Not Highlight

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: par1

PART 7, APPENDIX 7G: AUTHORIZED USER TRAINING FOR THE ORAL ADMINISTRATION ~~(7.36)~~ OF SODIUM IODIDE I-131 REQUIRING A WRITTEN DIRECTIVE IN QUANTITIES LESS THAN OR EQUAL ~~-~~TO 1.22 Gbq I-~~131~~ (33 mCi) ~~SODIUM IODIDE ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE~~ (7.36,3 USES)

The licensee shall require an authorized user ~~of~~ for the oral administration of sodium iodide I-131 requiring a written directive in quantities ~~of~~ less than or equal to 1.22 GBq (33 mCi), ~~of Na I-131 for which a written directive is required~~ to be a physician who has a current active State of Colorado license and:

7G1 ~~Has provided:~~**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.**

~~7G1.1 Evidence of current certification by a recognized medical specialty board (see 7G5); and~~

~~7G1.2 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 of unsealed radioactive materials using Na I-131 authorized under 7.36;~~

~~(1) Each preceptor authorized user supervising the experiential training required by Appendix 7G shall meet the requirements of Appendix 7G, or Appendix 7F (including experience in administering dosages in the same dosage category or categories listed in 7F2.1(3)), or Appendix 7H, or equivalent Agreement State or NRC requirements.~~

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~~2~~ Has satisfied the following criteria:

7G3~~2~~.1 Has ~~provided written attestation(s), signed by a preceptor authorized user, that the individual has~~ satisfactorily completed **80 hours of classroom and laboratory** training**,** ~~in basic radionuclide handling techniques~~ applicable to the medical use of sodium iodide **I-131** for procedures requiring a written directive**.**~~, including~~:

(1) ~~At least~~ **The** 80 hours of classroom and laboratory training **must include** ~~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

Formatted: Not Highlight
Formatted: Not Highlight
Formatted: Not Highlight
Formatted: Font: 10 pt, Not Highlight
Formatted: Font: 10 pt, Not Highlight
Formatted: Font: 10 pt, Not Highlight
Formatted: Font: 10 pt, Not Highlight
Formatted: Font: 10 pt
Formatted: Font: 10 pt, Not Highlight
Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: Indent: Hanging: 0.5"
Formatted: Font: 10 pt, Not Bold

(e) Radiation biology;

and

(2) **Has** ~~W~~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~~ing~~:

(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;

~~(3) Has administered dosages of radioactive drugs to patients or human research subjects:~~

~~(a) That include a minimum of 3 cases involving the oral administration of less than or equal to 1.22 GBq (33 mCi) of Na I-131; and~~

~~(b) Provided that the experience required by 7G2.1(3) may be obtained concurrently with the supervised work experience required by 7G2.1(2);~~

and

~~7G2.2~~**(3)** Has provided written attestation(s), ~~signed by a preceptor authorized user,~~ 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

Formatted: Font: 10 pt, Not Highlight

Formatted: Indent: Left: 0.5", Hanging: 0.5", No bullets or numbering, Tab stops: 1.5", Left + Not at 1.25"

Comment [JJ92]: Corrected reference, consistent with 10 CFR 35.392.

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

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Comment [JJ93]: Changed reference from 7.36.3 to the broader reference of 7.36.

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

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt, Not Highlight

~~(1)~~**(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~~3~~ Meets the following requirements for an experienced authorized user for 7.36,3 uses:~~Has demonstrated adequate prior experience as:~~

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;~~

~~or~~

~~7G3.2 An experienced authorized user for the medical use of unsealed radioactive materials using Na I-131 who:~~

~~(1) Was identified before October 25, 2005 (and thus need not comply with the requirements of 7G2) either on:~~

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

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

~~(2) Performs only those medical uses for which the authorized user identified in accord with 7G3.2(1) was authorized on October 25, 2005.~~

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.

Formatted: Indent: Left: 1.5", Numbered + Level: 1 + Numbering Style: a, b, c, … + Start at: 1 + Alignment: Left + Aligned at: 0.5" + Indent at: 0.75"

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: 10 pt, Not Highlight

Formatted: Indent: Left: 0"

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.

Formatted: Indent: Left: 0"

Formatted: Font: 10 pt

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: par2

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Indent: Hanging: 1"

Formatted: Font: 10 pt

Formatted: par3, Indent: Left: 1", Tab stops: 1.06", Left

Formatted: Font: 10 pt

Formatted: Font: 10 pt, Not Highlight

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)

Formatted: Not Highlight

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: Not Bold

~~**7G4** Training and experience required by Appendix 7G shall have been obtained:~~

~~7G4.1 Within the 7 years preceding the date of license application; or~~

~~7G4.2 Through documented subsequent continuing education and experience.~~

~~**7G5** 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 7G, a medical specialty board shall require that each candidate for certification to meet all of the requirements of 7G2.~~

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

PART 7, APPENDIX 7H: AUTHORIZED USER TRAINING FOR THE ORAL ADMINISTRATION OF SODIUM IODIDE I-131 REQUIRING A WRITTEN DIRECTIVE IN QUANTITIES ~~(7.36) OF~~ GREATER THAN 1.22 GBq ~~1-131~~ (33 mCi) (7.36.4 USES) ~~SODIUM IODIDE ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE~~

The licensee shall require an authorized user for~~of~~ the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 GBq (33 mCi), ~~of Na I-131 for which a written directive is required~~ to be a physician who has a current active State of Colorado license and:

7H1 ~~Has provided:~~**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.**

~~7H1.1 Evidence of current certification by a recognized medical specialty board (see 7H5); and~~

~~7H1.2 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 of unsealed radioactive materials using Na I-131 in activities greater than 1.22 GBq (33 mCi) authorized under 7.36;~~

~~(1) Each preceptor authorized user supervising the experiential training required by Appendix 7H shall meet the requirements of Appendix 7H, or Appendix 7F (including experience in administering dosages in the same dosage category or categories listed in 7F2.1(3)), or equivalent Agreement State or NRC requirements.~~

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

7H~~3~~2 Has satisfied the following criteria:

7H~~2~~3.1 Has ~~provided written attestation(s), signed by a preceptor authorized user, that the individual has~~ satisfactorily completed **80 hours of classroom and laboratory** training**,** ~~in basic radionuclide handling techniques~~ applicable to the medical use of sodium iodide **I-131** for procedures requiring a written directive**.**~~, including:~~

(1) **The**~~At least~~ 80 hours of classroom and laboratory training ~~in the following areas~~**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

Formatted: Not Highlight
Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: Font: 10 pt, Not Highlight
Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: Indent: Hanging: 0.5"
Formatted: Font: Not Bold

(e) Radiation biology;

and

(2) **Has** ~~W~~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~~ing~~:

(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

(~~3~~f) **Administering** ~~Has administered~~ dosages ~~of radioactive drugs~~ 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;**~~:~~

~~(a) That include a minimum of 3 cases involving the oral administration of greater than 1.22 GBq (33 mCi) of Na I-131; and~~

~~(b) Provided that the experience required by 7H2.1(3) may be obtained concurrently with the supervised work experience required by 7H2.1(2);~~

and

~~7H2.2~~ **(3)** Has provided written attestation(s), ~~signed by a preceptor authorized user,~~ 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

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]

Formatted: Font: 10 pt

Formatted: Font: 10 pt

(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

7H53 Meets the following requirements for an experienced authorized user for 7.36.4 usesHas demonstrated adequate prior experience as:

7H35.1 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.authorized user identified on a current facility license or permit under Appendix 7H, under Appendix 7F for uses listed in 7F2.1(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 in activities greater than 1.22 GBq (33 mCi) authorized under 7.36;

or

7H3.2 An experienced authorized user for the medical use of unsealed radioactive materials using Na I-131 in activities greater than 1.22 GBq (33 mCi) who:

(1) Was identified before October 25, 2005 (and thus need not comply with the requirements of 7H2) either on:

(a) An NRC or Agreement State license; or

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

(2) Performs only those medical uses for which the authorized user identified in accord with 7H3.2(1) was authorized on October 25, 2005.

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.

7H4 Training and experience required by Appendix 7H shall have been obtained:

Formatted: Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 1" + Indent at: 1.25", Tab stops: 1.25", Left + Not at 1.5"

Formatted: Indent: Left: 0", First line: 0"

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.

Formatted: upar2

Formatted: Indent: Left: 0", First line: 0"

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: par2

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: par2

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: par3, Indent: Left: 1", Tab stops: 0.31", Left

Formatted: Font: 10 pt, Not Highlight

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)

Formatted: Not Highlight

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: Not Bold

Formatted: Font: 10 pt

~~7H4.1 Within the 7 years preceding the date of license application; or~~

Formatted: Font: 10 pt

~~7H4.2 Through documented subsequent continuing education and experience.~~

Formatted: Font: 10 pt

~~**7H5** 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 7H, a medical specialty board shall require that each candidate for certification to meet all of the requirements of 7H2.~~

PART 7, APPENDIX 7I: AUTHORIZED USER TRAINING FOR THE PARENTERAL ADMINISTRATION ~~(7.36)~~ OF UNSEALED RADIOACTIVE MATERIAL REQUIRING A WRITTEN DIRECTIVE (7.36.5 USES)~~ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE~~

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:

7I1 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

7I2 Is an authorized user under Appendix 7K, Appendix 7M, or equivalent NRC or Agreement State requirements and who meets the requirements in 7I4;

or

7I3 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 7I4 of this section.

~~Has provided:~~

~~7I1.1 Evidence of current certification by a recognized medical specialty board (see 7I5); and~~

~~7I1.2 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 parenteral administration of unsealed radioactive material for which a written directive authorized under 7.36;~~

~~(1) Each preceptor authorized user supervising the experiential training required by Appendix 7I shall meet the requirements of Appendix 7I, or Appendix 7F (including experience in administering dosages in the same dosage category or categories listed in 7F2.1(3)), or equivalent Agreement State or NRC requirements.~~

or

7I~~4~~2 Has satisfied the following criteria:

7I~~4~~2.1 Has ~~provided written attestation(s), signed by a preceptor authorized user, that the individual has~~ satisfactorily completed **80 hours of classroom and laboratory** training ~~in basic radionuclide handling techniques~~ applicable to parenteral administrations**, for which** ~~requiring~~ 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.** ~~including:~~

(1) ~~At least 80 hours of c~~**The training must include**~~lassroom and laboratory training in the following areas~~:

Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: Font: (Default) Arial, 10 pt
Formatted: Font: (Default) Arial, 10 pt
Formatted: Font: (Default) Arial, 10 pt
Formatted: Font: (Default) Arial, 10 pt
Formatted: Font: (Default) Arial, 10 pt
Formatted: Not Highlight
Formatted: Font: (Default) Arial, 10 pt
Formatted: Font: (Default) Arial, 10 pt
Formatted: Normal (Web)
Formatted: Font: (Default) Arial, 10 pt
Formatted: Font: (Default) Arial, 10 pt
Formatted: Font: (Default) Arial, 10 pt
Formatted: Font: (Default) Arial, 10 pt
Formatted: Font: (Default) Arial, 10 pt
Formatted: Font: (Default) Arial, 10 pt, Not Highlight
Formatted: Font: (Default) Arial, 10 pt
Formatted: Indent: Left: 0"
Formatted: Indent: Left: 0", First line: 0"

(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 w**~~W~~ork experience **under the supervision of an authorized user who meets the requirements of 7I6, 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~~ing~~:

(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

~~(3) Has~~**(f) A**~~a~~dminister**ing**~~ed~~ dosages ~~of radioactive drugs~~ to patients or human research subjects **that include**:

(~~a~~i) **At least 3 cases involving the** ~~P~~**p**arenteral administration, for which a written directive is required, of any beta emitter**,** or a**ny** photon-emitting radionuclide with a photon energy less than 150 keV;

and/or

(~~b~~ii) **At least 3 cases involving the** ~~P~~**p**arenteral administration of any other radionuclide**,** for which a written directive is required;

Formatted: Indent: Left: 0", First line: 0"

Formatted: Font: 10 pt

Formatted: Font: 10 pt

and

~~7I2.2~~ **(3)** Has provided written attestation(s)~~, signed by a preceptor authorized user,~~ 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**~~authorized under 7.36~~. **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:

7I5.1 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

7I5.2 The individual must have had related, documented, continuing education and experience since the required training and experience was obtained.

or

7I6~~3~~ **Meets the following requirements for an experienced authorized user for 7.36.5 uses:**~~Has demonstrated adequate prior experience as:~~

7I~~3~~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 7I1 through 7I5.**~~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~~

~~7I3.2 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 7I2) either on:~~

Formatted: Indent: Left: 0", First line: 0"

Formatted: Indent: Left: 1.5", Hanging: 0.5", No bullets or numbering, Tab stops: 1.5", Left + Not at 1.25"

Formatted: Font: 10 pt

Formatted: Indent: Left: 1.5"

Formatted: Font: 10 pt

Formatted: Indent: Left: 0"

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.

Formatted: Indent: Left: 0"

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: 10 pt

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: par2

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: par2

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

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

~~(2) Performs only those medical uses for which the authorized user identified in accord with 7I3.2(1) was authorized on October 25, 2005.~~

7I6.2 Individuals not required to comply with the training requirements of 7I1 through 7I5 may serve as preceptors for, and supervisors of, applicants seeking authorization on licenses for the same uses for which these individuals are authorized.

~~**7I4** Training and experience required by Appendix 7I shall have been obtained:~~

~~7I4.1 Within the 7 years preceding the date of license application; or~~

~~7I4.2 Through documented subsequent continuing education and experience.~~

~~**7I5** 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 7I, a medical specialty board shall require that each candidate for certification to meet all of the requirements of 7I2.~~

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Comment [JJ100]: Correction to reference appropriate section per NRC comments – Nov 2011.

[RATS 2009-1; Compatibility B; 35.57]

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: 10 pt

Formatted: Font: 10 pt, Not Highlight

Formatted: Indent: Left: 0.5"

Formatted: Font: 10 pt

Formatted: Font: 10 pt, Not Highlight

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)

Formatted: Not Highlight

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: Not Bold

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

PART 7, APPENDIX 7J: AUTHORIZED USER TRAINING FOR USE OF SEALED SOURCES FOR DIAGNOSIS (7.40 USES) ~~ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE~~

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 ~~Has provided~~ **Is certified by** ~~evidence of current certification by a recognized a~~ ~~medical~~ 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.** ~~(see 7J5)~~; **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 ~~satisfactorily~~ completed **8 hours of classroom and laboratory** training in basic radionuclide handling techniques specifically applicable to the use of the device~~.~~ ~~including:~~

(1) ~~At least 8 hours of classroom and laboratory training in the following areas~~**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 ~~(2)~~ **Has completed** ~~T~~training in the use of the device for the uses requested.

~~7J2.2 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 an authorized user of a diagnostic sealed source for use in a device authorized under 7.40.~~

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

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

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: par1

Formatted: Font: 10 pt

Formatted: Indent: Left: 0", First line: 0"

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.

7J4.2 The individual must have had related, documented, continuing education and experience since the required training and experience was obtained.

or

7J5~~3~~ Meets the following requirements for an experienced authorized user for 7.40 uses~~Has demonstrated adequate prior experience as~~:

7J5~~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 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~~;

~~or~~

~~7J3.2 An experienced authorized user of a diagnostic sealed source for use in a device authorized under 7.40 who:~~

~~(1) Was identified before October 25, 2005 (and thus need not comply with the requirements of 7J2) either on:~~

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

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

~~(2) Performs only those medical uses for which the authorized user identified in accord with 7J3.2(1) was authorized on October 25, 2005.~~

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.

~~**7J5**~~**4** ~~Training and experience required by Appendix 7J shall have been obtained:~~

~~7J4.1 Within the 7 years preceding the date of license application; or~~

~~7J4.2 Through documented subsequent continuing education and experience.~~

~~**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).~~

Formatted: Indent: Left: 0"
Formatted: Indent: Hanging: 0.5"
Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: Font: 10 pt, Not Highlight
Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: par2
Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: Indent: Hanging: 1"
Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: par3, Indent: Left: 1"
Formatted: Font: 10 pt, Not Highlight
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)
Formatted: Not Highlight
Formatted: Font: 10 pt, Not Highlight
Formatted: Font: Not Bold
Formatted: Font: 10 pt
Formatted: Font: 10 pt

PART 7, APPENDIX 7K: AUTHORIZED USER TRAINING FOR THE USE OF MANUAL BRACHYTHERAPY SOURCES ~~USE~~ (7.42 USES) ~~ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE~~

The licensee shall require an authorized user of a~~n~~ 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 ~~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 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;

~~**meet the requirements of 10 CFR 35.490(a)(1) and 10 CFR 35.490(a)(2). NRC recognized specialty boards are posted on the NRC website at http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html.**~~ ~~Evidence of current certification by a recognized specialty board (see 7K5); and~~

~~7K1.2 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 of an manual brachytherapy source for the uses authorized under 7.42;~~

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

or

7K2 Has satisfied the following criteria:

7K2.1 Has ~~provided written attestation(s), signed by a preceptor authorized user, that the individual has~~ satisfactorily completed ~~700 total hours in~~ a structured educational program in **basic** radionuclide handling techniques applicable to the medical use of manual brachytherapy sources, **that** includ**es**~~ing~~:

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

(a) Radiation physics and instrumentation;

(b) Radiation protection;

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: 10 pt

Formatted: Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 1" + Indent at: 1.25", Tab stops: 1.25", Left + Not at 1.5"

Formatted: Indent: Hanging: 0.5"

(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 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 ~~unsealed~~ radioactive material;

(f) Using emergency procedures to control radioactive material;

and

7K2.2 ~~(3) Or h~~**H**as **completed** 3 years of supervised clinical experience in radiation oncology, under ~~the supervision of~~ an authorized user who meets the requirements **in 7K4,** ~~of this~~ 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~~2~~ 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:

Formatted: Indent: Left: 0", First line: 0"

Formatted: Font: 10 pt

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.

Formatted: Indent: Left: 0", First line: 0"

Formatted: Indent: Left: 0.5"

Formatted: Font: 10 pt

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: 10 pt

Formatted: Indent: Left: 0", First line: 0"

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Comment [JJ105]: Changed reference from 7K1 to the more specific reference of 7K1.1(1), consistent with 10 CFR 35.490.

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

Formatted: Font: 10 pt

Formatted: Font: 10 pt

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

7K~~4~~3 Meets the following requirements for an experienced authorized user for 7.42 uses: ~~Has demonstrated adequate prior experience as:~~

7K~~4~~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 7K1 through 7K3.** ~~authorized user identified on a current facility license or permit under Appendix 7K for uses listed in Appendix 7K, 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 an manual brachytherapy source for the uses authorized under 7.42;~~

~~or~~

~~7K3.2 An experienced authorized user of an manual brachytherapy source for the uses authorized under 7.42 who:~~

~~(1) Was identified before October 25, 2005 (and thus need not comply with the requirements of 7K2) either on:~~

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

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

~~(2) Performs only those medical uses for which the authorized user identified in accord with 7K3.2(1) was authorized on October 25, 2005.~~

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.

~~**7K4** Training and experience required by Appendix 7K shall have been obtained:~~

~~7K4.1 Within the 7 years preceding the date of license application; or~~

~~7K4.2 Through documented subsequent continuing education and experience.~~

~~**7K5** 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), a specialty board shall require that each candidate for certification:~~

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.

Formatted: Indent: Hanging: 0.5"

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Indent: Left: 1"

Formatted: Font: 10 pt

Formatted: Indent: Left: 0.5", First line: 0", Tab stops: 0.94", Left + Not at 1"

Formatted: Not Highlight

Formatted: Font: 10 pt

Formatted: Indent: Left: 0.5"

Formatted: Font: 10 pt, Not Highlight

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)

Formatted: Not Highlight

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: 10 pt

Formatted: Font: 10 pt

DRAFT 5 –02/16/2012

~~7K5.1 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 Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association; and~~

~~7K5.2 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 manual brachytherapy.~~

Formatted: par1

PART 7, APPENDIX 7L: AUTHORIZED USER TRAINING FOR OPHTHALMIC USE OF STRONTIUM-90 (7.42 USES) ~~ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE~~

The licensee shall require an authorized user of a~~n~~ ~~-~~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;**~~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 strontium-90 for ophthalmic radiotherapy uses authorized under 7.42;~~

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

or

7L2 Has satisfied the following criteria:

7L2.1 Has satisfactorily completed **24 hours of classroom and laboratory** training ~~in basic radionuclide handling techniques specifically~~ applicable to the **medical** use of strontium-90 for ophthalmic radiotherapy**.**~~, including:~~

(1) **The training must include**~~At least 24 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) ~~**Has satisfactorily completed**~~ 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, ~~that~~ **This supervised clinical training must involve**~~includes~~:

(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

Formatted: Font: 10 pt

Formatted: par1

Formatted: Indent: Hanging: 0.5"

Formatted: Indent: Left: 0", First line: 0"

Formatted: Indent: Left: 0", First line: 0"

~~7L2.2~~ **(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

7L~~4~~3 Meets the following requirements for an experienced authorized user for 7.42 opthalmic radiotherapy uses: ~~Has demonstrated adequate prior experience as:~~

7L~~3~~4.1 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.** ~~authorized user identified on a current facility license or permit under this Appendix 7L for uses listed in Appendix 7L, 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 strontium-90 for ophthalmic radiotherapy uses authorized under 7.42;~~

~~or~~

~~7L3.2 An experienced authorized user of strontium-90 for ophthalmic radiotherapy uses authorized under 7.42 who:~~

~~(1) Was identified before October 25, 2005 (and thus need not comply with the requirements of 7L2) either on:~~

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

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

~~(2) Performs only those medical uses for which the authorized user identified in accord with 7L3.2(1) was authorized on October 25, 2005.~~

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

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.

Formatted: par2

Formatted: Indent: Hanging: 0.5"

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: par2

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: par2

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Indent: Left: 0.5"

Formatted: Font: 10 pt, Not Highlight

authorization on licenses for the same uses for which these individuals are authorized.

~~**7L4** Training and experience required by Appendix 7L shall have been obtained:~~

~~7L4.1 Within the 7 years preceding the date of license application; or~~

~~7L4.2 Through documented subsequent continuing education and experience.~~

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)

Formatted: Not Highlight

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

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) ~~ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE~~

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.~~Has provided:~~

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;

~~Evidence of current certification by a recognized specialty board (see 7M5); and~~

~~7M1.2 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 each type of the therapeutic medical unit for which the individual is requesting authorized user status for the medical uses authorized under 7.48;~~

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

or

7M2 Has satisfied the following criteria:

7M2.1 Has ~~provided written attestation(s), signed by a preceptor authorized user, that the individual has~~ satisfactorily completed ~~700 total hours in~~ a structured educational program in **basic** radionuclide handling techniques applicable to the ~~medical~~ use of sealed sources in **a therapeutic medical unit**~~remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units,~~ **that** includ**es**~~ing~~:

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

(a) Radiation physics and instrumentation;

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Tab stops: 1.25", Left + Not at 1.5"

Formatted: Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 1" + Indent at: 1.25", Tab stops: 1.25", Left + Not at 1.5"

Formatted: par2

Formatted: Indent: Hanging: 0.5"

(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 ~~unsealed~~ 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**~~2~~ Has provided written attestation(s)~~, signed by a preceptor authorized user,~~ 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.~~, that:~~ **This training requirement may be satisfied by:**

Formatted: Font: 10 pt

Formatted: Indent: Left: 0.5"

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: 10 pt

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Indent: Left: 0", First line: 0"

Formatted: Indent: Left: 0", First line: 0"

~~(1) Includes:~~

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

~~(b) Safety procedures;~~

~~(c) Clinical use, and~~

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

~~(2) Is provided by either:~~

7M3.1~~(a)~~ Satisfactorily completing a vendor training program;

or

7M3.2~~(b)~~ **By receiving training** ~~Being~~ 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;

~~7M2.3 Or h~~**H**~~as completed 3 years of supervised clinical experience in radiation therapy, under the supervision of an authorized user who meets the requirements of this Appendix 7M, or equivalent Agreement State or NRC requirements, provided that the experience:~~

~~(1) 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 Committee on Post-Graduate Training of the American Osteopathic Association; and~~

~~(2) May be obtained concurrently with the supervised work experience required by 7M2.1(2); and~~

~~7M2.4 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 each type of the therapeutic medical unit for which the individual is requesting authorized user status for the medical uses authorized under 7.48.~~

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~~3~~ **Meets the following requirements for an experienced authorized user for 7.48 uses.** ~~Has demonstrated adequate prior experience as:~~

Formatted: par3

Formatted: par3, Indent: Left: 1"

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.

Formatted: Indent: Left: 0.5", Hanging: 0.5", Tab stops: Not at 0.5"

Formatted: Indent: Hanging: 0.5", Tab stops: Not at 0.5"

Formatted: Font: 10 pt

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: 10 pt

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: 10 pt

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: 10 pt

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: 10 pt

Formatted: Font: 10 pt, Not Highlight

Formatted: Font: 10 pt

7M53.1 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.** ~~authorized user identified on a current facility license or permit under Appendix 7M for uses listed in 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 each type of the therapeutic medical unit for which the individual is requesting authorized user status for the medical uses authorized under 7.48;~~

~~or~~

~~7M3.2 An experienced authorized user of the therapeutic medical unit authorized under 7.48 who:~~

~~(1) Was identified before October 25, 2005 (and thus need not comply with the requirements of 7M2) either on:~~

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

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

~~(2) Performs only those medical uses for which the authorized user identified in accord with 7M3.2(1) was authorized on October 25, 2005.~~

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.

~~**7M5** Training and experience required by Appendix 7M shall have been obtained:~~

~~7M54.1 Within the 7 years preceding the date of license application; or~~

~~7M54.2 Through documented subsequent continuing education and experience.~~

~~**7M5** 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), a specialty board shall require that each candidate for certification:~~

~~7M5.1 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 Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association;~~

~~7M5.2 Pass an examination, administered by diplomates 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.~~

Formatted: Font: 10 pt
Formatted: Font: 10 pt, Not Highlight
Formatted: Font: 10 pt
Formatted: Font: 10 pt, Not Highlight
Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: Indent: Hanging: 0.5"
Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: Indent: Left: 1"
Formatted: Font: 10 pt
Formatted: Font: 10 pt, Not Highlight
Formatted: Font: 10 pt
Formatted: Font: 10 pt, Not Highlight
Formatted: par3, Indent: Left: 1"
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)
Formatted: Not Highlight
Formatted: Font: 10 pt, Not Highlight
Formatted: Font: 10 pt
Formatted: Font: 10 pt
Formatted: Font: 10 pt

PART 7, APPENDIX 7N: NUCLEAR MEDICINE TECHNOLOGIST (NMT) ADEQUATE RADIATION 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 SSRCR Part Z for training requirements for NMTs, and therefore the current section is not being changed significantly.

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);

Formatted: Indent: Left: 0.5"

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.

Formatted: Indent: Hanging: 0.5"

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;

Formatted: Indent: Hanging: 1"

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;

Formatted: Indent: Hanging: 0.5"

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:** ~~Training and experience required by Appendix 7N shall have been obtained:~~

7N4.1 **The training and experience required by Appendix 7N shall have been obtained** ~~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.

or

7N4.2 **The individual must have had related,** ~~Through~~ documented**,** ~~subsequent~~ 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 7O: RADIATION THERAPY TECHNOLOGIST (RTT) ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE

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.

The licensee shall require the radiation therapy technologist using radioactive materials under the supervision of an authorized user to be an individual who:

7O1 Has provided:

7O1.1 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 7O5);

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);

Formatted: Indent: Left: 0.5"

and

7O1.2 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 7O shall meet the requirements of Appendix 7O, or equivalent Agreement State or NRC requirements.

Formatted: Indent: Hanging: 0.5"

or

7O2 Has satisfied the following criteria:

7O2.1 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;

Formatted: Indent: Left: 1"

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;

7O2.2 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;

Formatted: Indent: Hanging: 1"

or

7O3 Has demonstrated adequate prior experience as:

7O3.1 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;

Formatted: Indent: Hanging: 0.5"

or

7O3.2 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 7O2);

7O4 Meets the following recentness of training requirements: ~~Training and experience required by Appendix 7O shall have been obtained:~~

7O4.1 **The training and experience required by Appendix 7O shall have been obtained** ~~W~~within the 7 years preceding the date of license application **or amendment request**;

or

7O4.2 **The individual must have had related,** ~~Through~~ documented**,** ~~subsequent~~ continuing education and experience **since the required training and experience was obtained**.

7O5 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.

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.

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]

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.]

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:

"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 permitee 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 permitee 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 license 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 µCi), 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 µCi);

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 µCi);

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 uCi) 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). [1]

1 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-live; 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 µSv (0.1 mrem) per hour to 500 µSv (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 µCi of ^{99}Mo per mCi of ^{99m}Tc).

7.33.1.2 More than 0.02 kBq of strontium-82 per MBq of rubidium-82 chloride injection (0.02 µCi of ^{82}Sr per mCi of ^{82}Rb chloride);

7.33.1.3 More than 0.2 kBq of strontium-85 per MBq of rubidium-82 chloride injection (0.2 µCi of ^{85}Sr per mCi of ^{82}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 (µCi/ 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 µSv (0.1 mrem) per hour to 500 µSv (50 mrem) per hour and over the range of 10 µSv (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 GBq ^{131} 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 GBq ^{131} 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 GBq ^{131} 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 GBq ^{131} 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 µSv (0.1 mrem) per hour to 500 µSv (50 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 10 µSv (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:

7I1 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

7I2 Is an authorized user under Appendix 7K, Appendix 7M, or equivalent NRC or Agreement State requirements and who meets the requirements in 7I4;

or

7I3 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 7I4 of this section.

or

7I4 Has satisfied the following criteria:

7I4.1 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 7I6, 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:

7I5.1 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

7I5.2 The individual must have had related, documented, continuing education and experience since the required training and experience was obtained.

or

7I6 Meets the following requirements for an experienced authorized user for 7.36.5 uses:

7I6.1 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 7I1 through 7I5.

7I6.2 Individuals not required to comply with the training requirements of 7I1 through 7I5 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 opthalmic 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 7O: 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:

7O1 Has provided:

7O1.1 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 7O5);

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

7O1.2 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 7O shall meet the requirements of Appendix 7O, or equivalent Agreement State or NRC requirements.

or

7O2 Has satisfied the following criteria:

7O2.1 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;

7O2.2 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

7O3 Has demonstrated adequate prior experience as:

7O3.1 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

7O3.2 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 7O2);

7O4 Meets the following recentness of training requirements:

7O4.1 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

7O4.2 The individual must have had related, documented, continuing education and experience since the required training and experience was obtained.

7O5 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.

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]