Title 15 - Mississippi Department of Health

Part III – Office of Health Protection

Subpart 78 – Division of Radiological Health

CHAPTER 1 REGULATIONS FOR CONTROL OF RADIATION IN MISSISSIPPI

700 Use of Radionuclides In The Healing Arts

700.1 Purpose and Scope. Section 700 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 radiation safety of workers, the general public, patients, and human research subjects. The requirements and provisions of Section 700 are in addition to, and not in substitution for, other applicable provisions of these regulations. The requirements and provisions of these regulations apply to applicants and licensees subject to Section 700 unless specifically exempted.

700.2 Definitions. As used in Section 700, the following definitions apply:

"Address of Use" means the building or buildings that are identified on the license and 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 receiving, using or storing radioactive material.

"Authorized medical physicist" means an individual who:

Meets the requirements in 700.20(1) or 700.23; or

Is identified as an authorized medical physicist or teletherapy physicist on:

a specific medical use license or equivalent permit issued by the Agency, Nuclear Regulatory Commission, Agreement State or Licensing State;

a permit issued by the Agency, Nuclear Regulatory Commission, Agreement State or Licensing State broad scope medical use licensee; or

A medical use permit issued by a Nuclear Regulatory Commission master material licensee; or

A permit issued by a Nuclear Regulatory Commission master material license broad scope medical use permittee.

"Authorized nuclear pharmacist" means a pharmacist who:

Meets the requirements in 700.21(1) or 700.23; or

Is identified as an authorized nuclear pharmacist on:

a specific license that authorizes medical use or, the practice of nuclear pharmacy, issued by the Agency, Nuclear Regulatory Commission, Agreement State or Licensing State;

a permit issued by a Nuclear Regulatory Commission master material licensee that authorizes medical use or the practice of nuclear pharmacy;

a permit issued by an Agency, Nuclear Regulatory Commission, Agreement State or Licensing State broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy;

a permit issued by a Nuclear Regulatory Commission master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or

by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

Is designated as an authorized nuclear pharmacist in accordance with 300.12(10)(b)(iv).

"Authorized user" means a physician, dentist, or podiatrist who:

Meets the requirements in 700.23 and 700.39(1), 700.43(1), 700.48(1), 700.49(1), 700.50(1), 700.60(1), 700.61, 700.63(1), or 700.81(1); or

Is identified as an authorized user on:

a license issued by the Agency, Nuclear Regulatory Commission, Agreement State or Licensing State;

A permit issued by a Nuclear Regulatory Commission master material licensee that is authorized to permit the medical use of radioactive material;

A permit issued by an Agency, Nuclear Regulatory Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of radioactive material; or

A permit issued by a Nuclear Regulatory Commission 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.

"Client's address" means the address of use or a temporary jobsite for the purpose of providing mobile medical service in accordance with 700.34.

"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 to practice dentistry by the state in which the Agency is located.

"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.

"High dose-rate remote afterloader" (HDR) means a device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

"Low dose-rate remote afterloader"(LDR) means a device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the point or surface where the dose is prescribed.

"Management" means the chief executive officer or other individual having the authority to manage, direct, or administer the licensee's activities, or those persons' delegate or delegates.

“Manual brachytherapy”, as used in this Section, means a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed topically on or inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume.

"Medical institution" means an organization in which several medical disciplines are practiced.

"Medical use" means the intentional internal or external administration of radioactive material, or the radiation from radioactive material to patients or human research subjects under the supervision of an authorized user.

"Medium dose-rate remote afterloader" (MDR) means a device that remotely delivers a dose rate of greater than 2 gray (200 rads), but less than, or equal to, 12 gray (1200 rads) per hour at the treatment site.

"Misadministration" means an event that meets the criteria in 700.110(1).

"Mobile nuclear medicine service" means the transportation of radioactive material to and its medical use at the client's address.

"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.

"Pharmacist" means an individual licensed by the appropriate authority to practice pharmacy in the state in which the Agency is located.

"Physician" means a doctor of medicine or doctor of osteopathy licensed by the appropriate authority to prescribe drugs in the practice of medicine in the state in which the Agency is located.

"Podiatrist" means an individual licensed by the appropriate authority to practice podiatry in the state in which the Agency is located.

"Positron Emission Tomography (PET) radionuclide production facility" means a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

"Preceptor" means an individual who provides, directs, or verifies the training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a Radiation Safety Officer.

"Prescribed dosage" means the specified activity or range of activity of a radioactive drug as documented:

In a written directive as specified in 700.16; or

In accordance with the directions of the authorized user for procedures performed pursuant to 700.37 and 700.40.

"Prescribed dose" means:

For gamma stereotactic radiosurgery, the total dose as documented in the written directive; or

For teletherapy, the total dose and dose per fraction as documented in the written directive; or

For manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or

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 in the "high dose-rate" range, but:

Is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and

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" means an individual who:

Meets the requirements in 700.19(1) or 700.19(3)(a) and 700.23;

Is identified as a Radiation Safety Officer on:

a specific medical use license issued by the Agency, Nuclear Regulatory Commission or Agreement State license; or

A medical use permit issued by a Nuclear Regulatory Commission 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 any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

"Sealed Source and Device Registry" means the national registry that contains the registration certificates maintained by the Nuclear Regulatory

Commission, that summarizes 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 very precisely deliver a dose to a treatment site.

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

"Teletherapy" means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.

"Temporary jobsite" means a location where mobile medical services are conducted other than the location(s) of use authorized on the license.

"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.

"Type of use" means use of radioactive material as specified under 700.37, 700.40, 700.44, 700.52, 700.62, 700.64 or 700.82.

"Unit dosage" means a dosage that:

Is obtained or prepared in accordance with the regulations for uses described in 700.37, 700.40, or 700.44; and

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

"Visiting authorized user" means an authorized user who is not identified on the license of the licensee being visited.

"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 700.16.

700.3 Maintenance of Records. Each record required by Section 700 must be legible throughout the retention period specified by each Agency 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.

700.4 Provisions for Research Involving Human Subjects. A licensee may conduct research involving human subjects using radioactive material provided:

.1 That the research is conducted, funded, supported, or regulated by a Federal agency which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a licensee shall apply for and receive approval of a specific amendment to its Agency Nuclear Regulatory Commission license before conducting such research. Both types of licensees shall, at a minimum, obtain prior informed consent from the human subjects and obtain prior review and approval of the research activities by an "Institutional Review Board" in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects;

.2 The research involving human subjects authorized in 700.04(1) shall be conducted using radioactive material authorized for medical use in the license; and

.3 Nothing in 700.04 relieves licensees from complying with the other requirements in Section 700.

700.5 U.S. Food and Drug Administration, Federal, and State Requirements. Nothing in this Section relieves the licensee from complying with applicable U.S. Food and Drug Administration, other Federal, and State requirements governing radioactive drugs or devices.

700.6 Implementation.

.1 A licensee shall implement the provisions in Section 700 on the effective date of these regulations.

.2 When a requirement in Section 700 differs from the requirement in an existing license condition, the requirement in this Section shall govern.

.3 Any existing license condition that is not affected by a requirement in Section 700 remains in effect until there is a license amendment or license renewal.

.4 If a license condition exempted a licensee from a provision of Section 700 on the effective date of these regulations, it will continue to exempt a licensee from the corresponding provision in Section 700.

.5 If a license condition cites provisions in Section 700 that will be deleted on the effective date of these regulations, then the license condition remains in effect until there is a license amendment or license renewal that modifies or removes this condition.

.6 Licensees shall continue to comply with any license condition that requires it to implement procedures required by 700.67, 700.73 through 700.75 until there is a license amendment or renewal that modifies the license condition.

700.7 License Required.

.1 A person shall only manufacture, produce, prepare, acquire, receive, possess, use, or transfer radioactive material for medical use only in accordance with a specific license issued by the Agency, the Nuclear Regulatory Commission or an Agreement State, or as allowed in 700.07(2) or 700.07(3).

.2 An individual may receive, possess, use, or transfer radioactive material in accordance with the regulations in Section 700 under the supervision of an authorized user as provided in 700.15, unless prohibited by license condition.

.3 An individual may prepare unsealed radioactive material for medical use in accordance with the regulations in Section 700 under the supervision of an authorized nuclear pharmacist or authorized user as provided in 700.15, unless prohibited by license condition.

700.8 License Amendments. A licensee shall apply for and receive a license amendment:

.1 Before it receives, prepares, uses radioactive material for a type of use that is permitted under Section 700, but is not authorized on the licensee's current license issued pursuant to Section 700;

.2 Before it permits anyone, except a visiting authorized user described in 700.10, to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license;

.3 Before it changes Radiation Safety Officer.

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

.5 Before it adds to or changes the areas of use or address or address(es) of use identified in the application or on the license;

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

.7 Before it changes statements, representations, and procedures which are incorporated into the license; and

.8 Before it releases licensed facilities for unrestricted use.

700.9 Notifications.

.1 A license shall notify the Agency in writing within 30 days when:

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

.b The licensee's mailing address changes; or

.c The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in 300.31(2) of these regulations.

700.10 Visiting Authorized User.

.1 A licensee may permit any visiting authorized user to use licensed material for medical use under the terms of the licensee's license for 60 days each calendar year if:

.a The visiting authorized user has the prior written permission of the licensee's management and, if the use occurs on behalf of an institution, the institution's Radiation Safety Committee;

.b The licensee has a copy of a license issued by the Agency that identifies the visiting authorized user by name as an authorized user for medical use; and

.c Only those procedures for which the visiting authorized user is specifically authorized by the Agency license are performed by that individual.

.2 A licensee need not apply for a license amendment in order to permit a visiting authorized user to use licensed material as described in 700.10(1).

.3 A licensee shall retain copies of the records specified in 700.10(1) for 5 years after the visiting authorized user's last use of licensed material.

700.11 Mobile Medical Service Administrative Requirements.

.1 The Agency 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.

.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.

.3 A mobile medical service shall not have radioactive material delivered directly from the manufacturer or the distributor to the client's address of use, unless the client has a license allowing possession of the radioactive material. Radioactive material delivered to the client's address of use shall be received and handled in conformance with the client's license.

.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.

.5 A licensee providing mobile medical services shall retain the letter required in 700.11(2) in accordance with 700.93.

.6 A mobile medical service licensee shall, at a minimum, maintain the following documents on each mobile unit:

.a The current operating and emergency procedures;

.b A copy of the license;

.c Copies of the letter required by 700.11(2);

.d Current calibration records for each survey instrument and diagnostic equipment or dose delivery device in use; and

.e Survey records covering uses associated with the mobile unit during, at a minimum, the preceding 30 calendar days.

.7 A mobile medical service licensee shall maintain all records required by Sections 400 and 700 of these regulations at a location within the Agency's jurisdiction that is:

.a A single address of use:

.i Identified as the records retention location; and

.ii Staffed at all reasonable hours by individual(s) authorized to provide the Agency with access for purposes of inspection; or

.b When no address of use is identified on the license for records retention, the mobile unit:

.i Identified in the license; and

.ii Whose current client's address schedule and location schedule is reported to the Agency.

700.12 Exemptions Regarding Type A Specific Licenses of Broad Scope. A licensee possessing a specific license of broad scope for medical use is exempt from:

.1 The provisions of 700.08(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;

.2 The provisions of 700.08(5) regarding additions to or changes in the areas of use at the addresses specified in the license; and

.3 The provisions of 700.09 regarding notification to the Agency for new authorized users, new authorized nuclear pharmacists and new authorized medical physicists.

General Administrative Requirements

700.13 Authority and Responsibilities for the Radiation Protection Program.

.1 In addition to the radiation protection program requirements of 400.01 of these regulations, a licensee's management must approve in writing:

.a Requests for license application, renewal, or amendments before submittal to the Agency;

.b Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist or authorized medical physicist; and

.2 A licensee's management shall appoint a Radiation Safety Officer, who agrees in writing to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.

.3 For up to sixty days each year, a licensee may permit an authorized user or an individual qualified to be a radiation safety officer to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in 700.13(5), provided the licensee takes the actions required in 700.13(2),(4),(5) and (8). A licensee may simultaneously appoint more than one temporary RSO, if needed, to ensure that the licensee has a temporary RSO that satisfies the requirements to be an RSO for each of the different uses of radioactive material permitted by the license.

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

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

.a Identify radiation safety problems;

.b Initiate, recommend, or provide corrective actions;

.c Stop unsafe operations; and

.d Verify implementation of corrective actions.

.6 Licensees that are authorized for two or more different types of radioactive material use under 700.44, 700.52, 700.64, and 700.82, or two or more types of units under 700.64 shall establish a Radiation Safety Committee to oversee all uses of radioactive material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer, and may include other members as the licensee deems appropriate.

.7 A licensee's Radiation Safety Committee shall meet as necessary, but at a minimum shall meet at intervals not to exceed 6 months. The licensee shall maintain minutes of each required meeting in accordance with 700.83.

.8 To establish a quorum and to conduct business, one-half of the Committee's membership shall be present, including the Radiation Safety Officer and the management's representative.

.9 A licensee shall retain a record of actions taken pursuant to 700.13(1), 700.13(2) and 700.13(4) in accordance with 700.83.

700.14 Duties of Authorized User and Authorized Medical Physicist.

.1 A licensee shall assure that only authorized users for the type of radioactive material used:

.a 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

.b Direct, as specified in 700.15 and 700.16, or in license conditions, the administration of radioactive material for medical use to patients or human research subjects; and

.c Prepare and administer, or supervise the preparation and administration of radioactive material for medical use, in accordance with 700.07(2), (3), and 700.15.

.2 A licensee shall assure that only authorized medical physicists perform, as applicable:

.a Full calibration measurements as described in 700.70 through 700.72;

.b Periodic spot checks as described in 700.73, through 700.75; and

.c Radiation surveys as described in 700.77.

700.15 Supervision.

.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 700.07(2)shall:

.a In addition to the requirements in 1000.03 of these regulations, Instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of Section 700, and license conditions with respect to the use of radioactive material; and

.b 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 Section 700, and license conditions with respect to the medical use of radioactive material.

.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 700.07(3), shall:

.a Instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and

.b 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 Section 700, and license conditions.

.3 Unless physical presence as described in other sections of Section 700 is required, a licensee who permits supervised activities under 700.15(1) and 700.15(2) shall require an authorized user to be immediately available to communicate with the supervised individual.

.4 A licensee that permits supervised activities under 700.15(1) and 700.15(2) is responsible for the acts and omissions of the supervised individual.

700.16 Written Directives.

.1 A written directive must be dated and signed by an authorized user prior to administration of I-131 sodium iodide greater than 1.11 megabecquerel (30 μCi), any therapeutic dosage of radioactive material or 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 will be acceptable, provided that the information contained in the oral directive is documented as soon as possible in the patient's record and a written directive is prepared within 48 hours of the oral directive;

.2 The written directive must contain the patient or human research subject's name and the following:

.a For an administration of a dosage of radioactive drug containing radioactive material: the radioactive drug containing radioactive material, dosage, and route of administration;

.b For gamma stereotactic radiosurgery: the total dose, treatment site, and number of target coordinate settings per treatment for each anatomically distinct treatment site;

.c For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site;

.d For high dose rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or

.e For all other brachytherapy including LDR, MDR, and PDR:

.i Prior to implantation: treatment site, the radionuclide, and dose; and

.ii After implantation but prior to completion of the procedure: the radioisotope, treatment site, number of sources, and total source strength and exposure time (or, the total dose).

.3 A written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to the administration of the dosage of radioactive drug containing radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

.4 If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented as soon as possible in the patient's record and revised written directive is signed by the authorized user within 48 hours of the oral revision.

.5 The licensee shall retain the written directive in accordance with 700.84.

700.17 Procedures for Administrations Requiring a Written Directive.

.1 For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:

.a The patient's or human research subject's identity is verified before each administration; and

.b Each administration is in accordance with the written directive.

.2 The procedures required by 700.17(1) must, at a minimum, address the following items that are applicable for the licensee's use of radioactive material:

.a Verifying the identity of the patient or human research subject;

.b Verifying that the specific details of the administration are in accordance with the treatment plan, if applicable, and the written directive;

.c Checking both manual and computer-generated dose calculations; and

.d Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by 700.64 or 700.82.

700.18 Suppliers for Sealed Sources or Devices for Medical Use. For medical use a licensee shall use only:

.1 Sealed sources or devices initially manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to Section 300 of these regulations or the equivalent requirements of the Nuclear Regulatory Commission, an Agreement State or a Licensing State; or

.2 Sealed sources or devices non-commercially transferred from an Agency, Nuclear Regulatory Commission, an Agreement State or a Licensing State medical use licensee.

.3 Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to Section 300 of these regulations or the equivalent requirements of the Nuclear Regulatory Commission, an Agreement State or a Licensing State.

700.19 Training for Radiation Safety Officer. Except as provided in 700.22, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer (RSO) as provided in 700.13 to be an individual who:

1. Is certified by a specialty board whose certification process has been recognized by the Agency, Nuclear Regulatory Commission, or an Agreement State and who meets the requirements in Section 700.19(4) and (5).[1] To have its certification process recognized, a specialty board shall require all candidates for certification to:

.a

.i 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;

.ii 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

.iii Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation

[1] The names of board certifications which have been recognized by the Agency, Nuclear Regulatory Commission (NRC) or another Agreement State will be posted on the NRC's Web page.

physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

.b

.i 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;

.ii Have 2 years of full-time practical training and/or supervised experience in medical physics:

.i Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Nuclear Regulatory Commission or an Agreement State; or

.ii In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users in Sections 700.43 or 700.48;

.iii 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

.2 Has completed a structural educational program consisting of 200 hours of classroom and laboratory training as follows:

.a Radiation physics and instrumentation;

.b Radiation protection;

.c Mathematics pertaining to the use and measurement of radioactivity;

.d Radiation biology;

.e Radiation dosimetry; and

.f 1 year of full time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer; on an Agency, Nuclear Regulatory Commission or Agreement State license or a permit issued by a Nuclear Regulatory Commission master material licensee that authorizes similar type(s) of use(s) of radioactive material involving the following:

.i Shipping, receiving, and performing related radiation surveys;

.ii Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

.iii Securing and controlling radioactive material;

.iv Using administrative controls to avoid mistakes in the administration of radioactive material;

.v Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

.vi Using emergency procedures to control radioactive material; and

vii. Disposing of radioactive material; or

.3

.a Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Agency, Nuclear Regulatory Commission, or another Agreement State under Section 700.20(1) and has experience in radiation safety for similar types of use of radioactive material for which the licensee is seeking the approval of the individual as Radiation Safety Officer and who meets the requirements in Section.700.19(4) and (5); or

.b Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has Radiation Safety Officer responsibilities; and,

.4 Has obtained written attestation, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in Section 700.19(5) and in Section 700.19(1)(a)(i) and (ii) or Section 700.19(1)(b)(i) and (ii) or Section 700.19(2) or Section 700.19(3)(a) or (b), and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; and

.5 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 a Radiation Safety Officer, 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.

700.20 Training for Authorized Medical Physicist. Except as provided in 700.22, the licensee shall require the authorized medical physicist to be an individual who:

1. Is certified by a specialty board whose certification process has been recognized by the Agency, Nuclear Regulatory Commission or an Agreement State and who meets the requirements in 700.20(2)(b) and 700.20 (3).[2] To have its certification process recognized, a specialty board shall require all candidates for certification to:

   a. 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;

   b. Have 2 years of full-time practical training and/or supervised experience in medical physics:

      i. Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Agency, Nuclear Regulatory Commission or an Agreement State; or

      ii. In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in 700.60, or 700.81; and

   c. 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

2.

   a. 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

[2] The names of board certifications which have been recognized by the Agency, Nuclear Regulatory Commission (NRC) or another Agreement State will be posted on the NRC's Web page.

with energies greater than or equal to 1 million electron volts) and brachytherapy services and must include:

i. Performing sealed source leak tests and inventories;

ii. Performing decay corrections;

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

iv. Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

b. Has obtained written attestation that the individual has satisfactorily completed the requirements in 700.20(3) and 700.20(1)(a) and (b), or 700.20(2)(a) and 700.20(3), and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in 700.20, or the equivalent Nuclear Regulatory Commission 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

3. 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.

700.21 Training for an Authorized Nuclear Pharmacist. Except as provided in 700.22, the licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

.1 Is certified by a specialty board whose certification process has been recognized by the Agency, Nuclear Regulatory Commission or an Agreement State and who meets the requirements in 700.21(2)(b).[3] To have its certification process recognized, a specialty board shall require all candidates for certification to:

[3] The names of board certifications which have been recognized by the Agency, Nuclear Regulatory Commission (NRC) or another Agreement State will be posted on the NRC's Web page.

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

.b Hold a current, active license to practice pharmacy;

.c 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

.d 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, research and development; or

.2

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

.i 200 hours of classroom and laboratory training in the following areas:

.i Radiation physics and instrumentation;

.ii Radiation protection;

.iii Mathematics pertaining to the use and measurement of radioactivity;

.iv Chemistry of radioactive material for medical use; and

.v Radiation biology; and

.ii Supervised practical experience in a nuclear pharmacy involving:

.i Shipping, receiving, and performing related radiation surveys;

.ii Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate,

instruments used to measure alpha- or beta-emitting radionuclides;

.iii Calculating, assaying, and safely preparing dosages for patients or human research subjects;

.iv Using administrative controls to avoid misadministrations in the administration of radioactive material; and

.v Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

.b Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in 700.21(1)(a),(b) and (c) or 700.21(2)(a) and has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

700.22 Provisions for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Medical Physicist, Authorized User, Nuclear Pharmacist and Authorized Nuclear Pharmacist.

.1 An individual identified as a Radiation Safety Officer, a teletherapy or medical physicist, an authorized medical physicist, a nuclear pharmacist, or an authorized nuclear pharmacist on an Agency, Nuclear Regulatory Commission, an Agreement State license or a permit issued by an Agency, Nuclear Regulatory Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope that authorizes medical use or the practice of nuclear pharmacy, before the effective date of these regulations need not comply with the training requirements of 700.19, 700.20 and 700.21, respectively.

.2 Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on an Agency, Nuclear Regulatory Commission or Agreement State license, a permit issued by a Nuclear Regulatory Commission master material licensee, or a permit issued by an Agency, Nuclear Regulatory Commission or Agreement State broad scope licensee, or a permit issued by a Nuclear Regulatory Commission master material license broad scope permittee that authorizes medical use or the practice of nuclear pharmacy, issued before the effective date of the regulations who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of 700.39, 700.43, 700.48, 700.49, 700.50, 700.51, 700.60, 700.61, 700.63 and 700.81

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700.23 Recentness of Training. The training and experience specified in Section 700 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.

General Technical Requirements

700.24 Quality Control of Diagnostic Equipment. Each licensee shall establish written quality control procedures for all diagnostic equipment used for radionuclide studies. As a minimum, quality control procedures and frequencies shall be those recommended by equipment manufacturers or procedures which have been approved by the Agency. The licensee shall conduct quality control procedures in accordance with written procedures.

700.25 Possession, Use, Calibration, and Check of Dose Calibrators.

.1 A medical use licensee authorized to administer radiopharmaceuticals shall possess a dose calibrator and use it to measure the amount of activity administered to each patient. In the case where the ionization type dose calibrator cannot be used effectively to verify administered activity, the licensee shall use an alternative method. Any alternative method to the use of a dose calibrator shall be approved by the Agency in writing. Any alternative method shall provide for acceptable verification of constancy, accuracy, linearity and geometry dependence as applicable.

.2 Each licensee shall establish written quality control procedures for all dose calibrators used for measuring the amount of activity administered to a patient. As a minimum, quality control procedures and frequencies shall be those recommended by the American National Standards Institute or the licensee shall:

.a Check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. To satisfy the requirement of Section 700, the check shall be done on a frequently used setting with a sealed source of not less than 50 microcuries (1.85 MBq) with energies representative of the radionuclides in clinical use at the facility;

.b Test each dose calibrator for accuracy upon installation and at intervals not to exceed 12 months thereafter by assaying at least 2 sealed sources containing different radionuclides, the activity of which the manufacturer has determined within 5 percent of the stated activity, with minimum activity of 50 microcuries (1.85 MBq) and energies representative of the radionuclides in clinical use at the facility;

.c Test each dose calibrator for linearity upon installation and at intervals not to exceed 3 months thereafter over the range of use

between 30 microcuries (1.11 MBq) and the highest dosage that will be assayed; and

.d Test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used. The licensee shall keep a record of this test for the duration of the use of the dose calibrator.

.3 A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 10 microcuries (370 kBq) and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.

.4 A licensee shall also perform checks and tests required by 700.25(2) following adjustment or repair of the dose calibrator.

.5 A licensee shall retain a record of each check and test required by 700.25 in accordance with 700.87.

.6 A licensee shall use dose calibrator reference and calibration sources traceable to the National Institute of Standards and Technology (NIST), or other standards recognized as being equivalent by the NIST.

700.26 Calibration and Check of Survey Instruments.

.1 A licensee shall ensure that the survey instruments used to show compliance with Sections 400 and 700 of these regulations have been calibrated before first use, annually, and following repair.

.2 To satisfy the requirements of 700.26(1), the licensee shall:

.a Calibrate all required scale readings up to 10 millisieverts (1000 mrem) per hour with a radiation source;

.b Have each radiation survey instrument calibrated:

.i At energies appropriate for use and at intervals not to exceed 12 months or after instrument servicing, except for battery changes;

.ii For linear scale instruments, at two points located approximately one-third and two-thirds of full-scale on each scale; for logarithmic scale instruments, at mid-range of each decade, and at two points of at least one decade; and for digital instruments, at 3 points between 0.02 and 10 millisieverts (2 and 1000 mrem) per hour; and

.iii For dose rate instruments, so that an accuracy within plus or minus 20 percent of the true radiation dose rate can be demonstrated at each point checked.

.c Conspicuously note on the instrument the apparent dose rate from a dedicated check source as determined at the time of calibration, and the date of calibration.

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

.4 A licensee shall check each survey instrument for proper operation with the dedicated check source before each use. The licensee is not required to keep records of these checks.

.5 The licensee shall retain a record of each calibration required in 700.88 for 3 years.

700.27 Determination of Dosages of Radioactive Material for Medical Use.

.1 A licensee shall determine and record the activity of each dosage prior to medical use. For photon-emitting radioactive material, this determination shall be within 30 minutes prior to medical use.

.2 For a unit dosage, this determination must be made by:

.a direct measurement of radioactivity;

.b A decay correction, based on the activity or activity concentration determined by:

.i a manufacturer or preparer licensed pursuant to Section 300.12(10) of these regulations or equivalent provisions of the Nuclear Regulatory Commission, Agreement State or Licensing State;

.ii An Agency, Nuclear Regulatory Commission 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; or

.iii A PET radioactive drug producer licensed under Section 300.08(9) or equivalent Nuclear Regulatory Commission or Agreement State requirements.

.c For other than unit dosages, this determination must be made by:

.i Direct measurement of radioactivity;

.ii Combination of measurement of radioactivity and mathematical calculations; or

.iii Combination of volumetric measurements and mathematical calculations, based on the measurement made by:

.i a manufacturer or preparer licensed under Section 300.12(10) of these regulations or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

.ii a PET radioactive drug producer licensed under Section 300.08(9) or equivalent Nuclear Regulatory Commission or Agreement State requirements.

.3 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.

.4 A licensee shall retain a record of the dosage determination required by Section 700 in accordance with 700.89.

700.28 Authorization for Calibration, Transmission and Reference Sources. Any person authorized by 700.07 for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration, and reference use:

.1 Sealed sources manufactured and distributed by persons specifically licensed pursuant to Section 300 of these regulations or equivalent provisions of the Nuclear Regulatory Commission, Agreement State or Licensing State and that do not exceed 1.11 gigabecquerels (30 mCi) each;

.2 Any radioactive material with a half-life of 120 days or less in individual amounts not to exceed 555 megabecquerels (15 mCi);

.3 Any radioactive material with a half-life greater than 120 days in individual amounts not to exceed the smaller of:

.a 7.4 megabecquerels (200 μCi); or

.b 1000 times the quantities in Appendix B of Section 300 of these regulations; and

.4 Technetium-99m in amounts as needed.

700.29 Requirements for Possession of Sealed Sources and Brachytherapy Sources.

.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 Agency.

.2 A licensee in possession of a sealed source shall:

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

.b Test the source for leakage at intervals not to exceed 6 months or at intervals approved by the Agency, another Agreement State, a Licensing State or the Nuclear Regulatory Commission in the Sealed Source and Device Registry.

.3 To satisfy the leak test requirements of 700.29(2), the licensee shall assure that:

.i Leak tests are capable of detecting the presence of 0.005 microcurie (185 Bq) of radioactive material on the test sample, or in the case of radium, the escape of radon at the rate of 0.001 microcurie (37 Bq) per 24 hours;

.ii Test samples are taken from the source or from the surfaces of the device in which the source is mounted or stored on which radioactive contamination might be expected to accumulate; and

.iii Test samples are taken when the source is in the "off" position.

.4 A licensee shall retain leak test records for 5 years. The records shall contain the model number, and serial number, if assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample expressed in microcuries (becquerels), a description of the method used to measure each test sample, the date of the test, and the signature of the Radiation Safety Officer.

.5 If the leak test reveals the presence of 185 becquerels (0.005 μCi) or more of removable contamination, the licensee shall:

.a Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements of Sections 300 and 400 of these regulations; and

.b File a report with the Agency within 5 days of receiving the leak test results in accordance with 700.112.

.6 A licensee in possession of a sealed source or brachytherapy source, except for gamma stereotactic radiosurgery sources, shall conduct a physical inventory of all such sources at intervals not to exceed 3 months. The licensee shall retain each inventory record in accordance with 700.90.

700.30 Labels. Each syringe and vial that contains a radioactive drug shall be labeled to identify the radioactive drug. Each syringe shield and vial shield shall also be labeled unless the label on the syringe or vial is visible when shielded.

700.31 Syringe Shields and Vial Shields.

.1 A licensee shall keep syringes that contain radioactive material to be administered in a radiation shield.

.2 A licensee shall require each individual who prepares or administers radiopharmaceuticals to use a syringe radiation shield unless the use of the shield is contraindicated for that patient.

.3 A licensee shall require each individual preparing or handling a vial that contains a radioactive drug to keep the vial in a vial radiation shield.

700.32 Surveys for Ambient Radiation Dose Rate and Contamination.

.1 A licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

.2 A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radioactive wastes are stored.

.3 A licensee shall conduct the surveys required by 700.32(1) and (2) so as to be able to measure dose rates as low as 1 microsievert (0.1 mrem) per hour.

.4 A licensee shall establish dose rate action levels for the surveys required by 700.32(1) and (2) and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if a dose rate exceeds an action level.

.5 A licensee shall survey for removable contamination each week of use all areas where radiopharmaceuticals are routinely prepared for use or administered and each week where radioactive materials are stored.

.6 A licensee shall conduct the surveys required by 700.32(5) so as to be able to detect contamination on each wipe sample of 2000 disintegrations per minute (33.3 Bq).

.7 A licensee shall establish removable contamination action levels for the surveys required by 700.32(5) and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds action levels.

.8 A licensee does not need to perform the surveys required by 700.32(1) in area(s) where patients or human research subjects are confined when they can not be released pursuant to 700.33.

.9 A licensee shall retain a record of each survey in accordance with 700.91.

700.33 Release Individuals Containing Radioactive Drugs or Implants.

.1 A licensee may authorize the release from its control of any individual who has been administered radioactive drugs or 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 millisievert (0.5 rem).[4]

.2 For patients administered radioactive material for which a written directive is required, a licensee shall provide the released individual, or the individual's parent or guardian, with oral and written instructions on 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 millisievert (0.1 rem). If the total effective dose equivalent to a breast-feeding infant or child could exceed 1 millisievert (0.1 rem) assuming there were no interruption of breast-feeding, the instructions shall also include:

.a Guidance on the interruption or discontinuation of breast-feeding; and

.b Information on the potential consequences, if any, of failure to follow the guidance.

.3 The licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with 700.92.

.4 The licensee shall maintain a record of instructions provided to breast-feeding women in accordance with 700.92.

700.34 Mobile Nuclear Medicine Service Technical Requirements. A licensee providing mobile nuclear medicine service shall:

.1 Transport to each client's address only syringes or vials containing prepared drugs or radioactive material that are intended for reconstitution of radioactive drug kits;

.2 Bring into each client's address all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;

[4] The current revision of the 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).

.3 Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at client's address;

.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;

.5 Check survey instruments for consistent response with a dedicated check source before use at each client's address;

.6 Prior to leaving a client's address, perform area surveys and surveys for removable contamination in all areas of use, to ensure compliance with Section 400 of these regulations;

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

.8 Retain a record of each survey required by 700.34(6) in accordance with 700.93.

700.35 Storage and Control of Volatiles and Gases.

.1 A licensee shall store volatile radioactive material and radioactive gases in a radiation shield and container.

.2 A licensee shall store and use a multi-dose container in a properly functioning fume hood.

.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 Section 400 of these regulations.

.4 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.

.5 A licensee shall check the operation of collection systems monthly and measure the ventilation rates in areas of use at intervals not to exceed 6 months and measure the ventilation rates in areas of use at intervals not to exceed 6 months. Records of these checks and measurements shall be maintained for 3 years.

700.36 Decay-In-Storage.

.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 in ordinary trash without regard to its radioactivity if the licensee:

.a Monitors radioactive material at the container surface before disposal as ordinary trash and determines that its radioactivity cannot be distinguished from the background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding;

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

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

.2 For radioactive material disposed in accordance with 700.36(1), the licensee shall retain a record of each disposal in accordance with 700.94.

Specific Requirements for the Use of Radioactive Material for Uptake, Dilution, or Excretion Studies

700.37 Use of Unsealed Radioactive Material for Uptake, Dilution, or Excretion Studies for which a Written Directive is not Required. A licensee may use any unsealed radioactive material, in quantities that do not require a written directive, for a diagnostic use involving measurements of uptake, dilution, or excretion that is:

.1 Obtained from:

.a a manufacturer or preparer licensed pursuant to Section 300.12(10) of these regulations or equivalent regulations of an Agreement State, a Licensing State, or the Nuclear Regulatory Commission; or

.b A PET radioactive drug producer licensed under Section 300.08(9) or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

.2 Excluding production of PET radionuclides, prepared by:

.a an authorized nuclear pharmacist,

.b a physician who is an authorized user and who meets the requirements specified in 700.43 or 700.48 and 700.43(3)(a)(ii)(vii), or

.c an individual under the supervision, as specified in 700.15, of the authorized nuclear pharmacist in 700.37(2)(a) or the physician who is an authorized user in 700.37(2)(b); or;

.3 Obtained from and prepared by an Agency, Nuclear Regulatory Commission, Agreement State or Licensing 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; or

.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.

700.38 Possession of Survey Instrument. A licensee authorized to use radioactive material for uptake, dilution, and excretion studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrems) per hour. The instrument shall be operable and calibrated in accordance with 700.26.

700.39 Training for Uptake, Dilution, and Excretion Studies. Except as provided in 700.22, the licensee shall require the authorized user of an unsealed radioactive material for the uses authorized under 700.37 to be a physician who:

1. Is certified by a medical specialty board whose certification process has been recognized by the Agency, Nuclear Regulatory Commission or an Agreement State and who meets the requirements in Section 700.39(3)(b)[5]. To have its certification process recognized, a specialty board shall require all candidates for certification to:

    a. Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies as described in 700.39(3)(a)(i) through (3)(a)(ii)(vi); and

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

2. Is an authorized user under Sections 700.43, 700.48, or equivalent Nuclear Regulatory Commission, or Agreement State requirements; or 700.39(3)(a)

3.

    a. 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 material for uptake, dilution, and excretion studies. The training and experience must include:

[5] The names of board certifications which have been recognized by the Agency, Nuclear Regulatory Commission (NRC) or another Agreement State will be posted on the NRC's Web page.

.i Classroom and laboratory training in the following areas:

.i Radiation physics and instrumentation;

.ii Radiation protection;

.iii Mathematics pertaining to the use and measurement of radioactivity;

.iv Radiation biology; and

.v Chemistry of radioactive material for medical use; and

.ii Work experience, under the supervision of an authorized user who meets the requirements in Sections 700.39, 700.43, 700.48, or equivalent Nuclear Regulatory Commission or Agreement State requirements, involving:

.i Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

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

.iii Calculating, measuring, and safely preparing patient or human research subject dosages;

.iv Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;

.v Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

.vi Administering dosages of radioactive drugs to patients or human research subjects; and

.b Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in Sections 700.39, 700.43, 700.48, or equivalent Nuclear Regulatory Commission, or Agreement State requirements, that the individual has satisfactorily completed the requirements in Section 700.39(1)(a) or 700.39(3)(a) and has achieved a level of competency sufficient to function independently

as an authorized user for the medical uses authorized under 700.37.

Specific Requirements for the Use of Unsealed Radioactive Material - Written Directive Not Required

700.40 Use of Unsealed Radioactive Material for Imaging and Localization Studies for which a Written Directive is not Required. A licensee may use, for imaging and localization studies, any radioactive material prepared for medical use, in quantities that do not require a written directive as described in 700.16 that is:

.1 Obtained from:

.a a manufacturer or preparer licensed pursuant to Section 300.12(10) of these regulations or equivalent regulations of another Agreement State, a Licensing State, or the Nuclear Regulatory Commission;

.b A PET radioactive drug producer licensed under Section 300.08(9) or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

.2 Excluding production of PET radionuclides, prepared by:

.a an authorized nuclear pharmacist;

.b a physician who is an authorized user and who meets the requirements specified in 700.43 or 700.48 and 700.43(3)(a)(ii)(vii); or

.c an individual under the supervision, as specified in 700.15, of the authorized nuclear pharmacist in 700.40(2)(a) or the physician who is an authorized user in 700.40(2)(b); or;

.3 Obtained from and prepared by an Agency, Nuclear Regulatory Commission, Agreement State or Licensing 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; or

.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.

.5 Provided the conditions of 700.35 are met, a licensee shall use radioactive aerosols or gases only if specific application is made to and approved by the Agency.

700.41 Radionuclide Contaminants.

.1 A licensee shall not administer to humans a radioactive drug containing:

.a More than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 μCi of Mo-99 per mCi of Tc-99m);

.b More than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 μCi of Sr-82 per mCi of Rb-82 chloride);

.c More than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 μCi of Sr-85 per mCi of Rb-82).

.2 To demonstrate compliance with 700.41(1), the licensee preparing radioactive drugs from radionuclide generators shall:

.a Measure the concentration of radionuclide contaminant in the first eluate after receipt of a molybdenum-99/technetium-99m generator;

.b Measure the concentration of radionuclide contaminant in each eluate or extract, as appropriate for other generator systems.

.3 A licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators shall measure the molybdenum-99 concentration in each eluate or extract.

.4 A licensee who must measure radionuclide contaminant concentration shall retain a record of each measurement in accordance with 700.95.

.5 A licensee shall report immediately to the Agency each occurrence of concentration exceeding the limits specified in 700.41(1).

700.42 Possession of Survey Instruments. A licensee authorized to use radioactive material for imaging and localization studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrems) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 10 microsieverts (1 mrem) per hour to 10 millisieverts (1000 mrems) per hour. The instruments shall be operable and calibrated in accordance with 700.26.

700.43 Training for Imaging and Localization Studies. Except as provided in 700.22, the licensee shall require the authorized user of unsealed radioactive material for the uses authorized under 700.40 to be a physician who:

1. Is certified by a medical specialty board whose certification process has been recognized by the Agency, Nuclear Regulatory Commission, or an

Agreement State and who meets the requirements in Section 700.43(3)(b).[6] To have its certification process recognized, a specialty board shall require all candidates for certification to:

.a Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for imaging and localization studies as described in Section 700.43(3)(a)(i) through (3)(a)(ii)(vii); and

.b Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

.2 Is an authorized user under Section 700.48 and meets the requirements in 700.43(3)(a)(ii)(vii), or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

.3

.a Has completed 700 hours of training and experience, 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:

.i Classroom and laboratory training in the following areas:

.i Radiation physics and instrumentation;

.ii Radiation protection;

.iii Mathematics pertaining to the use and measurement of radioactivity;

.iv Chemistry of radioactive material for medical use; and

.v Radiation biology.

.ii Work experience under the supervision of an authorized user who meets the requirements in Section 700.43, or 700.43(3)(a)(ii)(vii), and Section 700.48, or equivalent Nuclear Regulatory Commission or Agreement State requirements, involving:

[6] The names of board certifications which have been recognized by the Agency, Nuclear Regulatory Commission (NRC) or another Agreement State will be posted on the NRC's Web page.

.i Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

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

.iii Calculating measuring, and safely preparing patient or human research subject dosages;

.iv Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;

.v Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

.vi Administering dosages of radioactive drugs to patients or human research subjects; and

.vii Eluting generator systems, appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

.b Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in Section 700.43, or Section 700.48 and 700.43(3)(a)(ii)(vii), or equivalent Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in 700.43(1)(a) or 700.43(3)(a) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under Sections 700.37 and 700.40.

Specific Requirements for the Use of Unsealed Radioactive Material - Written Directive Required of Unsealed Radioactive Material - Written Directive Required

700.44 Use of Unsealed Radioactive Material for Which a Written Directive is Required. A licensee may use any unsealed radioactive material for diagnostic or therapeutic medical use for which a written directive is required that has been:

.1 Obtained from:

.a a manufacturer or preparer licensed in accordance with Section 300.12(10) of these regulations or equivalent regulations of another Agreement State, a Licensing State, or the Nuclear Regulatory Commission; or

.b A PET radioactive drug producer licensed under Section 300.08(9) or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

.2 Excluding production of PET radionuclides, prepared by

.a an authorized nuclear pharmacist,

.b a physician who is an authorized user and who meets the requirements specified in 700.43 or 700.48, or

.c an individual under the supervision, as specified in 700.15; of the authorized nuclear pharmacist in 700.44(2)(a) or the physician who is an authorized user in 700.44(2)(b); or

.3 Obtained from and prepared by an Agency, Nuclear Regulatory Commission, Agreement State, or Licensing State licensee in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by the FDA for use in research; or

.4 Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA.

700.45 Safety Instruction. In addition to the requirements of 1000.03 of these regulations:

.1 A licensee shall provide radiation safety instruction for all personnel caring for patients or human research subjects that have received therapy with a radioactive drug, and cannot be released in accordance with 700.33. The training must be provided initially and at least annually. The instruction must be appropriate to the personnel's assigned duties and include the following:

.2 To satisfy 700.45(1), the instruction shall describe the licensee's procedures for:

.a Patient or human research subject control;

.b Visitor control to include the following;

.i Routine visitation to hospitalized individuals in accordance with Section 400 of these regulations;

.ii Contamination control;

.iii Waste control; and

.iv Notification of the Radiation Safety Officer, or his or her designee, and the authorized user if the patient or the human research subject dies or has a medical emergency.

.3 A licensee shall keep a record of individuals receiving instruction required in accordance with 700.96.

700.46 Safety Precautions.

.1 For each patient or the human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with 700.33, a licensee shall:

.a Quarter the patient or the human research subject either in:

.i A private room with a private sanitary facility; or

.ii A room, with a private sanitary facility, with another individual who also has received similar radiopharmaceutical therapy and who cannot be released in accordance with 700.33; and

.b Visibly post the patient's or the human research subject's door with a "Caution: Radioactive Material(s)" sign and note on the door or on the patient's or the human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room;

.c Authorize visits by individuals under 18 years of age only on a case-by-case basis with the approval of the authorized user after consultation with the Radiation Safety Officer;

.d Promptly after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of Section 400 of these regulations and retain for 3 years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in millirems per hour, the instrument used to make the survey, and the initials of the individual who made the survey;

.e Either monitor material and items removed from the patient's or the human research subject's room to determine that any contamination 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 these materials and items as radioactive waste;

.f Survey the patient's or the human research subject's room and private sanitary facility for removable contamination with a radiation detection survey instrument before assigning another patient or another human research subject to the room. The room must not be reassigned until removable contamination is less than 200 disintegrations per minute (3.33 Bq) per 100 square centimeters; and

.g Measure the thyroid burden of each individual who helped prepare or administer a dosage of iodine-131 within 3 days after administering the dosage, and retain for the period required by 400.47 of these regulations a record of each thyroid burden measurement, date of measurement, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the measurements. Other procedures acceptable to the Agency may be used for individuals who only prepare, but do not administer doses of stabilized I-131.

.2 The Radiation Safety Officer, or his or her designee, and the authorized user shall be notified immediately if the hospitalized patient dies or has a medical emergency.

700.47 Possession of Survey Instruments. A licensee authorized to use radioactive material for which a written directive is required, imaging and localization studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrems) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 10 microsieverts (1 mrem) per hour to 10 millisieverts (1000 mrems) per hour. The instruments shall be operable and calibrated in accordance with 700.26.

700.48 Training for Use of Unsealed Radioactive Material for Which a Written Directive Is Required. Except as provided in 700.22, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under 700.44 to be a physician who:

.1 Is certified by a medical specialty board whose certification process has been recognized by the Agency, Nuclear Regulatory Commission or an Agreement State and who meets the requirements in 700.48(2)(a)(ii)(vi)

and 700.48(2)(b).[7] To be recognized, a specialty board shall require all candidates for certification to:

.a 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 700.48(2)(a)(i) through (2)(a)(ii)(v). Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association; and

.b 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

.2

.a 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:

.i Classroom and laboratory training in the following areas:

.i Radiation physics and instrumentation;

.ii Radiation protection;

.iii Mathematics pertaining to the use and measurement of radioactivity;

.iv Chemistry of radioactive material for medical use; and

.v Radiation biology; and

.ii Work experience, under the supervision of an authorized user who meets the requirements in 700.48, or equivalent Nuclear Regulatory Commission or Agreement State requirements. A supervising authorized user, who meets the requirements in 700.48(2), must also have experience in administering dosages in the same dosage category or categories (i.e., 700.48(2)(a)(ii)(vi))

[7] The names of board certifications which have been recognized by the Agency, Nuclear Regulatory Commission (NRC) or another Agreement State will be posted on the NRC's Web page.

as the individual requesting authorized user status. The work experience must involve:

.i Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

.ii Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

.iii Calculating, measuring, and safely preparing patient or human research subject dosages;

.iv Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;

.v Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

.vi Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status—

.1 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;

.2 Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131[8];

.3 Parenteral administration of any beta emitter, or a photon- emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required; and/or

.4 Parenteral administration of any other radionuclide, for which a written directive is required; and

[8] Experience with at least 3 cases in Category (vi)(2) also satisfies the requirements Category (vi)(1)

.b Has obtained written attestation that the individual has satisfactorily completed the requirements in 700.48(1)(a) and 700.48(2)(a)(ii)(vi) or 700.48(2)(a) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 700.44. The written attestation must be signed by a preceptor authorized user who meets the requirements in 700.48 or equivalent Nuclear Regulatory Commission or Agreement State requirements. The preceptor authorized user, who meets the requirements in 700.48(2) must have experience in administering dosages in the same dosage category or categories (i.e., 700.48(2)(a)(ii)(vi)) as the individual requesting authorized user status.-

700.49 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 700.22, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries), to be a physician who:

.1 Is certified by a medical specialty board whose certification process includes all of the requirements in 700.49(3)(a) and (3)(b) and whose certification process has been recognized by the Agency, Nuclear Regulatory Commission or an Agreement State and who meets the requirements in 700.49 (3)(c)[9]; or

.2 Is an authorized user under 700.48 for uses listed in 700.48(2)(a)(ii)(vi)(1) or (2), 700.50, or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

.3

.a 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:

.i Radiation physics and instrumentation;

.ii Radiation protection;

.iii Mathematics pertaining to the use and measurement of radioactivity;

.iv Chemistry of radioactive material for medical use; and

.v Radiation biology; and

[9] The names of board certifications which have been recognized by the Agency, Nuclear Regulatory Commission (NRC) or another Agreement State will be posted on the NRC's Web page.

.b Has work experience, under the supervision of an authorized user who meets the requirements in 700.48, 700.49, 700.50, or equivalent Nuclear Regulatory Commission or Agreement State requirements. A supervising authorized user who meets the requirements in 700.48(2) must also have experience in administering dosages as specified in 700.48(2)(a)(ii)(vi)(1) or (2). The work experience must involve:-

.i Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

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

.iii Calculating, measuring, and safely preparing patient or human research subject dosages;

.iv Using administrative controls to prevent a misadministration involving the use of radioactive material;

.v Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

.vi 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

.c Has obtained written attestation that the individual has satisfactorily completed the requirements in 700.49(3)(a) and 700.49(3)(b) and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under 700.44 The written attestation must be signed by a preceptor authorized user who meets the requirements in 700.48, 700.49, 700.50, or equivalent Nuclear Regulatory Commission or Agreement State requirements. A preceptor authorized user, who meets the requirement in 700.48(2), must also have experience in administering dosages as specified in 700.48(2)(a)(ii)(vi)(1) or (2).

700.50 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 700.22, 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:

.1 Is certified by a medical specialty board whose certification process includes all of the requirements in 700.50(3)(a) and (3)(b), and whose certification has been recognized by the Agency, Nuclear Regulatory

Commission or an Agreement State, and who meets the requirements in 700.50(3)(c).[10]; or

.2 Is an authorized user under 700.48 for uses listed in 700.48(2)(a)(ii)(vi)(2) or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

.3

.a 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

.i Radiation physics and instrumentation;

.ii Radiation protection;

.iii Mathematics pertaining to the use and measurement of radioactivity;

.iv Chemistry of radioactive material for medical use; and

.v Radiation biology; and

.b Has work experience, under the supervision of an authorized user who meets the requirements in 700.48, 700.50, or equivalent Nuclear Regulatory Commission or Agreement State requirements. A supervising authorized user, who meets the requirements in 700.48(2), must also have experience in administering dosages as specified in 700.48(2)(a)(ii)(vi)(2). The work experience must involve:

.i Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

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

.iii Calculating, measuring, and safely preparing patient or human research subject dosages;

.iv Using administrative controls to prevent a misadministration involving the use of radioactive material;

[10] The names of board certifications which have been recognized by the Agency, Nuclear Regulatory Commission (NRC) or another Agreement State will be posted on the NRC's Web page.

.v Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

.vi 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

.c Has obtained written attestation that the individual has satisfactorily completed the requirements in 700.50(3)(a) and 700.50(3)(b), and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under 700.44. The written attestation must be signed by a preceptor authorized user who meets the requirements in 700.48, 700.50, or equivalent Nuclear Regulatory Commission or Agreement State requirements. A preceptor authorized user, who meets the requirements in 700.48(2), must also have experience in administering dosages as specified in 700.48(2)(a)(ii)(vi)(2).

700.51 Training for the Parenteral Administration of Unsealed Radioactive Material Requiring a Written Directive. Except as provided in 700.22, the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who:

.1 Is an authorized user under 700.48 for uses listed in 700.48(2)(a)(ii)(vi)(3) or 700.48(2)(a)(ii)(vi)(4), or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

.2 Is an authorized user under 700.60, 700.81, or equivalent Nuclear Regulatory Commission or Agreement State requirements and who meets the requirements in 700.51(4); or

.3 Is certified by a medical specialty board whose certification process has been recognized by the Agency, Nuclear Regulatory Commission or an Agreement State under 700.60 or 700.81, and who meets the requirements in 700.51(4).

.4

.a Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. The training must include

.i Radiation physics and instrumentation;

.ii Radiation protection;

.iii Mathematics pertaining to the use and measurement of radioactivity;

.iv Chemistry of radioactive material for medical use; and

.v Radiation biology; and

.b Has work experience, under the supervision of an authorized user who meets the requirements in 700.48, 700.51, or equivalent Nuclear Regulatory Commission or Agreement State requirements, in the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in 700.48 must have experience in administering dosages as specified in 700.48(2)(a)(ii)(vi)(3) and/or 700.48(2)(a)(ii)(vi)(4). The work experience must involve--

.i Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;

.ii Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

.iii Calculating, measuring, and safely preparing patient or human research subject dosages;

.iv Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;

.v Using procedures to contain spilled radioactive material safely, and using proper decontamination procedures; and

.vi Administering dosages to patients or human research subjects, that include at least 3 cases involving the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV and/or at least 3 cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and

.c Has obtained written attestation that the individual has satisfactorily completed the requirements in 700.51(2) or (3) of this section, and has achieved a level of competency sufficient to function independently

as an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in 700.48, 700.51, or equivalent Nuclear Regulatory Commission or Agreement State requirements. A preceptor authorized user, who meets the requirements in 700.48, must have experience in administering dosages as specified in 700.48(2)(a)(ii)(vi)(3) and/or 700.48(2)(a)(ii)(vi)(4).

Manual Brachytherapy

700.52 Use of Sealed Sources for Manual Brachytherapy. A licensee shall use brachytherapy sources for therapeutic medical uses:

.1 As approved in the Sealed Source and Device Registry; or

.2 In research in accordance with an effective Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of 700.18(1) are met.

700.53 Surveys After Source Implant and Removal.

.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.

.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.

.3 A licensee shall retain a record of surveys in accordance with 700.97.

700.54 Brachytherapy Sources Inventory.

.1 A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use.

.2 Promptly after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.

.3 A licensee shall maintain a record of the brachytherapy source accountability in accordance with 700.98.

700.55 Safety Instruction. In addition to the requirements of 1000.03 of these regulations:

.1 The licensee shall provide radiation safety instruction, initially and at intervals not to exceed 1 year, to all personnel caring for a patients or human research subjects that are undergoing implant therapy and cannot be released in accordance with 700.33. Instruction must be commensurate with the duties of the personnel and shall include the following. Refresher training shall be provided at intervals not to exceed 1 year.

.a Size and appearance of the brachytherapy sources;

.b Safe handling and shielding instructions in case of a dislodged source;

.c Patient or human research subject control;

.d Visitor control, including both:

.i Routine visitation of hospitalized individuals in accordance with 400.14(1)(a). of these regulations; and

.ii Visitation authorized in accordance with 400.14(3) of these regulations; and

.e Notification of the Radiation Safety Officer, or his or her designee, and or an authorized user if the patient or human research subject dies or has a medical emergency.; and

.2 A licensee shall maintain retain a record of individuals receiving instruction required by 700.96.

700.56 Safety Precautions for Patients or Human Research Subjects Receiving Brachytherapy.

.1 For each patient or human research subject that is patient receiving implant therapy and cannot be released in accordance with 700.33, a licensee shall:

.a Not place the patient or human research subject in the same room with a patient who is not receiving brachytherapy;

.b Visibly post the patient's or human research subject’s door with a "Caution: Radioactive Material(s)" sign and note on the door or 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;

.c Authorize visits by individuals under 18 years of age only on a case-by-case basis with the approval of the authorized user after consultation with the Radiation Safety Officer; and

.d Promptly after implanting the sources, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with Section 400 of these regulations and retain for 3 years a record of each survey that includes the time and date of the survey, a sketch of the area or list of points surveyed, the measured dose rate at several points expressed in millirems (μSv) per hour, the instrument used to make the survey, and the initials of the individual who made the survey.

.2 A licensee shall have emergency response equipment available near each treatment room to respond to a source that inadvertently becomes:

.a Dislodged from the patient; or

.b Lodged within the patient following removal of the source applicators.

.3 The Radiation Safety Officer or his or her designee, and the authorized user shall be notified immediately if the patient or human research subject dies or has a medical emergency.

700.57 Calibration Measurements of Brachytherapy Sealed Sources.

.1 Prior to the first medical use of a brachytherapy sealed source on or after the effective date of these regulations, a licensee shall perform the following:

.a Determine the source output or activity using a dosimetry system that meets the requirements of 700.69(1);

.b Determine source positioning accuracy within applicators; and

.c Use published protocols accepted by nationally recognized bodies to meet the requirements of 700.57(1)(a) and 700.57(1)(b).

.2 A licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with 700.57(1).

.3 A licensee shall mathematically correct the outputs or activities determined in 700.57(1) of this section for physical decay at intervals consistent with 1.0 percent physical decay.

.4 An authorized medical physicist shall perform or review the calculation measurements made pursuant to 700.57(1), 700.57(2), or 700.57(3).

.5 Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined in accordance with paragraphs 700.57(1), 700.57(2), and 700.57(3).

.6 A licensee shall retain a record of each calibration in accordance with 700.99.

.7 A licensee shall retain a record of decay calculations required by 700.57(5) in accordance with 700.100.

700.58 Therapy-related Computer Systems. The licensee shall perform acceptance testing on the treatment planning system in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

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

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

.3 The accuracy of isodose plots and graphic displays; and

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

700.59 Possession of Survey Instruments. A licensee authorized to use manual brachytherapy sources shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrems) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 10 microsieverts (1 mrem) per hour to 10 millisieverts (1000 mrems) per hour. The instruments shall be operable and calibrated in accordance with 700.26.

700.60 Training for Use of Manual Brachytherapy Sources. Except as provided in 700.22, the licensee shall require the authorized user of a manual brachytherapy source for the uses authorized under 700.52 for therapy to be a physician who:

.1 Is certified by a medical specialty board whose certification process has been recognized by the Agency, Nuclear Regulatory Commission or an Agreement State, and who meets the requirements in 700.60(2)(c).[11] To

[11] The names of board certifications which have been recognized by the Agency, Nuclear Regulatory Commission (NRC) or another Agreement State will be posted on the NRC's Web page.

have its certification process recognized, a specialty board shall require all candidates for certification to:

.a Successfully complete a minimum of 3 years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

.b 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

.2

.a Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:

.i 200 hours of classroom and laboratory training in the following areas;

.i Radiation physics and instrumentation;

.ii Radiation protection;

.iii Mathematics pertaining to the use and measurement of radioactivity; and

.iv Radiation biology.

.ii 500 hours of work experience under the supervision of an authorized user who meets the requirements in 700.60 or equivalent Nuclear Regulatory Commission or Agreement State requirements at a medical institution, involving:

.i Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

.ii Checking survey meters for proper operation;

.iii Preparing, implanting, and removing brachytherapy sources;

.iv Maintaining running inventories of material on hand

.v Using administrative controls to prevent a misadministration involving the use of radioactive material; and

.vi Using emergency procedures to control radioactive material; and

.b Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in 700.60 or equivalent Nuclear Regulatory Commission or Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by 700.60(2)(a)(ii); and

.c Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 700.60 or equivalent Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in 700.60(1)(a), or (2)(a) and 700.60.(2)(b) and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under 700.52.

700.61 Training for Ophthalmic Use of Strontium-90. Except as provided in 700.22, the licensee shall require the authorized user of a strontium-90 for ophthalmic uses authorized under 700.52 to be a physician who:

.1 Is an authorized user under 700.60 or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

.2

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

.i Radiation physics and instrumentation;

.ii Radiation protection;

.iii Mathematics pertaining to the use and measurement of radioactivity; and

.iv Radiation biology; and

.b 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:

.i Examination of each individual to be treated;

.ii Calculation of the dose to be administered;

.iii Administration of the dose; and

.iv Follow-up and review of each individual's case history; and

.c Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 700.60, 700.61, or equivalent Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in 700.61(1) and (2) and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

Sealed Sources For Diagnosis

700.62 Use of Sealed Sources for Diagnosis. A licensee shall only use sealed sources for diagnostic medical uses:

.1 Approved in the Sealed Source and Device Registry; and

.2 Handled in accordance with the manufacturer's radiation safety instructions.

700.63 Training for Use of Sealed Sources for Diagnosis. Except as provided in 700.22, the licensee shall require the authorized user of a diagnostic sealed source for the use in a device authorized under 700.52 to be a physician, dentist, or podiatrist who:

.1 Is certified by a specialty board whose certification process includes all of the requirements in 700.63(2) and (3)[12] and whose certification has been recognized by the Agency, Nuclear Regulatory Commission, or an Agreement State; or

[12] The names of board certifications which have been recognized by the Agency, Nuclear Regulatory Commission (NRC) or another Agreement State will be posted on the NRC's Web page.

.2 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 includes:

.a Radiation physics and instrumentation;

.b Radiation protection;

.c Mathematics pertaining to the use and measurement of radioactivity;

.d Radiation biology; and

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

Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

700.64 Use of Sealed Sources in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit. A licensee shall use sealed sources in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses:

.1 As approved in the Sealed Source and Device Registry; or

.2 In research in accordance with an effective Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of 700.18(a) are met.

700.65 Surveys of Patients and Human Research Subjects Treated with a Remote Afterloader Unit.

.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.

.2 A licensee shall retain a record of the surveys in accordance with 700.97.

700.66 Installation, Maintenance, Adjustment, and Repair.

.1 Only a person specifically licensed by the Agency, the Nuclear Regulatory Commission or an Agreement State 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).

.2 Except for low dose-rate remote afterloader units, only a person specifically licensed by the Agency, an Agreement State, Licensing State or the Nuclear Regulatory Commission shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

.3 For a low dose-rate remote afterloader unit, only a person specifically licensed by the Agency, an Agreement State, Licensing State or the Nuclear Regulatory Commission, or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.

.4 A licensee shall retain a record of the installation, maintenance, adjustment and repair done on remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with 700.101.

700.67 Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.

.1 A licensee shall:

.a Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;

.b Permit only individuals approved by the authorized user, Radiation Safety Officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s);

.c Prevent dual operation of more than one radiation producing device in a treatment room, if applicable; and

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

.i Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

.ii The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

.iii 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.

.2 A copy of the procedures required by 700.67(1)(d) must be physically located at the unit console.

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

.a The location of the procedures required by 700.67(1)(d); and

.b 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.

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

.a The procedures identified in 700.67(1)(d); and

.b The operating procedures for the unit.

.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.

.6 A licensee shall retain a record of individuals receiving instruction required by 700.67(4), in accordance with 700.96.

700.68 Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.

.1 A licensee shall control access to the treatment room by a door at each entrance.

.2 A licensee shall equip each entrance to the treatment room with an electrical interlock system that will:

.a Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

.b Cause the source(s) to be shielded promptly when an entrance door is opened; and

.c 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.

.3 A licensee shall have in each treatment room a permanent radiation monitor capable of continuously monitoring beam status.

.a Each radiation monitor shall be capable of providing visible notice of a teletherapy unit malfunction that results in an exposed or partially exposed source. The visible indicator of high radiation levels shall be observable by an individual entering the teletherapy room.

.b Each radiation monitor shall be equipped with a backup power supply separate from the power supply to the teletherapy unit. This backup power supply may be a battery system.

.c A radiation monitor shall be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for treatment of patients.

.d A licensee shall maintain a record of the check required by 700.68(3)(c) for 3 years. The record shall include the date of the check, notation that the monitor indicates when the source is exposed, and the initials of the individual who performed the check.

.e If a radiation monitor is inoperable, the licensee shall require any individual entering the treatment room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism. The instrument or dosimeter shall be checked with a dedicated check source for proper operation at the beginning of each day of use. The licensee shall keep a record as described in 700.68(3)(d).

.f A licensee shall promptly repair or replace the radiation monitor if it is inoperable.

.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.

.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.

.6 In addition to the requirements specified in 700.68(1) through 700.68(5), a licensee shall:

.a For medium dose-rate, and pulsed dose-rate remote afterloader units, require:

.i 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

.ii 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.

.b For high dose-rate remote afterloader units, require:

.i An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and

.ii 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.

.c 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.

.d Notify the Radiation Safety Officer, 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 A licensee shall have emergency response equipment available near each treatment room to respond to a source that inadvertently:

.a Remains in the unshielded position; or

.b Lodges within the patient following completion of the treatment.

700.69 Dosimetry Equipment.

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

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

.b The system shall have been calibrated within the previous 4 years; 18 to 30 months after that calibration, the system shall have been intercompared with another dosimetry system that was calibrated within the past 24 months by the National Institute of Standards and Technology (NIST) or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The results of the intercomparison meeting 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.

.2 The licensee shall have available for use a dosimetry system for spot-check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with 700.69(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 shall be the same system used to meet the requirement in 700.69(1).

.3 The licensee shall maintain a record of each calibration, intercomparison, and comparison in accordance with 700.102.

700.70 Full Calibration Measurements on Teletherapy Units.

.1 A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:

.a Before the first medical use of the unit;

.b Before medical use under the following conditions:

.i 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;

.ii Following replacement of the source or following reinstallation of the teletherapy unit in a new location; and

.iii 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

.c At intervals not exceeding 1 year.

.2 To satisfy the requirement of 700.70(1), full calibration measurements shall include determination of:

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

.b The coincidence of the radiation field and the field indicated by the light beam localizing device;

.c The uniformity of the radiation field and its dependence on the orientation of the useful beam;

.d Timer accuracy, constancy, and linearity;

.e "On-off" error; and

.f The accuracy of all distance measuring and localization devices in medical use.

.3 A licensee shall use the dosimetry system described in 700.69 to measure the output for one set of exposure conditions. The remaining radiation measurements required in 700.70(2)(a) may then be made using a dosimetry system that indicates relative dose rates.

.4 A licensee shall make full calibration measurements required by 700.70(1) in accordance with published protocols accepted by nationally recognized bodies.

.5 A licensee shall correct mathematically the outputs determined in 700.70(2)(a) 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.

.6 Full calibration measurements required by 700.70(1) and physical decay corrections required by 700.70(5) shall be performed by a medical physicist.

.7 A licensee shall maintain a record of each calibration in accordance with 700.103.

700.71 Full Calibration Measurements on Remote Afterloader Units.

.1 A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit:

.a Before the first medical use of the unit;

.b Before medical use under the following conditions:

.i Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and

.ii 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

.c At intervals not exceeding 1 quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and

.d At intervals not exceeding 1 year for low dose-rate remote afterloader units.

.2 To satisfy the requirement of 700.71(1), full calibration measurements must include, as applicable, determination of:

.a The output within +/- 5 percent;

.b Source positioning accuracy to within +/- 1 millimeter;

.c Source retraction with backup battery upon power failure;

.d Length of the source transfer tubes;

.e Timer accuracy and linearity over the typical range of use;

.f Length of the applicators; and

.g Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

.3 In addition to the requirements for full calibrations for low dose-rate remote afterloader units in 700.71(2), a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding one quarter.

.4 A licensee shall use the dosimetry system described in 700.69(1) to measure the output.

.5 A licensee shall make full calibration measurements required by 700.71(1) of this section in accordance with published protocols accepted by nationally recognized bodies.

.6 For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with 700.71(1) through 700.71(5).

.7 A licensee shall mathematically correct the outputs determined in 700.71(2)(a) for physical decay at intervals consistent with 1 percent physical decay.

.8 Full calibration measurements required by 700.71(1) and physical decay corrections required by 700.71(7) must be performed by the authorized medical physicist.

.9 A licensee shall retain a record of each calibration in accordance with 700.103.

700.72 Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units.

.1 A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit:

.a Before the first medical use of the unit;

.b Before medical use under the following conditions:

.i 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;

.ii Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and

.iii 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

.c 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.

.2 To satisfy the requirement of 700.72(1), full calibration measurements must include determination of:

.a The output within +/-3 percent;

.b Relative helmet factors;

.c Isocenter coincidence;

.d Timer accuracy and linearity over the range of use;

.e On-off error;

.f Trunnion centricity;

.g Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

.h Helmet microswitches;

.i Emergency timing circuits; and

.j Stereotactic frames and localizing devices (trunnions).

.3 A licensee shall use the dosimetry system described in 700.69(1) to measure the output for one set of exposure conditions. The remaining radiation measurements required in 700.72(2)(a) may be made using a dosimetry system that indicates relative dose rates.

.4 A licensee shall make full calibration measurements required by 700.72(1) in accordance with published protocols accepted by nationally recognized bodies.

.5 A licensee shall mathematically correct the outputs determined in 700.72(2)(a) at intervals not exceeding 1 month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.

.6 Full calibration measurements required by 700.72(1) and physical decay corrections required by 700.72(5) must be performed by the authorized medical physicist.

.7 A licensee shall retain a record of each calibration in accordance with 700.103.

700.73 Periodic Spot-Checks for Teletherapy Units.

.1 A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit at intervals not to exceed 1 month that include determination of:

.a Timer constancy and timer linearity over the range of use;

.b "On-off" error;

.c The coincidence of the radiation field and the field indicated by the light beam localizing device;

.d The accuracy of all distance measuring and localization devices used for medical use;

.e The output for one typical set of operating conditions measured with the dosimetry system described in 700.69(2) and

.f The difference between the measurement made in 700.73(1)(e) 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).

.2 A licensee shall perform spot-checks required by 700.73(1) in accordance with procedures established by the authorized medical physicist. The authorized medical physicist teletherapy physicist does not need to actually perform the spot-check measurements.

.3 A licensee shall have the authorized medical physicist teletherapy physicist review the results of each spot-check within 15 days. The authorized medical physicist teletherapy physicist shall promptly notify the licensee in writing of the results of each spot-check.

.4 A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility at intervals not to exceed 1 month. and after each source installation to assure proper operation of:

.a Electrical interlocks at each teletherapy room entrance;

.b 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);

.c Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;

.d Viewing and intercom systems;

.e Treatment room doors from inside and outside the treatment room; and

.f Electrically assisted treatment room doors with the teletherapy unit electrical power turned "off".

.5 If the results of the checks required in 700.73(4) indicate the malfunction of any system, A the 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.

.6 A licensee shall maintain a record of each spot-check required by 700.73(1) and (4) in accordance with 700.104.

700.74 Periodic Spot-Checks for Remote Afterloader Units.

.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:

.a At the beginning of each day of use of a high dose-rate, medium dose-rate or pulsed dose-rate remote afterloader unit;

.b Prior to each patient treatment with a low dose-rate remote afterloader unit; and

.c After each source installation.

.2 The licensee shall have the authorized medical physicist establish written procedures for performing the spot-checks required in 700.74(1). The authorized medical physicist need not actually perform the spot-check measurements.

.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.

.4 To satisfy the requirements of 700.74(1), spot-checks must, at a minimum, assure proper operation of:

.a Electrical interlocks at each remote afterloader unit room entrance;

.b Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

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

.d Emergency response equipment;

.e Radiation monitors used to indicate the source position;

.f Timer accuracy;

.g Clock (date and time) in the unit's computer; and

.h Decayed source(s) activity in the unit's computer.

.5 If the results of the checks required in 700.74(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.

.6 A licensee shall retain a record of each check required by 700.74(4) in accordance with 700.105.

700.75 Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units.

.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:

.a Monthly;

.b At the beginning of each day of use; and

.c After each source installation.

.2 The licensee shall have the authorized medical physicist:

.a Establish written procedures for performing the spot-checks required in 700.75(1); and

.b Review the results of each spot-check required by 700.75(1)(a) within 15 days of the check. The authorized medical physicist need not actually perform the spot-check measurements. The authorized medical physicist shall notify the licensee as soon as possible, in writing, of the results of the spot check.

.3 To satisfy the requirements of 700.75(1)(a), spot-checks must, at a minimum:

.a Assure proper operation of:

.i Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

.ii Helmet microswitches;

.iii Emergency timing circuits; and

.iv Stereotactic frames and localizing devices (trunnions).

.b Determine :

.i The output for one typical set of operating conditions measured with the dosimetry system described in 700.69(2);

.ii The difference between the measurement made in 700.75(3)(b)(i) 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);

.iii Source output against computer calculation;

.iv Timer accuracy and linearity over the range of use;

.v On-off error; and

.vi Trunnion centricity.

.4 To satisfy the requirements of 700.75(1)(b) and 700.75(1)(c), spot-checks must assure proper operation of:

.a Electrical interlocks at each gamma stereotactic radiosurgery room entrance;

.b Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;

.c Viewing and intercom systems;

.d Timer termination;

.e Radiation monitors used to indicate room exposures; and

.f Emergency off buttons.

.5 A licensee shall arrange for prompt repair of any system identified in 700.75(3) that is not operating properly.

.6 If the results of the checks required in 700.75(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 A licensee shall retain a record of each check required by 700.75(3) and 700.75(4) in accordance with 700.106.

700.76 Additional Technical Requirements for Mobile Remote Afterloader Units.

.1 A licensee providing mobile remote afterloader service shall:

.a 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

.b Account for all sources before departure from a client's address of use.

.2 In addition to the periodic spot-checks required by 700.74, 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 :

.a Electrical interlocks on treatment area access points;

.b Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

.c Viewing and intercom systems;

.d Applicators, source transfer tubes, and transfer tube-applicator interfaces;

.e Radiation monitors used to indicate room exposures;

.f Source positioning (accuracy); and

.g Radiation monitors used to indicate whether the source has returned to a safe shielded position.

.3 In addition to the requirements for checks in 700.76(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.

.4 If the results of the checks required in 700.76(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.

.5 A licensee shall retain a record of each check required by 700.76(2) in accordance with 700.107.

700.77 Radiation Surveys.

.1 In addition to the survey requirements in 400.17 of these regulations, a person licensed pursuant to Section 700 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.

.2 The licensee shall make the survey required by 700.77(1) 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).

.3 A licensee shall retain a record of the radiation surveys required by 700.77(1) in accordance with 700.108.

700.78 Five-Year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units.

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

.2 This inspection and servicing may only be performed by persons specifically licensed to do so by the Agency, an Agreement State, a Licensing State or the Nuclear Regulatory Commission.

.3 A licensee shall keep a record of the inspection and servicing in accordance with 700.109.

700.79 Therapy-Related Computer Systems. The licensee shall perform acceptance testing on the treatment planning system in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

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

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

.3 The accuracy of isodose plots and graphic displays;

.4 The accuracy of the software used to determine radioactive source positions from radiographic images; and

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

700.80 Possession of Survey Instruments. 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 microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrems) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 10 microsieverts (1 mrem) per hour to 10 millisieverts (1000 mrems) per hour. The instruments shall be operable and calibrated in accordance with 700.26.

700.81 Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units. Except as provided in 700.22, the licensee shall require the authorized user of a sealed source specified in 700.67 to be a physician who:

.1 Is certified by a medical specialty board whose certification process has been recognized by the Agency, Nuclear Regulatory Commission or an Agreement State and who meets the requirements in 700.81(2)(c) and (3)[13]. To have its certification process recognized, a specialty board shall require all candidates for certification to:

.a Successfully complete a minimum of 3 years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

.b 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

.2

.a 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:

.i 200 hours of classroom and laboratory training in the following area:

.i Radiation physics and instrumentation;

.ii Radiation protection;

[13] The names of board certifications which have been recognized by the Agency, Nuclear Regulatory Commission (NRC) or another Agreement State will be posted on the NRC's Web page.

.iii Mathematics pertaining to the use and measurement of radioactivity; and

.iv Radiation biology; and

.ii 500 hours of work experience, under the supervision of an authorized user who meets the requirements in 700.81 or equivalent Agreement State or Nuclear Regulatory Commission requirements at a medical institution, involving:

.i Reviewing of the full calibration measurements and periodic spot-checks;

.ii Preparing treatment plans and calculating treatment doses and times;

.iii Using administrative controls to prevent misadministrations involving the use of radioactive material;

.iv Implementing emergency procedures to be followed in the event of the abnormal operation of a medical unit or console; and

.v Checking and using survey meters; and

.vi Selecting the proper dose and how it is to be administered; and

.b Has completed 3 years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in 700.81, or equivalent Agreement State or Nuclear Regulatory Commission requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by 700.81(2)(a)(ii); and

.c Has obtained written attestation that the individual has satisfactorily completed the requirements in 700.81(1)(a) or 700.81(2)(a) and 700.81(2)(b), and 700.81(3), and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user who meets the requirements in 700.81 or

equivalent Nuclear Regulatory Commission or Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and

.3 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.

Other Medical Uses of Radioactive Material or Radiation from Radioactive Material

700.82 Other Medical Uses of Radioactive Material or Radiation from Radioactive Material. A licensee may use radioactive material or a radiation source approved for medical use that is not specifically addressed in Section 700 if:

.1 The applicant or licensee has submitted the information required by 700.08(2), 700.08(3), and 700.08(4); and

.2 The applicant or licensee has received written approval from the Agency, Nuclear Regulatory Commission, an Agreement State, or Licensing State in a license and uses the material in accordance with the regulations and specific conditions the Agency, Nuclear Regulatory Commission, Agreement State, or Licensing State considers necessary for the medical use of the material.

Records

700.83 Records of Authority and Responsibilities for Radiation Protection Programs.

.1 A licensee shall retain a record of actions taken by the licensee's management in accordance with 700.13(1) for 5 years. The record must include a summary of the actions taken and a signature of licensee management.

.2 The licensee shall retain a current copy of the authorities, duties and responsibilities of the Radiation Safety Officer as required by 700.13(4), and a signed copy of the Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by 700.13(2). The record must include the signature of the Radiation Safety Officer and licensee management.

.3 The minutes of each Radiation Safety Committee meeting held in accordance with 700.13(7) shall include:

.a The date of the meeting;

.b Members present;

.c Members absent; and

.d Summary of deliberations and discussions.

700.84 Records of Written Directives. A licensee shall retain a copy of each written directive as required by 700.16 for 3 years.

700.85 Records of Misadministrations. A licensee shall retain a record of misadministrations reported in accordance with 700.110 for 3 years. The record must contain the licensee's name; names of the individuals involved; the social security number or other identification number if one has been assigned, of the individual who is the subject of the misadministration; a brief description of the event; why it occurred; the effect, if any, on the individual; the actions, if any, taken, or planned, to prevent recurrence; and, whether the licensee notified the individual (or the individual's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

700.86 Record of a Dose to an Embryo/Fetus or a Nursing Child. A licensee shall retain a record of a dose to an embryo/fetus or a nursing child reported in accordance with 700.111 for 3 years. The record must contain the licensee's name; names of all the individuals involved; social security number or other identification number if one has been assigned to the embryo/fetus, pregnant individual, or nursing child who is the subject of the event; a brief description of the event; why it occurred; the effect, if any, on the embryo/fetus or nursing child; the actions, if any, taken, or planned, to prevent recurrence; and whether the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

700.87 Records of Calibrations of Instruments Used to Measure the Activity of Unsealed Radioactive Material. A licensee shall maintain a record of instrument calibrations required by 700.25 for 3 years. The records must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

700.88 Records of Survey Instrument Calibrations. A licensee shall maintain a record of survey instrument calibrations required by 700.26 for 3 years. The record must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

700.89 Records of Dosages of Unsealed Radioactive Material for Medical Use. A licensee shall maintain a record of dosage determinations required by 700.27 for 3 years. The record must contain the radioactive drug; the patient's or human research subject's name, or identification number if one has been assigned; prescribed dosage; the determined dosage, or a notation that the total activity is less than 1.1 megabecquerels (30 μCi); the date and time of the dosage determination; and the name of the individual who determined the dosage.

700.90 Records of Possession of Sealed Sources and Brachytherapy Sources. A licensee shall retain a record of the physical inventory of sealed sources and brachytherapy sources required by 700.29(6) for 3 years. The inventory record must contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

700.91 Records of Surveys for Ambient Radiation Exposure Rate. A licensee shall retain a record of each survey required by 700.32 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.

700.92 Records of the Release of Individuals Containing Radioactive Drugs or Implants Containing Radioactive Material.

.1 A licensee shall retain a record, signed by the authorized user, of the basis for authorizing the release of an individual, for 3 years after the date of release.

.2 A licensee shall retain a record, for 3 years after the date of release, that the instructions required by 700.33(2) were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 15 millisievert (0.1 rem).

700.93 Records of Administrative and Technical Requirements that Apply to the Provision of Mobile Services.

.1 A licensee shall retain a copy of the letter(s) that permits the use of radioactive material at a client's address of use, as required by 700.11(2), for 3 years after the last provision of service.

.2 A licensee shall retain the record of each survey required by 700.36(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.

700.94 Records of Decay-in-Storage. A licensee shall maintain records of the disposal of licensed materials, as required by 700.36, 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.

700.95 Records of Radionuclide Purity. A licensee shall maintain a record of the radionuclide contaminant concentration tests required by 700.41 for 3 years. The record must include, for each measured elution of radionuclide used to prepare a radioactive drug, the ratio of the measures expressed as kilobecquerel of contaminant per megabecquerel of desired radionuclide (microcuries/millicurie), or microgram of contaminant per megabecquerel of desired radionuclide (microgram/millicurie), the time and date of the measurement, and the name of the individual who made the measurement.

700.96 Records of Safety Instruction and Training. A licensee shall maintain a record of safety instructions and training required by 700.45, 700.55 and 700.67 for 3 years. The record must include a list of the topics covered, the date of the instruction or training, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

700.97 Records of Radiation Surveys of Patients and Human Research Subjects. A licensee shall maintain a record of the surveys required by 700.53 and 700.65 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.

700.98 Records of Brachytherapy Source Inventory.

.1 A licensee shall maintain a record of brachytherapy source accountability required by 700.54 for 3 years.

.2 For temporary implants, the record must include:

.a 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

.b The number and activity of sources not implanted, the time and date they were returned to storage, and the name of the individual who returned them to storage.

.3 For permanent implants, the record must include:

.a 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;

.b The number and activity of sources returned to storage, the date they were returned to storage, and the name of the individual who returned them to storage; and

.c The number and activity of sources permanently implanted in the patient or human research subject.

700.99 Records of Calibration Measurements on Brachytherapy Sources. A licensee shall maintain a record of the calibrations on brachytherapy sources required by 700.57 for 3 years after the last use of the source. The record must include the date of the calibration; the manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source; the source output or activity; source positioning accuracy within applicators; and the signature of the authorized medical physicist.

700.100 Records of Decay of Strontium-90 Sources for Opthalmic Treatments. The licensee shall maintain a record of the activity of a strontium-90 source required by 700.67 for the life of the source. The record must include the date and initial activity of the source as determined under 700.57, and for each decay calculation, the date, the source activity and the signature of the authorized medical physicist.

700.101 Records of Installation, Maintenance, Adjustment, and Repair. A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by 700.66 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.

700.102 Records of Dosimetry Equipment.

.1 A licensee shall retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with 700.69 for the duration of the license.

.2 For each calibration, intercomparison, or comparison, the record must include:

.a The date;

.b The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by 700.69(1) and 700.69(2);

.c The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and

.d The names of the individuals who performed the calibration, intercomparison, or comparison.

700.103 Records of Teletherapy, Remote Afterloader, and Gamma Stereotactic Radiosurgery Full Calibrations.

.1 A licensee shall maintain a record of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations required by 700.70, 700.71, and 700.72 for 3 years.

.2 The record must include:

.a The date of the calibration;

.b The manufacturer's name, model number, and serial number for the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit(s), the source(s), and instruments used to calibrate the unit;

.c The results and assessments of the full calibrations;

.d The results of the autoradiograph required for low dose-rate remote afterloader units; and

.e The signature of the authorized medical physicist who performed the full calibration.

700.104 Records of Periodic Spot-Checks for Teletherapy Units.

.1 A licensee shall retain a record of each periodic spot-check for teletherapy units required by 700.73 for 3 years.

.2 The record must include:

.a The date of the spot-check;

.b 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;

.c An assessment of timer linearity and constancy;

.d The calculated on-off error;

.e A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

.f The determined accuracy of each distance measuring and localization device;

.g The difference between the anticipated output and the measured output;

.h 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

.i 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.

700.105 Records of Periodic Spot-Checks for Remote Afterloader Units.

.1 A licensee shall retain a record of each spot-check for remote afterloader units required by 700.74 for 3 years.

.2 The record must include, as applicable:

.a The date of the spot-check;

.b The manufacturer's name, model number, and serial number for the remote afterloader unit and source;

.c An assessment of timer accuracy;

.d 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

.e 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.

700.106 Records of Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units.

.1 A licensee shall retain a record of each spot-check for gamma stereotactic radiosurgery units required by 700.75 for 3 years.

.2 The record must include:

.a The date of the spot-check;

.b 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;

.c An assessment of timer linearity and accuracy;

.d The calculated on-off error;

.e A determination of trunnion centricity;

.f The difference between the anticipated output and the measured output;

.g An assessment of source output against computer calculations;

.h 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

.i 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.

700.107 Records of Additional Technical Requirements for Mobile Remote Afterloader Units.

.1 A licensee shall retain a record of each check for mobile remote afterloader units required by 700.76 for 3 years.

.2 The record must include:

.a The date of the check;

.b The manufacturer's name, model number, and serial number of the remote afterloader unit;

.c Notations accounting for all sources before the licensee departs from a facility;

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

.e The signature of the individual who performed the check.

700.108 Records of Surveys of Therapeutic Treatment Units.

.1 A licensee shall maintain a record of radiation surveys of treatment units made in accordance with 700.77 for the duration of use of the unit.

.2 The record must include:

.a The date of the measurements;

.b The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;

.c Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and

.d The signature of the individual who performed the test.

700.109 Records of 5-Year Inspection for Teletherapy and Gamma Stereotactic Surgery Units.

.1 A licensee shall maintain a record of the 5-year inspections for teletherapy and gamma stereotactic radiosurgery units required by 700.78 for the duration of use of the unit.

.2 The record must contain:

.a The inspector's radioactive materials license number;

.b The date of inspection;

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

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

.e The signature of the inspector.

Reports

700.110 Reports and Notifications of Misadministrations.

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

.a A dose that differs from the prescribed dose by more than 0.05 Sievert (5 rem) effective dose equivalent, 0.5 Sievert (50 rem) to an organ or tissue, or 0.5 Sievert (50 rem) shallow dose equivalent to the skin; and either

.i The total dose delivered differs from the prescribed dose by 20 percent or more;

.ii The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

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

.b A dose that exceeds 0.05 Sievert (5 rem) effective dose equivalent, 0.5 Sievert (50 rem) to an organ or tissue, or 0.5 Sievert (50 rem) shallow dose equivalent to the skin from any of the following:

.i An administration of a wrong radioactive drug;

.ii An administration of a radioactive drug containing radioactive material by the wrong route of administration;

.iii An administration of a dose or dosage to the wrong individual or human research subject;

.iv An administration of a dose or dosage delivered by the wrong mode of treatment; or

.v A leaking sealed source.

.c A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sievert (50 rem) to an organ or tissue and 50 percent of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

.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.

.3 The licensee shall notify the Agency by telephone no later than the next calendar day after discovery of the misadministration.

.4 The licensee shall submit a written report to the Agency within 15 days after discovery of the misadministration.

.a The written report must include:

.i The licensee's name;

.ii The name of the prescribing physician;

.iii A brief description of the event;

.iv Why the event occurred;

.v The effect, if any, on the individual(s) who received the administration;

.vi Actions, if any, that have been taken, or are planned, to prevent recurrence;

vii. Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not; and

.b The report may not contain the individual's name or any other information that could lead to identification of the individual.

.5 The licensee shall provide notification of the misadministration to the referring physician and also notify the individual who is the subject of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the misadministration may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

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

.7 A licensee shall retain a record of a misadministration in accordance with 700.85. A copy of the record required under 700.85 shall be provided to the referring physician if other than the licensee, within 15 days after discovery of the misadministration.

700.111 Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child.

.1 A licensee shall report any dose to an embryo/fetus that is greater than 5 millisievert (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.

.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:

.a Is greater than 5 millisievert (500 mrem) total effective dose equivalent; or

.b Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

.3 The licensee shall notify by telephone the Agency no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in 700.111(1) or 700.111(2).

.4 The licensee shall submit a written report to the Agency within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in 700.111(1) or 700.111(2).

.a The written report must include:

.i The licensee's name;

.ii The name of the prescribing physician;

.iii A brief description of the event;

.iv Why the event occurred;

.v The effect on the embryo/fetus or the nursing child;

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

vii. 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.

.b 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.

.5 The licensee shall notify the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after of discovery of an event that would require

reporting under 700.111(1) or 700.111(2), unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother, when appropriate. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

.6 A licensee shall retain a record of a dose to an embryo/fetus or a nursing child in accordance with 700.86. A copy of the record required under 700.97 shall be provided to the referring physician, if other than the licensee, within 15 days after discovery of the event.

700.112 Reports of Leaking Sources. A licensee shall file a report with the Agency within 5 days if a leakage test required by 700.29 reveals the presence of 185 Becquerel (0.005 μCi) or more of removable contamination. The written report must include the model number and serial number if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken.