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.]

Adopted by the Board of Health October 19, 2022, effective date December 15, 2022.

PART 7: USE OF RADIONUCLIDES IN THE HEALING ARTS

USE OF RADIONUCLIDES IN THE HEALING ARTS

Section A – General Information

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.

7.1.5.1 Throughout this Part 7, federal regulations, state regulations, and standards or guidelines of outside organizations have been adopted and incorporated by reference. Unless a prior version of the incorporated material is otherwise specifically indicated, the materials incorporated by reference cited herein include only those versions that were in effect as of the most recent effective date of this Part 7 (December 15, 2022), and not later amendments or editions of the incorporated material.

7.1.5.2 Materials incorporated by reference are available for public inspection, and copies (including certified copies) can be obtained at reasonable cost, during normal business hours from the Colorado Department of Public Health and Environment, Hazardous Materials and Waste Management Division, 4300 Cherry Creek Drive South, Denver, Colorado 80246. Additionally, https://www.colorado.gov/cdphe/radregs identifies where the incorporated federal and state regulations are available to the public on the internet at no cost. A copy of the materials incorporated in this Part is available for public inspection at the state publications depository and distribution center.

7.1.5.3 Availability from Source Agencies or Organizations.

(1) All federal agency regulations incorporated by reference herein are available at no cost in the online edition of the Code of Federal Regulations (CFR) hosted by the U.S. Government Printing Office, online at www.govinfo.gov.

(2) All state regulations incorporated by reference herein are available at no cost in the online edition of the Code of Colorado Regulations (CCR) hosted by the Colorado Secretary of State's Office, online at https://www.sos.state.co.us/CCR/RegisterHome.do.

(3) Copies of the standards or guidelines of outside organizations are available either at no cost or for purchase from the source organizations listed below.

a. The Federal Policy for the Protection of Human Subjects: hhs.gov or https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html or

U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C.20201
Phone: 1-877-696-6775.

b. NUREG-1556, Vol. 9: nrc.gov or https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/ or

U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
Phone: 1-800-368-5642.

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.

"Associate Radiation Safety Officer" means, for the purposes of Part 7, an individual who:

(1) Meets the requirements in Appendix 7A and 7.65; and

(2) Is currently identified as an Associate Radiation Safety Officer for the types of use of radioactive material for which the individual has been assigned duties and tasks by the Radiation Safety Officer on:

a. A specific medical use license issued by the Department, NRC or an Agreement State;

b. A medical use permit issued by an NRC master material licensee.

"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 use license issued by the Department, NRC, or Agreement State;

b. A medical use permit issued by an NRC master material licensee;

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 permittee.

"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 licensee that authorizes medical use or the practice of nuclear pharmacy;

c. A permit issued by an NRC or Agreement State broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or

d. A permit issued by an NRC master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or

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

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

"Authorized user" (AU) means a physician, dentist, or podiatrist who meets the applicable requirements of Appendix 7D through Appendix 7M; or

(1) Is identified as an authorized user on:

a. A Department, NRC, or Agreement State license that authorizes the medical use of radioactive material;

b. A permit issued by an NRC master material licensee that is authorized to permit the medical use of radioactive material;

c. A permit issued by an NRC or Agreement State specific licensee of broad scope that is authorized to permit the medical use of radioactive material; or

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

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

“Brachytherapy source” means a radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

“Client” means, for mobile medical service, the person for whom, or in conjunction with whom, medical service is provided.

“Client's address” means the address of use for the purpose of providing mobile medical service in accordance with 7.27.

“Dedicated check source” means a radioactive source that is used to assure the consistent response of a radiation detection or measurement device over several months or years.

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

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

“HDR”, see high dose-rate remote afterloader.

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

“LDR”, see low dose-rate remote afterloader.

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

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

“Manual brachytherapy” means a type of therapy in which brachytherapy sources are manually applied or inserted.

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

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

"Medical event" means an event that meets the criteria in 7.21.1 or 7.21.2.

"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 brachytherapy device that remotely delivers a dose rate of greater than 2 gray (200 rads) per hour, but less than, or equal to 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

"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.

"Ophthalmic physicist" means an individual who:

(1) Meets the requirements in 7.41.6.1(2) and 7.65; and

(2) Is identified as an ophthalmic physicist on a:

a. Specific medical use license issued by the Department, NRC or an Agreement State;

b. Permit issued by the Department, NRC or Agreement State broad scope medical use licensee;

c. Medical use permit issued by a NRC master material licensee; or

d. Permit issued by a NRC master material license broad scope medical use permittee.

"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 authorized user, an authorized medical physicist, an authorized nuclear pharmacist, a Radiation Safety Officer, an Associate Radiation Safety Officer (see appendices 7A through 7M, and 7P).

"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.

“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 all the registration certificates, generated by both the Nuclear Regulatory Commission and the Agreement States, 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

7.3.1.1 A person may manufacture, produce, acquire, receive, possess, prepare, 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 7.3.1.2.

7.3.1.2 A specific license is not needed for an individual who:

(1) Receives, possess, uses, or transfers radioactive material in accordance with the regulations under the supervision of an authorized user as provided in 7.10, unless prohibited by license condition; or

(2) Prepares unsealed radioactive material for medical use in accordance with the regulations under the supervision of an authorized nuclear pharmacist or authorized user as provided in 7.10, unless prohibited by license condition.

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 Part 3, Section 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 must 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 Department Form R-12 (7C) that includes the facility diagram, equipment, and training and experience qualifications of the Radiation Safety Officer, Associate Radiation Safety Officer(s), authorized user(s), authorized medical physicist(s), ophthalmic physicist(s), and authorized nuclear pharmacist(s); 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:

(1) Any additional aspects of the medical use of the material that are applicable to radiation safety that are not addressed in, or differ from:

(a) Section A through C (7.1 through 7.29);

(b) Sections D through H (recordkeeping requirements);

(c) Section I (7.65);

(d) Appendix 7A, 7B, 7C and 7P;

(2) Identification of and commitment to follow the applicable radiation safety program requirements in Sections D through H that are appropriate for the specific 7.62 medical use;

(3) Any additional specific information on:

(a) Radiation safety precautions and instructions;

(b) Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

(c) Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety; and

(4) Any other information requested by the Department in its review of the application.

7.3.4.5 An applicant that satisfies the requirements specified in Part 3, Section 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 Part 4, Sections 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 Part 4, Section 4.14; or

(b) The client's personnel are instructed as described in Part 10, Section 10.3 and monitored for exposure in accordance with Part 4, Section 4.18 unless the licensee can demonstrate that Section 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, issued under Part 3 of these regulations, 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 identified in the application or on 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 7.5.2.1 for an authorized user, an authorized nuclear pharmacist, an authorized medical physicist or an ophthalmic physicist;

7.3.6.6 The provisions of 7.5.2.5; and

7.3.6.7 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 physical protection of material and are otherwise in the public interest.

7.4 License amendments.

A licensee shall apply for and must receive a license amendment:

7.4.1 Before it receives, prepares, or uses radioactive material for a type of use that is permitted under this part but is not authorized on the licensee's current license issued under this part;

7.4.2 Before it permits anyone to work as an authorized user, authorized medical physicist, ophthalmic physicist, or an authorized nuclear pharmacist under the license, except:

7.4.2.1 For an authorized user, an individual who meets the requirements in Appendix 7P and one or more of the following: Section 7D1 of Appendix D, Section 7E1 of Appendix E, Section 7F1 of Appendix F, Section 7G1 of Appendix 7G, Section 7H1 of Appendix 7H, Section 7K1 of Appendix K, Section 7J1 of Appendix J, or Section 7M1 of Appendix M;

7.4.2.2 For an authorized nuclear pharmacist, an individual who meets the requirements in Section 7C1 of Appendix 7C and 7.65;

7.4.2.3 For an authorized medical physicist, an individual who meets the requirements in Section 7B1 of Appendix 7B and 7.65;

7.4.2.4 An individual who is identified as an authorized user, an authorized nuclear pharmacist, authorized medical physicist, or an ophthalmic physicist:

(1) On a NRC or Agreement State license or other equivalent permit or license recognized by the Department that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy;

(2) On a permit issued by a NRC or Agreement State specific license of broad scope that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy;

(3) On a permit issued by a NRC master material licensee that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy; or

(4) By a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists.

7.4.2.5 A physician, podiatrist, or dentist who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses or a nuclear pharmacist who used only accelerator-produced radioactive materials in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, and for only those materials and uses performed before these dates.

7.4.3 Before it changes a Radiation Safety Officer, except as provided in 7.7.3;

7.4.4 Before it permits anyone to work as an Associate Radiation Safety Officer, or before the Radiation Safety Officer assigns duties to an Associate Radiation Safety Officer that differ from those for which this individual is authorized on the license;

7.4.5 Before it receives radioactive material in excess of the amount or in a different physical or chemical form, or receives a different radionuclide than is authorized on the license;

7.4.6 Before it adds to or changes the areas of use identified in the application or on the license, including areas used in accordance with either 7.30 or 7.32 if the change includes addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide/PET radioactive drug production area. Other areas of use where radioactive material is used only in accordance with either 7.30 or 7.32 are exempt;

7.4.7 Before it changes the address(es) of use identified in the application or on the license;

7.4.8 Before it changes statements, representations, and procedures which are incorporated into the license; or

7.4.9 Before it releases licensed facilities for unrestricted use.

7.4.10 Before it revises procedures required by 7.51, 7.58, 7.59, and 7.61, as applicable, where such revision reduces radiation safety; and

7.4.11 Before it receives a sealed source from a different manufacturer or of a different model number than authorized by its license unless the sealed source is used for manual brachytherapy, is listed in the Sealed Source and Device Registry, and is in a quantity and for an isotope authorized by the license.

7.5 Notifications and maintenance of records.

7.5.1 A licensee shall provide the Department, no later than 30 days after the date that the licensee permits an individual to work under the provisions of 7.4.2 as an authorized user, authorized medical physicist, ophthalmic physicist, or authorized nuclear pharmacist:

7.5.1.1 A copy of the board certification and, as appropriate, verification of completion of:

(1) Training for the authorized medical physicist under 7B3 of Appendix 7B;

(2) Any additional case experience required in 7F2.1(2)(f) of Appendix 7F for an authorized user under 7.36; or

(3) Device specific training in 7M3 of Appendix 7M for the authorized user under 7.48; or

7.5.1.2 A copy of the Department, NRC or Agreement State license, the permit issued by a NRC master material licensee, the permit issued by a NRC or Agreement State licensee of broad scope, the permit issued by a NRC master material license broad scope permittee, or documentation that only accelerator-produced radioactive materials, discrete sources of radium-226, or both, were used for medical use or in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC for each individual whom the licensee permits to work under the provisions of this section.

7.5.2 A licensee shall notify the Department in writing no later than 30 days after:

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

7.5.2.2 The licensee permits an individual qualified to be a Radiation Safety Officer under Appendix 7A and 7.65 to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer in accordance with 7.7.6.

7.5.2.3 The licensee's mailing address changes;

7.5.2.4 The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in Part 3, Section 3.15.2 of these regulations; or

7.5.2.5 The licensee has added to or changed the areas of use identified in the application or on the license where radioactive material is used in accordance with either 7.30 or 7.32 if the change does not include addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide/PET radioactive drug production area; or

7.5.2.6 The licensee obtains a sealed source for use in manual brachytherapy from a different manufacturer or with a different model number than authorized by its license for which it did not require a license amendment as provided in 7.4.11. The notification must include the manufacturer and model number of the sealed source, the isotope, and the quantity per sealed source.

7.5.3 The licensee shall submit the documents required in 7.5.1 and 7.5.2 to the Department.

7.5.4 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.

Section B – General Administrative Requirements

7.7 Authority and responsibilities for the radiation protection program

7.7.1 In addition to the radiation protection program requirements of Part 4, Section 4.5 of these regulations, a licensee's management shall 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 licensee-approved procedures and regulatory requirements. A licensee's management may appoint, in writing, one or more Associate Radiation Safety Officers (ARSO) to support the RSO. The RSO, with written agreement of the licensee's management, must assign the specific duties and tasks to each ARSO. These duties and tasks are restricted to the types of use for which the ARSO is listed on a license. The RSO may delegate duties and tasks to the ARSO but shall not delegate the authority or responsibilities for implementing the radiation protection program.

7.7.3 For up to 60 days each year, a licensee may permit an individual qualified to be a Radiation Safety Officer, under Appendix 7A and 7.65, to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in 7.7.6, if the licensee takes the actions required in 7.7.2, 7.7.5, 7.7.6, and 7.7.7 and notifies the Department in accordance with 7.5.2.

7.7.4 A licensee may simultaneously appoint more than one temporary Radiation Safety Officer in accordance with 7.7.3, if needed to ensure that the licensee has a temporary Radiation Safety Officer that satisfies the requirements to be a Radiation Safety Officer for each of the different types of uses of radioactive material permitted by the license.

7.7.5 A licensee shall establish the authority, duties, and responsibilities of the Radiation Safety Officer in writing.

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

7.7.6.1 Identify radiation safety problems;

7.7.6.2 Initiate, recommend, or provide corrective actions;

7.7.6.3 Stop unsafe operations; and

7.7.6.4 Verify implementation of corrective actions.

7.7.7 A licensee shall retain a record of actions taken under 7.7.1, 7.7.2, and 7.7.5 as follows:

Records of authority and responsibilities for radiation protection programs.

7.7.7.1 A licensee shall retain a record of actions taken by the licensee's management in accordance with 7.7.1 for 5 years. The record must include a summary of the actions taken and a signature of licensee management.

7.7.7.2 The licensee shall retain a copy of both authority, duties, and responsibilities of the Radiation Safety Officer as required by 7.7.5, and a signed copy of each Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by 7.7.2, for the duration of the license. The records must include the signature of the Radiation Safety Officer and licensee management.

7.7.7.3 For each Associate Radiation Safety Officer appointed under 7.7.2, the licensee shall retain, for 5 years after the Associate Radiation Safety Officer is removed from the license, a copy of the written document appointing the Associate Radiation Safety Officer signed by the licensee's management.

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 7.3.1.2(1) shall:

7.10.1.1 In addition to the requirements of Part 10, Section 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 7.3.1.2(2), shall:

7.10.2.1 In addition to the requirements of Part 10, Section 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).

7.10.5 A licensee who permits supervised activities under 7.10.1 and 7.10.2 shall require that the administration of radioactive material or radiation from radioactive material under the supervision of an authorized user be performed only by:

7.10.5.1 A physician;

7.10.5.2 An individual who meets the requirements of Appendix 7B or 7N;

7.10.5.3 An individual in training in medical physics while under personal supervision of an individual meeting the requirements of Appendix 7B;

7.10.5.4 An individual in training in nuclear medicine technology while under personal supervision of an individual meeting the requirements of Appendix 7N; or

7.10.5.5 An individual otherwise authorized in writing by the Department, or through license condition(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, before the 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.

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 is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within 48 hours of the oral directive.

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;

7.11.2.5 For permanent implant brachytherapy:

(1) Before implantation: the treatment site, the radionuclide, and the total source strength: and

(2) After implantation but before the patient leaves the post treatment recovery area: the treatment site, the number of sources implanted, the total source strength implanted, and the date; or

7.11.2.6 For all other brachytherapy, including LDR, MDR, and PDR:

(1) Before implantation: the treatment site, radionuclide, and dose; and

(2) After implantation but before completion of the procedure: the radionuclide; treatment site; number of sources; total source strength and exposure time (or the total dose); and date.

7.11.3 A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

7.11.3.1 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 is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.

7.11.4 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 At a minimum, the procedures required by 7.12.1 must 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 administration is in accordance with the treatment plan, if applicable, and the written directive;

7.12.2.3 Checking both manual and computer-generated dose calculations;

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 or 7.62.

7.12.2.5 Determining if a medical event, as defined in 7.21, has occurred; and

7.12.2.6 Determining, for a permanent implant brachytherapy, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented.

7.12.3 A licensee shall retain a copy of the procedures required under 7.12.1 for the duration of the license.

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 7.3.1.2(1), 7.3.1.2(2) 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.

For medical use, a licensee may only 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 an Agreement State or NRC;

7.14.2 Sealed source or devices non-commercially transferred from a Part 7 licensee or an Agreement State or NRC 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 an Agreement State or NRC.

Section C – General Technical 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 calibration of instruments used to measure the activity of unsealed radioactive material.

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 calibrate the survey instruments used to show compliance with Part 4 and Part 7 before first use, annually at intervals not to exceed 12 months, and following a repair that affects the calibration. A licensee shall:

7.17.1.1 Calibrate all scales with readings up to 10 mSv (1000 mrem) per hour with a radiation source;

7.17.1.2 Calibrate two separate readings on each scale or decade that will be used to show compliance; and

7.17.1.3 Conspicuously note on the instrument the date of calibration.

7.17.2 A licensee may not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than 20 percent.

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

7.17.3.1 Model and serial number of the instrument;

7.17.3.2 Date of the calibration;

7.17.3.3 Results of the calibration; and

7.17.3.4 Name of the individual who performed the calibration.

7.18 Determination of dosages of unsealed radioactive material for medical use.

7.18.1 A licensee shall determine and record the activity of each dosage before 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 an 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.

(3) A PET radioactive drug producer licensed under Part 3, Section 3.8.10 or equivalent NRC or Agreement State requirements.

7.18.3 For other than unit dosages, the determination by 7.18.1 shall be made by:

7.18.3.1 Direct measurement of radioactivity; or

7.18.3.2 Combination of measurement of radioactivity and mathematical calculations; or

7.18.3.3 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 an Agreement State, or NRC.

(2) A PET radioactive drug producer licensed under Part 3, Section 3.8.10 or equivalent NRC or Agreement State requirements.

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;

7.18.5.3 Prescribed dosage;

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

7.18.5.5 Date and time of the dosage determination; and

7.18.5.6 Name of the individual who determined the dosage.

7.19 Authorization for calibration, transmission and reference sources.

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

7.19.1.1 Sealed sources, not exceeding 1.11 GBq (30 mCi) each, manufactured and distributed by a person licensed under Part 3, by NRC under 10 CFR 32.74 or equivalent Agreement State regulations;

7.19.1.2 Sealed sources, not exceeding 1.11 GBq (30 mCi) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under Part 3, by NRC under 10 CFR 32.74 or equivalent Agreement State regulations, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions;

7.19.1.3 Any radioactive material with a half-life not longer than 120 days or less in individual amounts not to exceed 0.56 GBq (15 mCi);

7.19.1.4 Any radioactive material with a half life longer than 120 days in individual amounts not to exceed the smaller of 7.4 MBq (200 uCi) or 1000 times the quantities in Part 3 Schedule 3B; or

7.19.1.5 Technetium-99m in amounts as needed.

7.19.2 Radioactive material in sealed sources authorized by this provision shall not be:

7.19.2.1 Used for medical use as defined in 7.2 except in accordance with the requirements in 7.40; or

7.19.2.1 Combined (i.e., bundled or aggregated) to create an activity greater than the maximum activity of any single sealed source authorized under 7.19.

7.19.3 A licensee using calibration, transmission, and reference sources in accordance with the requirements in 7.19.1 or 7.19.2 need not list these sources on a specific medical use license.

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:

7.20.2.1 Test the source for leakage before its first use unless the licensee has a certificate from the supplier indicating that the sources was tested within 6 months before transfer to the licensee; and

7.20.2.2 Test the source for leakage at intervals not to exceed 6 months or at intervals approved by the Department, an Agreement State, or the NRC in the Sealed Source and Device Registry.

7.20.2.3 A licensee shall retain records of leak tests required by 7.20.2 for 3 years. The records must include the model number, and serial number if one has been assigned, of each source tested; the identity of each source by radionuclide and its estimated activity; the results of the test; the date of the test; and the name of the individual who performed the test.

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 must contain the model number of each source, and serial number if one has been assigned, the identity of each source by radionuclide and its estimated activity, the location of each source, and the name of the individual who performed the inventory.

7.21 Report and notification of a medical event.

7.21.1 A licensee shall report any event as a medical event, except for an event that results from patient or human research subject intervention, in which:

7.21.1.1 The administration of radioactive material or radiation from radioactive material, except permanent implant brachytherapy, results in:

(1) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage 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

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

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

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

(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:

(a) An administration of a wrong radioactive drug containing radioactive material or the wrong radionuclide for a brachytherapy procedure;

(b) An administration of a radioactive drug containing radioactive material by the wrong route of administration;

(c) An administration of a dose or dosage to the wrong individual or human research subject;

(d) An administration of a dose or dosage delivered by the wrong mode of treatment; or

(e) A leaking sealed source.

(3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by:

(a) 0.5 Sievert (50 rem) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and

(b) 50 percent or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.

7.21.1.2 For permanent implant brachytherapy, the administration of radioactive material or radiation from radioactive material (excluding sources that were implanted in the correct site but migrated outside the treatment site) that results in:

(1) The total source strength administered differing by 20 % or more from the total source strength documented in the post-implantation portion of the written directive;

(2) The total source strength administered outside of the treatment site exceeding 20 % of the total source strength documented in the post-implantation portion of the written directive; or

(3) An administration that includes any of the following:

(a) The wrong radionuclide;

(b) The wrong individual or human research subject;

(c) Sealed source(s) implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the written directive; or

(d) A leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue.

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 by telephone the Department no later than the next calendar day after discovery of the medical event.

7.21.4 The licensee shall submit a written report to the Department within 15 days after discovery of the medical event.

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) What actions, if any, have been taken, or are planned to prevent recurrence; and

(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 medical event to the referring physician and also notify the individual who is the subject of the medical event 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 medical event, because of any delay in notification. To meet the requirements of 7.21.5, the notification of the individual who is the subject of the medical event 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 medical event, or to that individual's responsible relatives or guardians.

7.21.7 A licensee shall:

7.21.7.1 Annotate a copy of the report provided to the Department with the:

(1) Name of the individual who is the subject of the event; and

(2) Identification number or if no other identification number is available, the social security number of the individual who is the subject of the event; and

7.21.7.2 Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

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 Part 4, section 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 Department 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 Department 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 provide notification of the event to 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 7.23.5, 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:

7.23.6.1 Annotate a copy of the report provided to the Department with the:

(1) Name of the pregnant individual or the nursing child who is the subject of the event; and

(2) Identification number or if no other identification number is available, the social security number of the individual who is the subject of the event.

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 Labeling of vials and syringes.

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 unsealed radioactive material or implants containing radioactive material.

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 to its radioactivity if it:

7.29.1.1 Monitors radioactive material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and

7.29.1.2 Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee; and

7.29.2 Records of Decay-in-Storage.

A licensee shall retain a record of each disposal permitted under 7.29.1 as follows:

7.29.2.1 A licensee shall maintain records of the disposal of licensed materials, as required by 7.29, 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.

Section D – Unsealed Radioactive Material – Written Directive Not Required

7.30 Use of unsealed radioactive material for uptake, dilution, and excretion studies for which a written directive is not required.

7.30.1 Except for quantities that require a written directive under 7.11.2, a licensee may use any unsealed radioactive material prepared for medical use for uptake, dilution, or excretion studies that is:

7.30.1.1 Obtained from:

(1) A manufacturer or preparer licensed under Part 3, Section 3.12.10 or equivalent regulations of an Agreement State, or NRC; or;

(2) A PET radioactive drug producer licensed under Part 3, Section 3.8.10 or equivalent regulations of an Agreement State or NRC; or

7.30.1.2 Excluding production of PET radionuclides, prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements specified in Appendix 7E, or Appendix 7F and Section 7E3.1(2)(g) of Appendix 7E; or

(3) An individual under the supervision, as specified in 7.10, of the authorized nuclear pharmacist in 7.30.1.2(1) or the physician who is an authorized user in 7.30.1.2(2); or

7.30.1.3 Obtained from and prepared by a Department, Agreement 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 Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

7.30.2 Training For Uptake, Dilution, And Excretion Studies.

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

7.31 Reserved

7.32 Use of unsealed radioactive material for imaging and localizations studies for which a written directive is not required.

Except for quantities that require a written directive under 7.11, a licensee may use any unsealed radioactive material prepared for medical use for imaging and localization studies that is:

7.32.1 Obtained from:

7.32.1.1 A manufacturer or preparer licensed pursuant to Part 3, Section 3.12.10 or equivalent regulations of an Agreement State, or NRC; or

7.32.1.2 A PET radioactive drug producer licensed under Part 3, Section 3.8.10; or

7.32.2 Excluding production of PET radionuclides, prepared by:

7.32.2.1 An authorized nuclear pharmacist;

7.32.2.2 A physician who is an authorized user and who meets the requirements specified in Appendix 7E, or Appendix 7F and 7E3.1(2)(g); or

7.32.2.3 An individual under the supervision, as specified in 7.10, of the authorized nuclear pharmacist in 7.32.2.1 or the physician who is an authorized user in 7.32.2.2;

7.32.3 Obtained from and prepared by a Department, Agreement 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

7.32.4 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.

7.32.5 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 Permissible molybdenum-99, strontium-82, and strontium-85 concentrations.

7.33.1 A licensee may not administer to humans a radioactive drug that contains:

7.33.1.1 More than 0.15 kBq of molybdenum-99 per MBq of technetium-99m (0.15 µCi of 99Mo per mCi of 99mTc); or

7.33.1.2 More than 0.02 kBq of strontium-82 per MBq of rubidium-82 chloride injection (0.02 µCi of 82Sr per mCi of 82Rb chloride); or more than 0.2 kBq of strontium-85 per MBq of rubidium-82 chloride injection (0.2 µCi of 85Sr per mCi of 82Rb).

7.33.2 A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radioactive drug shall measure the molybdenum-99 concentration in each eluate from a generator to demonstrate compliance with 7.33.1.

7.33.3 A licensee that uses a strontium-82/rubidium-82 generator for preparing a rubidium-82 radioactive drug shall, before the first patient use of the day, measure the concentration of radionuclides strontium-82 and strontium-85 to demonstrate compliance with 7.33.1.

7.33.4 If a licensee is required to measure the molybdenum-99 concentration or strontium-82 and strontium-85 concentrations, the licensee shall retain a record of each measurement as follows:

7.33.4.1 A licensee shall maintain a record of the molybdenum-99 concentration or strontium-82 and strontium-85 concentration tests required by 7.33.2 and 7.33.3 for 3 years. The record must include:

(1) For each measured elution of technetium-99m, the ratio of the measures expressed as kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (or microcuries of molybdenum per millicurie of technetium), the time and date of the measurement, and the name of the individual who made the measurement; or

(2) For each measured elution of rubidium-82, the ratio of the measures expressed as kilobecquerel of strontium-82 per megabecquerel of rubidium-82 (or microcuries of strontium-82 per millicurie of rubidium), kilobecquerel of strontium-85 per megabecquerel of rubidium-82 (or microcuries of strontium-85 per millicurie of rubidium), the time and date of the measurement, and the name of the individual who made the measurement.

7.33.5 The licensee shall report any measurement that exceeds the limits in 7.33.1 at the time of generator elution, as follows:

Report and notification for an eluate exceeding permissible molybdenum-99, strontium-82, and strontium-85 concentrations.

7.33.5.1 The licensee shall notify by telephone the Department and the distributor of the generator within 7 calendar days after discovery that an eluate exceeded the permissible concentration listed in 7.33.1 at the time of generator elution. The telephone report to the Department must include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects, when the distributor was notified, and the action taken.

7.33.5.2 The licensee shall submit a written report to the Department within 30 calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report must include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; and the probable cause and an assessment of failure in the licensee's equipment, procedures or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination; and the information in the telephone report as required by 7.33.5.1.

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 Reserved

Section E – 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 identified in 7F2.1(2)(f) prepared for medical use and for which a written directive is required that is:

7.36.1.1 Obtained from:

(1) A manufacturer or preparer licensed under Part 3, Section 3.12.10 or equivalent regulations of NRC or an Agreement State; or

(2) A PET radioactive drug producer licensed under Part 3, Section 3.8.10 or equivalent Agreement State or NRC regulations; or

7.36.1.2 Excluding production of PET radioactive material, prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements specified in Appendix 7E, or Appendix 7F; or

(3) An individual under the supervision, as specified in 7.10, of the authorized nuclear pharmacist in 7.36.1.2(1) or the physician who is authorized under 7.36.1.2(2); or

7.36.1.3 Obtained from and prepared by a Department, Agreement State, or NRC licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA; or

7.36.1.4 Prepared by the licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA.

7.36.2 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 Training For Oral Administration of < / = 1.22 GBq 131I (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 131I (33 mCi) sodium iodide requiring a written directive under 7.36 to meet the requirements of Appendix 7G.

7.36.4 Training For Oral Administration Of > 1.22 GBq 131I (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 131I (33 mCi) sodium iodide requiring a written directive under 7.36 to meet the requirements of Appendix 7H.

7.36.5 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 A licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who cannot be released in accordance with 7.26. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include:

7.37.1.1 Patient or human research subject control;

7.37.1.2 Visitor control, including:

(1) Routine visitation to hospitalized individuals in accordance with Part 4, Section 4.14.1.1 of these regulations; and

(2) Visitation authorized in accordance with Part 4, Section 4.14.2;

7.37.1.3 Contamination control;

7.37.1.4 Waste control; and

7.37.1.5 Notification of the RSO, or his or her designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.

7.37.2 A licensee shall retain a record of individuals receiving safety instructions required by 7.37 and maintain such records for 3 years. The record must include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

7.38 Safety precautions.

7.38.1 For each patient or human research subject who cannot be released under 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 therapy with unsealed radioactive material and who also cannot be released in accordance with 7.26; and

7.38.1.2 Visibly post the patient's or the human research subject's room with a "Radioactive Materials" sign.

7.38.1.3 Note on the door or in 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; and

7.38.1.4 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 the materials and items as radioactive waste.

7.38.2 A licensee shall 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 or dies.

7.39 Reserved.

Section F – Sealed Sources for Diagnosis

7.40 Use of sealed sources and medical devices for diagnosis.

7.40.1 A licensee must use only sealed sources that are not in medical devices for diagnostic medical uses if the sealed sources are approved in the Sealed Source and Device Registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

7.40.2 A licensee must only use medical devices containing sealed sources for diagnostic medical uses if both the sealed sources and medical devices are approved in the Sealed Source and Device Registry for diagnostic medical uses. The diagnostic medical devices may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

7.40.3 Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of 7.14.1 are met.

7.40.4 Training for use of sealed sources and medical devices for diagnosis.

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

Section G – Manual Brachytherapy

7.41 Calibration measurements of brachytherapy sources.

7.41.1 Before the first medical use of a brachytherapy source, a licensee shall have:

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

7.41.1.2 Determined source positioning accuracy within applicators; and

7.41.1.3 Used published protocols currently accepted by nationally recognized bodies to meet the requirements of 7.41.1.1 and 7.41.1.2.

7.41.2 Instead of a licensee making its own measurements as required in 7.41.1, the 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 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 A licensee shall retain a record of each calibration as follows:

7.41.5.1 A licensee shall maintain a record of the calibrations of brachytherapy sources required by 7.41.1 for 3 years after the last use of the source.

7.41.5.2 The record must include:

(1) The date of the calibration;

(2) The manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source;

(3) The source output or activity;

(4) The source positioning accuracy within the applicators; and

(5) The name of the individual, the source manufacturer, or the calibration laboratory that performed the calibration.

7.41.6 Strontium-90 sources for ophthalmic treatments.

7.41.6.1 Licensees who use strontium-90 for ophthalmic treatments must ensure that certain activities as specified in 7.41.6.2 are performed by either:

(1) An authorized medical physicist; or

(2) An individual who:

(a) Is identified as an ophthalmic physicist on a specific medical use license issued by NRC or an Agreement State; permit issued by a NRC or Agreement State broad scope medical use licensee; medical use permit issued by a NRC master material licensee; or permit issued by a NRC master material license broad scope medical use permittee; and

(b) Holds a master's or doctor's degree in physics, medical physics, other physical sciences, engineering, or applied mathematics from an accredited college or university; and

(c) Has successfully completed 1 year full-time training in medical physics and an additional year of full-time work experience under the supervision of a medical physicist; and

(d) Has documented training in:

(i) The creation, modification, and completion of written directives;

(ii) Procedures for administrations requiring a written directive; and

(iii) Performing the calibration measurements of brachytherapy sources as detailed in 7.41.1 through 7.41.5.

7.41.6.2 The individuals who are identified in 7.41.6.1 must:

(1) Calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under 7.41.1 through 7.41.5; and

(2) Assist the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the administration is in accordance with the written directive. These procedures must include the frequencies that the individual meeting the requirements in 7.41.6.1 will observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the administrations were in accordance with the written directives.

7.41.6.3 Licensees must retain a record of the activity of each strontium-90 source as follows:

(1) A licensee shall maintain a record of the activity of a strontium-90 source required by 7.41.6 for the life of the source.

(2) The record must include:

(a) The date and initial activity of the source as determined under 7.41.1 through 7.41.5; and

(b) For each decay calculation, the date and the source activity as determined under 7.41.6.

7.42 Use of sealed sources for manual brachytherapy.

7.42.1 A licensee must use only brachytherapy sources:

7.42.1.1 Approved in the Sealed Source and Device Registry for manual brachytherapy use. The manual brachytherapy sources may be used for manual brachytherapy uses that are not explicitly listed in the Sealed Source and Device Registry, but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

7.42.1.2 In research to deliver therapeutic doses for medical use in accordance with an active 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.

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

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 Part 4, Section 4.14.1.1; and

(2) Visitation authorized in accordance with Part 4, Section 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 retain a record of individuals receiving safety instructions required by 7.43.1 and maintain such records for 3 years. The record must include a list of the topics covered, the date of the instruction, the names(s) of the attendee(s), and the name(s) of the individual(s) who provided 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 an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

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 As soon as possible after removing brachytherapy sources from a patient or a human research subject, 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:

(1) The number and activity of sources 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) The number and activity of sources returned to storage, 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:

(1) The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;

(2) The number and activity of sources not implanted, the date they were returned to storage, the date they were returned to storage, and the name of the individual who returned them to storage; and

(3) The number and activity of sources 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 7.46.2 for 3 years. Each record must 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 of therapy-related computer systems 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;

7.47.2.2 The accuracy of dose, dwell time, and treatment time calculations at representative points;

7.47.2.3 The accuracy of isodose plots and graphic displays; and

7.47.2.4 The accuracy of the software used to determine radioactive source positions from radiographic images.

Section H - Photon Emitting Remote Afterloader Units, Teletheraphy 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 must only use sealed sources:

7.48.1.1 Approved and as provided for in the Sealed Source and Device Registry in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units to deliver therapeutic doses for medical uses; or

7.48.1.2 In research involving photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of 7.14.1 are met.

7.48.2 A licensee must use photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units:

7.48.2.1 Approved in the Sealed Source and Device Registry to deliver a therapeutic dose for medical use. These devices may be used for therapeutic medical treatments that are not explicitly provided for in the Sealed Source and Device Registry, but must be used in accordance with radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

7.48.2.2 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.

7.48.3 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, an 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, an Agreement 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, an Agreement 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 of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units for 3 years. For each installation, maintenance, adjustment and repair, the record must 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.

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 remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

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);

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. These procedures 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 must be physically located at the unit console.

7.51.3 A licensee shall post instructions at the unit console to inform the operator of:

7.51.3.1 The location of the procedures required by 7.51.1.4; and

7.51.3.2 The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

7.51.4 Operational and safety training.

7.51.4.1 Prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit, a licensee shall ensure that vendor operational and safety training is provided to all individuals who will operate the unit. The vendor operational and safety training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training.

7.51.4.2 A licensee shall provide operational and safety instructions, initially and at least annually, to all individuals who operate the unit at the facility, as appropriate to the individual's assigned duties. The instructions shall include instruction in:

(1) The procedures identified in 7.51.1.4; and

(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 retain a record of individuals receiving instruction required by 7.51.4 in accordance with the following:

(1) A licensee shall maintain a record of the operational and safety instructions required by 7.51.4 for 3 years. The record must include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

7.51.7 A licensee shall retain a copy of the procedures required by 7.51.1.4 and 7.51.4.2(2) until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.

7.52 Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

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 will:

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 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 applicable emergency response equipment available near each treatment room to respond to a source:

7.52.7.1 Remaining in the unshielded position; or

7.52.7.2 Lodged 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 must be met:

7.53.1.1 The system must 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 must 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 retain a record of each calibration, intercomparison, and comparison for the duration of the license. For each calibration, intercomparison, or comparison, the record must 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 was 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).

Records of surveys of therapeutic treatment units

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 individual 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 that include 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 notify the licensee as soon as possible 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 7.58.4, and a copy of the procedures required by 7.58.2 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, and a copy of the procedures required by 7.59.2 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 for mobile remote afterloader units 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, 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 Before the first use on a given day; and

7.61.1.3 After each source installation.

7.61.2 A licensee shall:

7.61.2.1 Perform the measurements required by 7.61.1 in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

7.61.2.2 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.

7.61.3 To satisfy the requirements of 7.61.1 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 spot-check for gamma stereotactic radiosurgery units 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.

7.61.8 A licensee shall retain a copy of the procedures required by 7.61.2 until the licensee no longer possesses the gamma stereotactic radiosurgery unit.

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 Department, an Agreement State, or NRC in a license and uses the material in accordance with the regulations and specific conditions that the Department, Agreement State, or NRC considers necessary for the medical use of the material.

7.63 Full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units

7.63.1 A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during each source replacement to assure proper functioning of the source exposure mechanism and other safety components. The interval between each full inspection servicing shall not exceed 5 years for each teletherapy unit and shall not exceed 7 years for each gamma stereotactic radiosurgery unit.

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

Records of full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units.

7.63.3 A licensee shall maintain a record of the full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units required by 7.63 for the duration of the use of the unit.

7.63.4 The record required by 7.63.3 must contain:

7.63.4.1 The inspector's radioactive materials license number;

7.63.4.2 The date of inspection;

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

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

7.63.4.5 The signature of the inspector.

7.64 Therapy-related computer systems.

7.64.1 The licensee shall perform acceptance testing on the treatment planning system in accordance with published protocols accepted by nationally recognized bodies.

7.64.2 At a minimum, the acceptance testing required by 7.64.1 shall include, as applicable, verification of:

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

7.64.2.2 The accuracy of dose, dwell time, and treatment time calculations at representative points;

7.64.2.3 The accuracy of isodose plots and graphic displays; and

7.64.2.4 The accuracy of the software used to determine radioactive source positions from radiographic images.

7.64.2.5 The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

Section I – Recentness of training.

7.65 The training and experience specified in 7.65.1 through 7.65.6 must have been obtained within the 7 years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

7.65.1 Section B, Section I, Appendix 7A, 7B, 7C, and 7P.

7.65.2 Section D, Appendix 7D, and 7E.

7.65.3 Section E, Appendix 7F, 7G, 7H and 7I.

7.65.4 Section F, Appendix 7J.

7.65.5 Section G, Appendix 7K and Appendix 7L.

7.65.6 Section H, and Appendix 7M.

PART 7, APPENDIX 7A: TRAINING FOR RADIATION SAFETY OFFICER (RSO) AND ASSOCIATE RADIATION SAFETY OFFICER (ARSO)

Except as provided in Appendix 7P, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer (RSO) or an individual assigned duties and tasks as an Associate Radiation Safety Officer (ARSO) as provided in 7.7 to be an individual who:

7A1 Is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in 7A4 of this Appendix. The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page. 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;

(2) Have 5 or more years of professional experience in health physics (graduate training may be substituted for no more than 2 years of the required experience) including at least 3 years in applied health physics;

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:

(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 or therapeutic services under the direction of physicians who meet the requirements for Authorized Users in Appendix 7P, 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

7A2.1 Has completed a structured educational program consisting of both:

(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) One year of full-time radiation safety experience, under the supervision of the individual identified as the RSO, on a NRC or an Agreement State license or permit issued by a NRC master material licensee that authorizes similar type(s) of use(s) of radioactive material. An Associate Radiation Safety Officer may provide supervision for those areas for which the Associate Radiation Safety Officer is authorized on a NRC or an Agreement State license or permit issued by a NRC master material licensee. The full-time radiation safety experience must involve the following:

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

(b) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and 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

7A2.2 This individual must obtain a written attestation, signed by a preceptor RSO or ARSO who has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual is seeking approval as a RSO or an ARSO. The written attestation must state that the individual has satisfactorily completed the requirements in 7A2.1 and 7A4 of Appendix 7A and is able to independently fulfill the radiation safety related duties as a RSO or as an ARSO for a medical use license;

or

7A3

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 7B, Section 7B1, has experience with the radiation safety aspects of similar types of use of radioactive material for which the licensee seeks the approval of the individual as RSO or an ARSO, and meets the requirements in 7A4.

or

7A3.2 Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on a Department, NRC or an Agreement State license, a permit issued by a NRC master material licensee, a permit issued by a NRC or an Agreement State licensee of broad scope, or a permit issued by a NRC master material license broad scope permittee, has experience with the radiation safety aspects of similar types of use of radioactive material for which the licensee seeks the approval of the individual as the RSO or ARSO, and meets the requirements in 7A4;

or

7A3.3 Has experience with the radiation safety aspects of the types of use of radioactive material for which the individual is seeking simultaneous approval both as the Radiation Safety Officer and the authorized user on the same new medical use permit issued by a NRC master material licensee. The individual must also meet the requirements in 7A4.

and

7A4 Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by an RSO, an Associate RSO, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

PART 7, APPENDIX 7B: TRAINING FOR AN AUTHORIZED MEDICAL PHYSICIST (AMP)

Except as provided in Appendix 7P, the licensee shall require the authorized medical physicist to be an individual who:

7B1 Is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in 7B3 of this Appendix. The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

7B1.1 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;

7B1.2 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 whose certification process has been recognized under 7B1 by the NRC or an Agreement State;

or

(2) 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 in Appendix 7P, Appendix 7K or Appendix 7M;

and

7B1.3 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

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 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. This training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services and must include:

(1) Performing sealed source leak tests and inventories;

(2) Performing decay corrections;

(3) Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable;

and

(4) Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable;

and

7B2.2 Has obtained written attestation that the individual has satisfactorily completed the requirements in 7B2.1 and 7B3, and is able to independently fulfill the radiation safety-related duties 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 Appendix 7B, Appendix 7P, 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 training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

PART 7, APPENDIX 7C: TRAINING FOR AND AUTHORIZED NUCLEAR PHARMACIST (ANP)

Except as provided in Appendix 7P, the licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

7C1 Is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

7C1.1 Have graduated from a pharmacy program accredited by the Accreditation Council for Pharmacy Education (ACPE) (previously named the American Council on Pharmaceutical Education) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

7C1.2 Hold a current, active license to practice pharmacy;

7C1.3 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

7C1.3 Pass an examination in nuclear pharmacy administered by diplomates of the specialty board, that 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

7C2.1 Has completed 700 hours in a structured educational program consisting of both:

(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 medical events 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 obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in 7C2.1, and is able to independently fulfill the radiation safety related duties as an authorized nuclear pharmacist.

PART 7, APPENDIX 7D: TRAINING FOR UPTAKE, DILUTION AND EXCRETION STUDIES

Except as provided in Appendix 7P, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under 7.30 to be a physician who:

7D1 Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State. The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

7D1.1 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);

7D1.2 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

7D3.1 Has 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 in Appendix 7P, 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 medical event 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 obtained written attestation that the individual has satisfactorily completed the requirements in 7D3.1 and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under 7.30. The attestation must be obtained from either:

(1) A preceptor authorized user who meets the requirements in Appendix 7P, Appendix 7D, Appendix 7E, or Appendix 7F, or equivalent NRC or Agreement State requirements; or

(2) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Appendix 7P, Appendix 7D, Appendix 7E, Appendix 7F, or equivalent NRC or Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be 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 Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 7D3.1.

PART 7, APPENDIX 7E: TRAINING FOR IMAGING AND LOCALIZATION STUDIES

Except as provided in Appendix 7P, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under 7.32 to be a physician who:

7E1 Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State. The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

7E1.1 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

7E1.2 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

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 material for imaging and localization studies. The training and experience 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 in Appendix 7P, 7E, or 7F and 7E3.1(2)(g), or equivalent NRC or Agreement State requirements. An authorized nuclear pharmacist who meets the requirements in Appendix 7C or Appendix 7P may provide the supervised work experience for 7E3.1(2)(g). 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 medical event involving the use of unsealed radioactive material;

(e) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

(f) Administering dosages to patients or human research subjects; and

(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 obtained written attestation that the individual has satisfactorily completed the requirements in 7E3.1 and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under 7.30 and 7.32. The attestation must be obtained from either:

(1) A preceptor authorized user who meets the requirements in Appendix 7P, 7E, or 7F and 7E3.1(2)(g), or equivalent NRC or Agreement State requirements;

or

(2) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Appendix 7P, 7E, or 7F and 7E3.1(2)(g), or equivalent NRC or Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be 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 Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 7E3.1.

PART 7, APPENDIX 7F: TRAINING FOR USE OF UNSEALED RADIOACTIVE MATERIAL FOR WHICH A WRITTEN DIRECTIVE IS REQUIRED

Except as provided in Appendix 7P, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under 7.36 to be a physician who:

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 7F2.1(2)(f). The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page. To be recognized, a specialty board shall require all candidates for certification to:

7F1.1 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 Council on Postdoctoral Training of the American Osteopathic Association;

and

7F1.2 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

7F2.1 Has 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 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 Appendix 7P, 7F, or equivalent Agreement State or NRC requirements. A supervising authorized user, who meets the requirements in 7F2, 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 medical event 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 from the three categories in 7F2.1(2)(f). Radioactive drugs containing radionuclides in categories not included in 7F2.1(2)(f) are regulated under 7.62. This work experience must involve a minimum of three 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 gigabecquerels (33 millicuries) of sodium iodide I-131, for which a written directive is required;

(ii) Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131;[2]

(iii) Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy less than 150 keV, for which a written directive is required;

and

7F2.2 Has obtained written attestation that the individual has satisfactorily completed the requirements in 7F2.1 and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under 7.36. The attestation must be obtained from either:

(1) A preceptor authorized user who meets the requirements in 7P, 7F, or equivalent Agreement State requirements and has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status; or

(2) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in 7P, 7F, or equivalent Agreement State or NRC requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be 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 Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 7F2.1.

2 Experience with at least three cases in Category 7F2.1(2)(f)(ii) also satisfies the requirement in Category 7F2.1(2)(f)(i).

PART 7, APPENDIX 7G: 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)

Except as provided in Appendix 7P, the licensee shall require an authorized user for the oral administration of sodium iodide requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries), to be a physician who:

7G1 Is certified by a medical specialty board whose certification process includes all of the requirements in 7G3.1 and 7G3.2 of this Appendix and whose certification process has been recognized by the NRC or an Agreement State. The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page;

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

7G3.1 Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity;

(4) Chemistry of radioactive material for medical use; and

(5) Radiation biology;

and

7G3.2 Has work experience, under the supervision of an authorized user who meets the requirements in Appendix 7P, Appendix 7F, Appendix 7G, Appendix 7H or equivalent Agreement State or NRC requirements. A supervising authorized user, who meets the requirements in 7F2, must also have experience in administering dosages as specified in 7F2.1(2)(f)(i) or 7F2.1(2)(f)(ii). The work experience must involve:

(1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(2) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(3) Calculating, measuring, and safely preparing patient or human research subject dosages;

(4) Using administrative controls to prevent a medical event involving the use of radioactive material;

(5) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

and

(6) 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

7G3.3 Has obtained written attestation that the individual has satisfactorily completed the requirements in 7G3.1 and 7G3.2, and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under 7.36. The attestation must be obtained from either:

(1) A preceptor authorized user who meets the requirements in Appendix 7P, Appendix 7F, Appendix 7G, Appendix 7H, or equivalent NRC or Agreement State requirements and has experience administering dosages as specified in 7F2.1(2)(f)(i) or 7F2.1(2)(f)(ii);

or

(2) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Appendix 7P, Appendix 7F, Appendix 7G, Appendix 7H, or equivalent NRC or Agreement State requirements, has experience in administering dosages as specified in 7F2.1(2)(f)(i) or 7F2.1(2)(f)(ii), and concurs with the attestation provided by the residency program director. The residency training program must be 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 Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 7G3.1 and 7G3.2.

PART 7, APPENDIX 7H: TRAINING FOR THE ORAL ADMINISTRATION OF SODIUM IODIDE I-131 REQUIRING A WRITTEN DIRECTIVE IN QUANTITIES GREATER THAN 1.22 GIGABECQUERELS (33 millicuries)

Except as provided in Appendix 7P, 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 Gigabecquerels (33 millicuries), to be a physician who:

7H1 Is certified by a medical specialty board whose certification process includes all of the requirements in 7H3.1, and 7H3.2 and whose certification has been recognized by the NRC or an Agreement State. The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page;

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

7H3.1 Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity;

(4) Chemistry of radioactive material for medical use; and

(5) Radiation biology;

and

7H3.2 Has work experience, under the supervision of an authorized user who meets the requirements in Appendix 7P, Appendix 7F, Appendix 7H or equivalent Agreement State or NRC requirements. A supervising authorized user, who meets the requirements in 7F2, must also have experience in administering dosages as specified in 7F2.1(2)(f)(ii). The work experience must involve:

(1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(2) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(3) Calculating, measuring, and safely preparing patient or human research subject dosages;

(4) Using administrative controls to prevent a medical event involving the use of radioactive material;

(5) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

and

(6) 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

7H3.3 Has obtained written attestation that the individual has satisfactorily completed the requirements in 7H3.1 and 7H3.2, and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under 7.36. The attestation must be obtained from either:

(1) A preceptor authorized user who meets the requirements in Appendix 7P, Appendix 7F, or Appendix 7H, or equivalent NRC or Agreement State requirements and has experience in administering dosages as specified in 7F2.1(2)(f)(ii); or

and

(2) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Appendix 7P, Appendix 7F, Appendix 7H, or equivalent NRC or Agreement State requirements, has experience in administering dosages as specified in F2.1(2)(f)(ii), and concurs with the attestation provided by the residency program director. The residency training program must be 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 Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 7H3.1 and 7H3.2.

PART 7, APPENDIX 7I: TRAINING FOR THE PARENTERAL ADMINISTRATION OF UNSEALED RADIOACTIVE MATERIAL REQUIRING A WRITTEN DIRECTIVE

7I1 Except as provided in Appendix 7P, the licensee shall require an authorized user for the parenteral administration requiring a written directive to be a physician who:

7I1.1 Is an authorized user under Appendix 7F for uses listed in 7F2.1(2)(f)(iii), or equivalent NRC or Agreement State requirements;

or

7I1.2 Is an authorized user under Appendix 7K, Appendix 7M, or equivalent NRC or Agreement State requirements and who meets the requirements in 7I2;

or

7I1.3 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 7I2 of this section.

7I2 The physician:

7I2.1 Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations listed in 7F2.1(2)(f)(iii). The training must include:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity;

(4) Chemistry of radioactive material for medical use;

and

(5) Radiation biology;

and

7I2.2 Has work experience under the supervision of an authorized user who meets the requirements of Appendix 7P, Appendix 7F, Appendix 7I, or equivalent Agreement State or NRC requirements, in the parenteral administrations listed in 7F2.1(2)(f)(iii).A supervising authorized user, who meets the requirements in Appendix 7F, 7I, or equivalent Agreement State or NRC requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status. The work experience must involve:

(1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(2) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(3) Calculating, measuring, and safely preparing patient or human research subject dosages;

(4) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(5) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

and

(6) Administering dosages to patients or human research subjects that include at least 3 cases involving the parenteral administrations as specified in 7F2.1(2)(f)(iii)

and

7I2.3 Has obtained written attestation that the individual has satisfactorily completed the requirements in7I2.1 or 7I2.2, and is able to independently fulfill the radiation safety-related duties as an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive. The attestation must be obtained from either:

(1) A preceptor authorized user who meets the requirements in Appendix 7P, Appendix 7F, 7I, or equivalent Agreement State or NRC requirements. A preceptor authorized user who meets the requirements in Appendix 7F, 7I, or equivalent Agreement State or NRC requirements, must have experience in administering dosages in the same category or categories as the individuals requesting authorized user status;

or

(2) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Appendix 7P, Appendix 7F, Appendix 7I, or equivalent Agreement State or NRC requirements, has experience in administering dosages in the same dose category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be 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 Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 7I2.1 and 7I2.2.

PART 7, APPENDIX 7J: TRAINING FOR USE OF SEALED SOURCES AND MEDICAL DEVICES FOR DIAGNOSIS

Except as provided in Appendix 7P, the licensee shall require the authorized user of a diagnostic sealed source or a device authorized under 7.40 to be a physician, dentist, or podiatrist who:

7J1 Is certified by a specialty board whose certification process includes all of the requirements in 7J3 and 7J4 and whose certification process has been recognized by the NRC or an Agreement State. The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page;

or

7J2 Is an authorized user for uses listed in 7.32 or equivalent NRC or Agreement State requirements;

or

7J3 Has completed 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity;

(4) Radiation biology;

and

7J4 Has completed training in the use of the device for the uses requested.

PART 7, APPENDIX 7K: TRAINING FOR USE OF MANUAL BRACHYTHERAPY SOURCES

Except as provided in Appendix 7P, the licensee shall require an authorized of a manual brachytherapy source for the uses authorized under 7.42 to be a physician who:

7K1 Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State. The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

7K1.1 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 Council on Postdoctoral Training of the American Osteopathic Association;

and

7K1.2 Pass an examination, administered by diplomates 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

7K2.1 Has completed a structured educational program in basic radionuclide handling techniques applicable to the 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 Appendix 7P, Appendix 7K, or equivalent NRC or Agreement State requirements at a medical facility authorized to use radioactive materials under 7.42, 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 medical event 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 Appendix 7P, Appendix 7K, 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 Council on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by 7K2.1

and

and

7K2.3 Has obtained written attestation that the individual has satisfactorily completed the requirements in 7K2.1 and 7K2.2 and is able to independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy sources for the medical uses authorized under 7.42. The attestation must be obtained from either:

(1) A preceptor authorized user who meets the requirements in Appendix 7P, Appendix 7K, or equivalent Agreement State or NRC requirements.

or

(2) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Appendix 7P, Appendix 7K, or equivalent Agreement State or NRC requirements, and concurs with the attestation provided by the residency program director. The residency training program must be 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 Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 7K2.1 and 7K2.2.

PART 7, APPENDIX 7L: TRAINING FOR OPHTHALMIC USE OF STRONTIUM-90

Except as provided in Appendix 7P, the licensee shall require the authorized of strontium-90 for ophthalmic radiotherapy to be a physician who:

7L1 Is an authorized user under Appendix 7K or equivalent NRC or Agreement State requirements;

or

7L2

7L2.1 Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity; and

(4) Radiation biology;

and

7L2.2 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:

(1) Examination of each individual to be treated;

(2) Calculation of the dose to be administered;

(3) Administration of the dose; and

(4) Follow-up and review of each individual's case history;

and

7L3.3 Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in Appendix 7P, Appendix 7K, Appendix 7L, or equivalent NRC or Agreement State requirements, that the individual has satisfactorily completed the requirements of 7L2.1 and 7L2.2 and is able to independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.

PART 7, APPENDIX 7M: TRAINING FOR USE OF REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS

Except as provided in Appendix 7P, the licensee shall require an authorized user of a sealed source for a use authorized under 7.48 to be a physician who:

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 7M3. The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

7M1.1 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 Council on Postdoctoral Training of the American Osteopathic Association;

and

7M1.2 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;

or

7M2

7M2.1 Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source 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; and

(d) Radiation biology;

and

(2) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in Appendix 7P, Appendix 7M, or equivalent Agreement State or NRC requirements at a medical facility that is authorized to use radioactive materials in 7.48, 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 medical event 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 Appendix 7P, 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 Council on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by 7M2.1(2);

and

7M2.3 Has obtained written attestation that the individual has satisfactorily completed the requirements in 7M2.1 and 7M2.2 and 7M3; and is able to independently fulfill the radiation safety-related duties as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The attestation must be obtained from either:

(1) A preceptor authorized user who meets the requirements in Appendix 7P, Appendix 7M, or equivalent Agreement State or NRC requirements for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status;

or

(2) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Appendix 7P, Appendix 7M, or equivalent Agreement State or NRC requirements, for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be 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 Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 7M2.1 and 7M2.2.

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 satisfactory completion of a training program provided by the vendor for new users or 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.

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 can, upon the request of the Department, demonstrate:

7N1 Evidence of:

7N1.1 Current registration with The American Registry of Radiologic Technologists with competency in Nuclear Medicine (ARRT(N));

or

7N1.2 Current certification by The Nuclear Medicine Technology Certification Board in Nuclear Medicine (CNMT);

or

7N1.3 Being board-eligible to take the CNMT or ARRT(N) examination;

or

7N1.4 Current certification by a specialty board recognized in writing by the Department;

or

7N2 Is able to demonstrate adequate prior experience as:

7N2.1 A full-time nuclear medicine technologist for a minimum of two years during the past five-year period prior to August 14, 2020 under the supervision of an authorized user and has achieved a level of competency sufficient to function independently as a nuclear medicine technologist;

or

7N2.2 An experienced nuclear medicine technologist working at a facility holding a Department license before October 25, 2005.

PART 7, APPENDIX 7O: RESERVED

PART 7, APPENDIX 7P: TRAINING FOR EXPERIENCED RADIATION SAFETY OFFICER, TELETHERAPY OR MEDICAL PHYSICIST, AUTHORIZED MEDICAL PHYSICIST, AUTHORIZED USER, NUCLEAR PHARMACIST, AND AUTHORIZED NUCLEAR PHARMACIST.

7P1

7P1.1 An individual identified on a Department, NRC or an Agreement State license or a permit issued by a Department, NRC or an Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope as a Radiation Safety Officer, a teletherapy or medical physicist, an authorized medical physicist, a nuclear pharmacist or an authorized nuclear pharmacist on or before August 14, 2020 need not comply with the training requirements of Appendix 7A, 7B, or 7C, respectively, except the Radiation Safety Officers and authorized medical physicists identified in 7P1.1 must meet the training requirements in 7A4 of Appendix 7A or 7B3 of Appendix 7B, as appropriate, for any material or uses for which they were not authorized prior to this date.

7P1.2 Any individual certified by the American Board of Health Physics in Comprehensive Health Physics; American Board of Radiology; American Board of Nuclear Medicine; American Board of Science in Nuclear Medicine; Board of Pharmaceutical Specialties in Nuclear Pharmacy; American Board of Medical Physics in radiation oncology physics; Royal College of Physicians and Surgeons of Canada in nuclear medicine; American Osteopathic Board of Radiology; or American Osteopathic Board of Nuclear Medicine on or before October 24, 2005, need not comply with the training requirements of Appendix 7A to be identified as a Radiation Safety Officer or as an Associate Radiation Safety Officer on an NRC or an Agreement State license or NRC master material license permit for those materials and uses that these individuals performed on or before October 24, 2005.

7P1.3 Any individual certified by the American Board of Radiology in therapeutic radiological physics, Roentgen ray and gamma ray physics, xray and radium physics, or radiological physics, or certified by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2005, need not comply with the training requirements for an authorized medical physicist described in Appendix 7B, for those materials and uses that these individuals performed on or before October 24, 2005.

7P1.4 A Radiation Safety Officer, a medical physicist, or a nuclear pharmacist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses or in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of Appendix 7A, 7B, or 7C respectively, when performing the same uses. A nuclear pharmacist, who prepared only radioactive drugs containing accelerator-produced radioactive materials, or a medical physicist, who used only accelerator-produced radioactive materials, at the locations and during the time period identified in 7P1.4, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates, for the purposes of the regulations.

7P2

7P2.1 Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the NRC or an Agreement State, a permit issued by a NRC master material licensee, a permit issued by a NRC or an Agreement State broad scope licensee, or a permit issued by a NRC master material license broad scope permittee on or before August 14, 2020, who perform only those medical uses for which they were authorized on or before that date need not comply with the training requirements of Sections D through H.

7P2.2 Physicians, dentists, or podiatrists not identified as authorized users for the medical use of radioactive material on a license issued by the NRC or an Agreement State, a permit issued by a NRC master material licensee, a permit issued by a NRC or an Agreement State broad scope licensee, or a permit issued in accordance with a NRC master material broad scope license on or before October 24, 2005, need not comply with the training requirements of Sections D through H for those materials and uses that these individuals performed on or before October 24, 2005, as follows:

(1) For uses authorized under 7.30 or 7.32, or oral administration of sodium iodide I–131 requiring a written directive for imaging and localization purposes, a physician who was certified on or before October 24, 2005, in nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology by the American Board of Radiology; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or American Osteopathic Board of Nuclear Medicine in nuclear medicine;

(2) For uses authorized under 7.36, a physician who was certified on or before October 24, 2005, by the American Board of Nuclear Medicine; the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or the American Osteopathic Board of Radiology after 1984;

(3) For uses authorized under 7.42 or 7.48, a physician who was certified on or before October 24, 2005, in radiology, therapeutic radiology or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and

(4) For uses authorized under 7.40, a physician who was certified on or before October 24, 2005, in radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

7P2.3 Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses performed at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of Sections D through H when performing the same medical uses. A physician, dentist, or podiatrist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses at the locations and time period identified in 7P2, qualifies as an authorized user for those materials and uses performed before these dates, for the purposes of the regulations.

7P3 Individuals who need not comply with training requirements as described in Appendix 7P may serve as preceptors for, and supervisors of, applicants seeking authorization on Department licenses for the same uses for which these individuals are authorized.

Editor's Notes

6 CCR 1007-1 has been divided into separate parts for ease of use. Versions prior to 04/01/2007 are located in the first section, 6 CCR 1007-1. Prior versions can be accessed from the All Versions list on the rule's current version page. To view versions effective on or after 04/01/2007, select the desired part of the rule, for example 6 CCR 1007-1 Part 01 or 6 CCR 1007-1 Part 10.

History

Part 07 rules 7.2, 7.3.1-7.3.4, 7.4.2.1, 7.8.1, 7.10.2.1-.2, 7.10.3, 7.11.2, 7.13.2, 7.14-7.15, 7.16.2-.4, 7.18.2-.3, 7.19.3.2, 7.20.3-.4, 7.25-7.26, 7.27.6-.7, 7.29.1, 7.30.1, 7.32.1, 7.33.2, 7.36.1, 7.48.1.2, 7.50.1-.2, 7.59.4, Appendices 7A-7O eff. 03/30/2012.

Entire rule eff. 08/14/2020.

Part 07 rules 7.1.5.1, 7.2, 7.3.1.1, 7.3.2.3, 7.3.4.5, 7.3.5.7, 7.3.5.8, 7.3.6, 7.4.2.4, 7.5.2.4, 7.7.1, 7.10-7.10.2.2, 7.23-7.23.7, 7.40.3, 7.41, 7.43.2.4-7.44.3, 7.47-7.48.3, 7.58-7.58.6.9, Appendix 7A 7A3.2, 7A3.3, Appendix 7C 7C1.1, Appendix 7P 7P2.2 eff. 12/15/2022.