Part G

USE OF RADIONUCLIDES IN THE HEALING ARTS

General Regulatory Information

Sec. G.1 Purpose and Scope. This part establishes requirements and provisions for the use of radionuclides in the healing arts and for issuance of licenses authorizing the medical use of this material. These requirements and provisions provide for the protection of the public health and safety. The requirements and provisions of this part are in addition to, and not in substitution for, others in these regulations. The requirements and provisions of these regulations apply to applicants and licensees subject to this part unless specifically exempted.

Sec. G.2 Definitions. As used in this part, the following definitions apply:

"Area of use" means a portion of a physical structure that has been set aside for the purpose of receiving, preparing, using, or storing radioactive material.

“Authorized medical physicist” means an individual who:

(1) Meets the requirements in G.51(a) and G.59, or

(2) Is identified as an authorized medical physicist or teletherapy physicist on:

(i) A specific medical use license issued by the NRC or Agreement State;

(ii) A medical use permit issued by an NRC master material licensee;

(iii) A permit issued by an NRC or Agreement State broad scope medical use licensee; or

(iv) A permit issued by an NRC master material license broad scope medical use permittee.

“Authorized user” means a physician, dentist, or podiatrist who:

(1) Meets the requirements in G.59 and G.190(a), G.290(a), G.390(a), G.392(a), G.394(a), G.490(a), G.590(a), or G.690(a); or

(2) Is identified as an authorized user on:

(i) An Agreement State or NRC license that authorizes the medical use of radioactive material;

(ii) A permit issued by an NRC master material licensee that is authorized to permit the medical use of radioactive material;

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

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

"Brachytherapy" means a method of radiation therapy in which sources are used to deliver a radiation dose at a distance of up to a few centimeters by surface, intracavitary, intraluminal, or interstitial application.

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

“Client’s address” means the area of use or a temporary job site for the purpose of providing mobile medical service in accordance with G.80.

"Dedicated check source" means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years. This source may also be used for other purposes.

“High dose-rate remote afterloader” means a brachytherapy 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” means a brachytherapy 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” 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.

"Mobile medical 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 teletherapy unit for a specified set of exposure conditions.

“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 unsealed radioactive material as documented:

(1) In a written directive; or

(2) In accordance with the directions of the authorized user for procedures performed pursuant to G.100 and G.200.

"Recordable event" means the administration of:

(1) A radiopharmaceutical or radiation without a written directive where a written directive is required;

(2) A radiopharmaceutical or radiation where a written directive is required without daily recording of each administered radiopharmaceutical dosage or radiation dose in the appropriate record;

(3) A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodide I-125 or I-131 when both:

(i) The administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage, and

(ii) The difference between the administered dosage and the prescribed dosage exceeds 15 microcuries;

(4) A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131, when the administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage;

(5) A teletherapy radiation dose when the calculated weekly administered dose exceeds the weekly prescribed dose by 15 percent or more of the weekly prescribed dose; or

(6) A brachytherapy radiation dose when the calculated administered dose differs by more than 10 percent of the prescribed dose.

"Teletherapy physicist" means an individual identified as the qualified teletherapy physicist on an Agency license.

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

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

Secs. G.3 – G.5 Reserved.

Sec. G.6 Provisions for the Protection of Human Research Subjects.

(a) A licensee may conduct research involving human research subjects only if it uses the radioactive materials specified on its license for the uses authorized on its license.

(b) If the research is conducted, funded, supported, or regulated by a Federal agency that has implemented the Federal Policy for the Protection of Human Subjects (Federal Policy), the licensee shall, before conducting research:

(1) Obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy; and

(2) Obtain "informed consent," as defined and described in the Federal Policy, from the human research subject.

(c) If the research will not be conducted, funded, supported, or regulated by a Federal agency that has implemented the Federal Policy, the licensee shall, before conducting research, apply for and receive a specific amendment to its Agency medical use license. The amendment request must include a written commitment that the licensee will, before conducting research:

(1) Obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy; and

(2) Obtain "informed consent," as defined and described in the Federal Policy, from the human research subject.

(d) Nothing in this section relieves licensees from complying with the other requirements in this part.

Secs. G.7 – G.10 Reserved.

Sec. G.11 License Required.

(a) A person shall not manufacture, produce, acquire, receive, possess, prepare, use, or transfer radioactive material for medical use except in accordance with a specific license issued by the Agency, the NRC, or any other Agreement State, or as allowed in G.11(b) or G.11(c).

(b) Unless prohibited by license condition, an individual may receive, possess, use, or transfer radioactive material in accordance with the regulations in this part under the supervision of an authorized user as provided in G.27.

(c) An individual may prepare unsealed radioactive material for medical use in accordance with the regulations in this part under the supervision of an authorized nuclear pharmacist or authorized user as provided in G.27, unless prohibited by license condition.

(d) Exemptions. A licensee possessing a Type A specific license of broad scope for medical use is exempt from the following:

(1) The provisions of G.12(b)(2);

(2) The provisions of G.12(b)(5) regarding additions to or changes in the areas of use only at the addresses specified in the license;

(3) The provisions of §G.14(a);

(4) The provisions of §G.14(b)(1) for an authorized user or an authorized nuclear pharmacist; and

(5) Requesting amendments requesting sealed sources and devices manufactured and distributed in accordance with Sec. C.28(l).

Sec. G.12 License Applications and Amendments.

(a) Applications.

(1) An application for a license, license amendment, or license renewal must be signed by the applicant's or licensee's management.

(2) An application for a license, license amendment, or license renewal under this part must be made by filing the application on a form prescribed by the Agency.

(3) An applicant that satisfies the requirements specified in Sec. C.27(b) may apply for a Type A specific license of broad scope.

(b) Amendments. A licensee shall apply for and must receive a license amendment:

(1) Before it receives, prepares, or uses radioactive material for a type of use that is permitted under this part but not permitted by the license issued pursuant to this part;

(2) Before it permits anyone to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license except an individual who is:

(i) An authorized user in each category of use certified by the organizations specified in G.51(a), G.57(a), G.390(a), G.392(a), G.394(a), G.396(a), G.490(a), G.491(a) and G.590(a);

(ii) An authorized nuclear pharmacist certified by the organization specified in G.55(a);

(iii) Identified as an authorized user or an authorized nuclear pharmacist on a license issued by the Agency, the NRC or any other Agreement State that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy, respectively; or

(iv) Identified as an authorized user or an authorized nuclear pharmacist on a permit issued by the Agency, the NRC or any other Agreement State licensee of broad scope that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy, respectively;

(3) Before it changes Radiation Safety Officers or teletherapy physicists;

(4) Before it orders radioactive material in excess of the amount, or radionuclide or form different than authorized on the license; and

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

Sec. G.13 Reserved.

Sec. G.14 Notifications.

(a) A licensee shall provide to the Agency a copy of the board certification, the Agency or Agreement State license, or the permit issued by the licensee of broad scope for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user or an authorized nuclear pharmacist pursuant to G.12(b)(2)(i) through G.12(b)(2)(iv).

(b) A licensee shall notify the Agency by letter no later than 30 days after:

(1) An authorized user, an authorized nuclear pharmacist, Radiation Safety Officer, or teletherapy physicist permanently discontinues performance of duties under the license or has a name change; or

(2) The licensee's mailing address changes.

(c) The licensee shall mail the documents required in this section to the appropriate address identified in Sec. A.12.

Secs. G.15 – G.23 Reserved.

General Administrative Requirements

Sec. G.24 Authority and Responsibilities for the Radiation Protection Program.

(a) In addition to the radiation protection program requirements of Sec. D.101, a licensee's management shall approve in writing:

(1) Requests for a license application, renewal, or amendment before submittal to the Agency; and

(2) Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist.

(b) 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.

(c) For up to 60 days each year, a licensee may permit an authorized user or an individual qualified to be a Radiation Safety Officer, under G.50 and G.59, to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in G.24(g), if the licensee takes the actions required in G.24(b), G.24(e), G.24(g), and G.24(h) and notifies the Agency in accordance with G.14.

(d) A licensee may simultaneously appoint more than one temporary Radiation Safety Officer in accordance with G.24(c) if needed to ensure that the licensee has a temporary Radiation Safety Officer that satisfies the requirements to be a Radiation Safety Officer for each of the different types of uses of radioactive material permitted by the license.

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

(f) Reserved.

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

(1) Identify radiation safety problems;

(2) Initiate, recommend, or provide corrective actions;

(3) Stop unsafe operations; and,

(4) Verify implementation of corrective actions.

(h) ALARA Program.

(1) Each licensee shall develop and implement a written program to maintain radiation doses and releases of radioactive material in effluents to unrestricted areas as low as reasonably achievable in accordance with Sec. D.1 of these regulations.

(2) To satisfy the requirement of G.24(h)(1):

(i) The management, Radiation Safety Officer, and all authorized users shall participate in the establishment, implementation, and operation of the program as required by these regulations or the Radiation Safety Committee; or

(ii) For licensees that are not medical institutions, management and all authorized users shall participate in the program as required by the Radiation Safety Officer.

(3) The ALARA program shall include an annual review by the Radiation Safety Committee for licensees that are medical institutions, or management and the Radiation Safety Officer for licensees that are not medical institutions, of summaries of the types and amounts of radioactive material used, occupational dose reports, and continuing education and training for all personnel who work with or in the vicinity of radioactive material. The purpose of the review is to ensure that individuals make every reasonable effort to maintain occupational doses, doses to the general public, and releases of radioactive material as low as reasonably achievable.

(4) The licensee shall retain a current written description of the ALARA program for the duration of the license. The written description shall include:

(i) A commitment by management to keep occupational doses as low as reasonably achievable;

(ii) A requirement that the Radiation Safety Officer brief management once each year on the radiation safety program;

(iii) Personnel exposure investigational levels as established in accordance with G.26(b)(9) that, when exceeded, will initiate an investigation by the Radiation Safety Officer of the cause of the exposure; and

(iv) Personnel exposure investigational levels that, when exceeded, will initiate a prompt investigation by the Radiation Safety Officer of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence.

(i) A licensee shall retain a record of actions taken under G.24(a), G.24(b), and G.24(e) in accordance with G.2024.

Sec. G.25 Radiation Safety Officer.

(a) A licensee shall appoint a Radiation Safety Officer responsible for implementing the radiation safety program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's radioactive material program.

(b) The Radiation Safety Officer shall:

(1) Investigate overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, and disposals, and other deviations from approved radiation safety practice and implement corrective actions as necessary;

(2) Implement written policy and procedures for:

(i) Authorizing the purchase of radioactive material;

(ii) Receiving and opening packages of radioactive material;

(iii) Storing radioactive material;

(iv) Keeping an inventory record of radioactive material;

(v) Using radioactive material safely;

(vi) Taking emergency action if control of radioactive material is lost;

(vii) Performing periodic radiation surveys;

(viii) Performing checks and calibrations of survey instruments and other safety equipment;

(ix) Disposing of radioactive material;

(x) Training personnel who work in or frequent areas where radioactive material is used or stored; and

(xi) Keeping a copy of all records and reports required by the Agency regulations, a copy of these regulations, a copy of each licensing request and license and amendments, and the written policy and procedures required by the regulations; and

(3) For medical use not sited at a medical institution, approve or disapprove radiation safety program changes with the advice and consent of management prior to submittal to the Agency for licensing action; or

(4) For medical use sited at a medical institution or private medical licensee that is authorized for one or more therapeutic use, assist the Radiation Safety Committee in the performance of its duties.

Sec. G.26 Radiation Safety Committee. Each medical institution licensee shall establish a Radiation Safety Committee to oversee the use of radioactive material. Each private medical licensee that is authorized for one or more therapeutic use shall also establish a Radiation Safety Committee.

(a) The Committee shall meet the following administrative requirements:

(1) Membership must consist of at least 3 individuals and shall include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service (if applicable), and a representative of management who is neither an authorized user nor a Radiation Safety Officer. Other members may be included as the licensee deems appropriate.

(2) The Committee shall meet at least once each calendar quarter.

(3) The minutes of each Radiation Safety Committee meeting shall include:

(i) The date of the meeting;

(ii) Members present;

(iii) Members absent;

(iv) Summary of deliberations and discussions;

(v) Recommended actions and the numerical results of all ballots; and

(vi) Documentation of any reviews required in Sec. D.101(c) and G.26(b).

(4) The Committee shall provide each member with a copy of the meeting minutes, and retain one copy until the Agency authorizes its disposition.

(b) To oversee the use of licensed material, the Committee shall:

(1) Be responsible for monitoring the institutional program to maintain occupational doses as low as reasonably achievable;

(2) Review, on the basis of safety and with regard to the training and experience standards of this part, and approve or disapprove any individual who is to be listed as an authorized user, an authorized nuclear pharmacist, the Radiation Safety Officer, or teletherapy physicist before submitting a license application or request for amendment or renewal; or

(3) Review, pursuant to Sections G.12(b)(2)(i) through (iv), on the basis of the board certification, the license, or the permit identifying an individual, and approve or disapprove any individual prior to allowing that individual to work as an authorized user or authorized nuclear pharmacist;

(4) Review on the basis of safety and approve or disapprove each proposed method of use of radioactive material;

(5) Review on the basis of safety, and approve with the advice and consent of the Radiation Safety Officer and the management representative, or disapprove procedures and radiation safety program changes prior to submittal to the Agency for licensing action;

(6) Review quarterly, with the assistance of the Radiation Safety Officer, occupational radiation exposure records of all personnel working with radioactive material;

(7) Review quarterly, with the assistance of the Radiation Safety Officer, all incidents and misadministrations involving radioactive material with respect to cause and subsequent actions taken;

(8) Review annually, with the assistance of the Radiation Safety Officer, the radioactive material program; and

(9) Establish a table of investigational levels for occupational dose that, when exceeded, will initiate investigations and considerations of action by the Radiation Safety Officer.

Sec. G.27 Supervision.

(a) A licensee who permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by G.11(b) shall:

(1) Instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of this chapter, and license conditions with respect to the use of radioactive material; and

(2) Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures established by the licensee, written directive procedures, regulations of this chapter, and license conditions with respect to the medical use of radioactive material.

(b) 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 G.11(c), shall:

(1) Instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual’s involvement with radioactive material; and

(2) Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, written radiation protection procedures established by the licensee, the regulations of this chapter, and license conditions.

(c) A licensee that permits supervised activities under paragraphs (a) and (b) of this section is responsible for the acts and omissions of the supervised individual.

Secs. G.28 – G.39 Reserved.

Sec. G.40 Written Directives.

(a) A written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries (μCi)), any therapeutic dosage of unsealed radioactive material or any therapeutic dose of radiation from radioactive material.

(b) If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within 48 hours of the oral directive.

(c) The written directive must contain the patient or human research subject's name and the following information:

(1) For any administration of quantities greater than 1.11 MBq (30 μCi) of sodium iodide I-131: the dosage;

(2) For an administration of a therapeutic dosage of unsealed radioactive material other than sodium iodide I-131: the radioactive drug, dosage, and route of administration;

(3) For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;

(4) For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site;

(5) For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or

(6) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:

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

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

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

(e) If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.

(f) The licensee shall retain a copy of the written directive in accordance with G.2040.

Sec. G.41 Procedures for Administrations Requiring a Written Directive.

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

(1) Prior to each administration, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive; and

(2) Each administration is in accordance with the written directive.

(b) At a minimum, the procedures required by G.41(a) must address the following items that are applicable to the licensee's use of radioactive material:

(1) Verifying the identity of the patient or human research subject;

(2) Verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;

(3) Checking both manual and computer-generated dose calculations; and

(4) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by G.600.

(c) A licensee shall retain a copy of the procedures required in G.41 in accordance with G.2041.

Secs. G.42 – G.48 Reserved.

Sec. G.49 Suppliers for Sealed Sources or Devices for Medical Use. For medical use, a licensee may only use:

(a) Sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued under Sec. C., 10 CFR Part 30 and 10 CFR 32.74, or the equivalent requirements of an Agreement State;

(b) Sealed sources or devices noncommercially transferred from a 10 CFR Part 35 licensee or an Agreement State medical use licensee; or

(c) Teletherapy sources manufactured and distributed in accordance with a license issued under 10 CFR Part 30 or the equivalent requirements of an Agreement State.

Sec. G.50 Training For Radiation Safety Officer.

Except as provided in G.57, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in G.24 to be an individual who:

(a) Is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in G.50(d) and G.50(e) (the names of board certifications which have been recognized by the NRC or an Agreement State will be posted on the NRC's Web page):

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

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

(2) (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:

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

(b) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users in G.290, G.390; and

(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

(b) Has completed a structured educational program consisting of both:

(1) 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) Radiation biology; and

(v) Radiation dosimetry; and

(2) One year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on an NRC or Agreement State license or permit issued by an NRC 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

(c) (1) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by an Agreement State or the NRC under G.51(a) 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 G.50(d) and G.50(e); or

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

(d) Has obtained written attestation, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in G.50 and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; and

(e) 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.

Sec. G.51 Training for an Authorized Medical Physicist.

Except as provided in G.57, the licensee shall require the authorized medical physicist to be an individual who:

(a) Is certified by a specialty board whose certification process has been approved by the NRC or an Agreement State and who meets the requirements in G.51(b)(2) and G.51(c). The names of board certifications which have been approved by the NRC or an Agreement State will be posted on the NRC's Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

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

(2) 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 NRC 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 G.490 or G.690; and

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

(b) (1) Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed 1 year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services and must include:

(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

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in G.51(c) and G.51(a)(1) and (2), or G.51(b)(1) and G.51(c), 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 G.51, or equivalent Agreement State or NRC requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

(c) 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.

Secs. G.52 – G.54 Reserved.

Sec. G.55 Training for an Authorized Nuclear Pharmacist.

Except as provided in G.57, the licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

(a) Is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in G.55(b)(2). The names of board certifications which have been recognized by the NRC or an Agreement State will be posted on the NRC's Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

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

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

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

(4) Pass an examination in nuclear pharmacy administered by diplomates of the specialty board, 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

(b) Has completed:

(1) 700 hours in a structured educational program consisting of both:

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

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

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

(e) Radiation biology; and

(ii) Supervised practical experience in a nuclear pharmacy involving:

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

(b) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

(c) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

(d) Using administrative controls to avoid misadministrations in the administration of radioactive material; and

(e) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

(2) Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in G.55(a)(1), (a)(2), and (a)(3) or G.55(b)(1) and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

Sec. G.56 Reserved.

Sec. G.57 Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Medical Physicist, Authorized User, Nuclear Pharmacist, and Authorized Nuclear Pharmacist.

(a) An individual identified as a Radiation Safety Officer, a teletherapy physicist or authorized medical physicist, or an authorized nuclear pharmacist on an NRC or Agreement State license or a permit issued by an NRC or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope before the effective date of these regulations need not comply with the training requirements of G.50, G.51, or G.55, respectively.

(b) Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the NRC or Agreement State, a permit issued by an NRC master material licensee, a permit issued by an NRC or Agreement State broad scope licensee, or a permit issued by an NRC master material license broad scope permittee who perform only those medical uses for which they were authorized before the effective date of these regulations need not comply with the training requirements of G.100 through G.690.

Sec. G.58 Reserved.

Sec. G.59 Recentness of Training.

The training and experience specified in Sec. G.55 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

Sec. G.60.A Possession, Use, Calibration, and Check of Instruments to Measure Dosages of Alpha- or Beta-emitting Radionuclides.

(a) This section does not apply to unit dosages of alpha- and beta-emitting radionuclides that are obtained from a manufacturer or preparer licensed by the Agency pursuant to Sec. C.28(j), or licensed by the NRC or any other Agreement State pursuant to provisions equivalent to Sec. C.28(j).

(b) For other than unit dosages obtained pursuant to paragraph (a) of this section, a licensee shall possess and use instrumentation to measure the radioactivity of alpha- and beta-emitting radionuclides. The licensee shall have procedures for the use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha- and beta-emitting radionuclides prior to administration to each patient or human research subject. In addition, the licensee shall:

(1) Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

(2) Check each instrument for constancy and proper operation at the beginning of each day of use.

Sec. G.60.B Possession, Use, Calibration, and Check of Dose Calibrators.

(a) 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 or human research subject.

(b) A licensee shall:

(1) Check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. To satisfy the requirement of this section, the check shall be done on a frequently used setting with a sealed source of not less than 10 microcuries (370 kBq) of radium-226 or 50 microcuries (1.85 MBq) of any other photon-emitting radionuclide with a half-life greater than 90 days;

(2) 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 10 microcuries (370 kBq) for radium-226 and 50 microcuries (1.85 MBq) for any other photon-emitting radionuclide, and at least one of which has a principal photon energy between 100 keV and 500 keV;

(3) Test each dose calibrator for linearity upon installation and at least quarterly thereafter over a range from the highest dosage that will be administered to a patient or human research subject to 1.1 megabecquerels (30 microcuries); and

(4) 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.

(c) 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.

(d) A licensee shall also perform checks and tests required by G.60.B(b) following adjustment or repair of the dose calibrator.

(e) A licensee shall retain a record of each check and test required by G.60.B(b) for 3 years. The records required by G.60.B(b) shall include:

(1) For G.60.B(b)(1), the model and serial number of the dose calibrator, the identity and calibrated activity of the radionuclide contained in the check source, the date of the check, the activity measured, the instrument settings, and the initials of the individual who performed the check;

(2) For G.60.B(b)(2), the model and serial number of the dose calibrator, the model and serial number of each source used and the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, the instrument settings, and the identity of the individual performing the test;

(3) For G.60.B(b)(3), the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, and the identity of the individual performing the test; and

(4) For G.60.B(b)(4), the model and serial number of the dose calibrator, the configuration and calibrated activity of the source measured, the activity of the source, the activity measured and the instrument setting for each volume measured, the date of the test, and the identity of the individual performing the test.

Sec. G.61 Calibration and Check of Survey Instruments.

(a) A licensee shall ensure that the survey instruments used to show compliance with this part have been calibrated before first use, annually, and following repair.

(b) To satisfy the requirements of G.61(a), the licensee shall:

(1) Calibrate all required scale readings up to 1000 millirems (10 mSv) per hour with a radiation source;

(2) For each scale that shall be calibrated, calibrate two readings separated by at least 50 percent of scale rating; and

(3) 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.

(c) To satisfy the requirements of G.61(b), the licensee shall consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent, and shall conspicuously attach a correction chart or graph to the instrument.

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

(e) The licensee shall retain a record of each calibration required in G.61(a) for 3 years. The record shall include:

(1) A description of the calibration procedure; and

(2) A description of the source used and the certified dose rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

(f) To meet the requirements of G.61(a), G.61(b), and G.61(c), the licensee may obtain the services of individuals licensed by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State to perform calibrations of survey instruments. Records of calibrations which contain information required by G.61(e) shall be maintained by the licensee.

Sec. G.62 Reserved.

Sec. G.63 Determination of Dosages of Unsealed Radioactive Material for Medical Use.

(a) A licensee shall determine and record the activity of each dosage before medical use;

(b) For a unit dosage, this determination must be made by:

(1) Direct measurement of radioactivity; or

(2) A decay correction, based on the activity or activity concentration determined by:

(i) A manufacturer or preparer licensed under Sec. C.28, or equivalent NRC or Agreement State requirements; or

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

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

(1) Direct measurement of radioactivity;

(2) Combination of measurement of radioactivity and mathematical calculations; or

(3) Combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer or preparer licensed under Sec. C.28, or equivalent NRC or Agreement State requirements.

(d) Unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent.

(e) A licensee shall retain a record of the dosage determination required by G.2063.

Sec. G.64 Reserved.

Sec. G.65 Authorization for Calibration, Transmission, and Reference Sources. Any person authorized by G.11 for medical use of radioactive material may receive, possess, and use any of the following radioactive material for check, calibration, transmission, and reference use:

(a) Sealed sources, not exceeding 1.11 GBq (30 mCi) each, manufactured and distributed by a person licensed under Sec. C.28, or equivalent NRC or Agreement State requirements.

(b) Sealed sources, not exceeding 1.11 GBq (30 mCi) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under Sec. C.28 or equivalent NRC or Agreement State regulations, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions.

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

(d) Any radioactive material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 7.4 MBq (200 μCi) or 1000 times the quantities in Sec. D Appendix C.

(e) Technetium-99m in amounts as needed.

Sec. G.66 Reserved.

Sec. G.67 Requirements for Possession of Sealed Sources and Brachytherapy Sources.

(a) A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer.

(b) A licensee in possession of a sealed source shall:

(1) 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

(2) Test the source for leakage at intervals not to exceed 6 months or at other intervals approved by the NRC or an Agreement State in the Sealed Source and Device Registry.

(c) To satisfy the leak test requirements of this section, the licensee shall measure the sample so that the leak test can detect the presence of 185 Bq (0.005 μCi) of radioactive material in the sample.

(d) A licensee shall retain leak test records in accordance with G.2067(a).

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

(1) Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements in Sec D.401; and

(2) File a report within 5 days of the leak test in accordance with Sec. D.1206.

(f) A licensee need not perform a leak test on the following sources:

(1) Sources containing only radioactive material with a half-life of less than 30 days;

(2) Sources containing only radioactive material as a gas;

(3) Sources containing 3.7 MBq (100 μCi) or less of beta or gamma-emitting material or 0.37 MBq (10 μCi) or less of alpha-emitting material;

(4) Seeds of iridium-192 encased in nylon ribbon; and

(5) Sources stored and not being used. However, the licensee shall test each such source for leakage before any use or transfer unless it has been leak tested within 6 months before the date of use or transfer.

(g) A licensee in possession of sealed sources or brachytherapy sources, except for gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such sources in its possession. The licensee shall retain each inventory record in accordance with G.2067(b).

Sec. G.68 Reserved.

Sec. G.69 Labeling of Vials and Syringes.

Each syringe and vial that contains unsealed radioactive material must be labeled to identify the radioactive drug. Each syringe shield and vial shield must also be labeled unless the label on the syringe or vial is visible when shielded.

Sec. G.70 Surveys for Contamination and Ambient Radiation Dose Rate.

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

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

(c) A licensee shall conduct the surveys required by G.70(a) and G.70(b) so as to be able to measure dose rates as low as 0.1 millirem (1 μSv) per hour.

(d) A licensee shall establish dose rate action levels for the surveys required by G.70(a) and G.70(b) and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if a dose rate exceeds an action level.

(e) A licensee shall survey for removable contamination once each week all areas where radiopharmaceuticals are prepared for use or administered and each week where radioactive materials are stored.

(f) A licensee shall conduct the surveys required by G.70(e) so as to be able to detect contamination on each wipe sample of 200 disintegrations per minute (33.3 Bq).

(g) A licensee shall establish removable contamination action levels for the surveys required by G.70(e) and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds action levels.

(h) A licensee shall retain a record of each survey required by G.70(a), (b), and (e) for 3 years. The record must include the date of the survey, a sketch of each area surveyed, action levels established for each area, the measured dose rate at several points in each area expressed in millirems (microsieverts) per hour or the removable contamination in each area expressed in disintegrations per minute (becquerels) per 100 square centimeters, the serial number and the model number of the instrument used to make the survey or analyze the samples, and the initials of the individual who performed the survey.

Secs. G.71 – G.74 Reserved.

Sec. G.75 Release of Individuals Containing Unsealed Radioactive Material or Implants Containing Radioactive Material.

(a) A licensee may authorize the release from its control of any individual who has been administered unsealed radioactive material 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 mSv (0.5 rem).[1]

(b) A licensee shall provide the released individual, or the individual's parent or guardian, with instructions, including 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 mSv (0.1 rem). If the total effective dose equivalent to a nursing infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption of breast-feeding, the instructions must also include:

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

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[1] 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).

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

(c) A licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with G.2075(a).

(d) The licensee shall maintain a record of instructions provided to a breast-feeding female in accordance with G.2075(b).

Secs. G.76 – G.79 Reserved.

Sec. G.80 Provision of Mobile Medical Service.

(a) A licensee providing mobile medical service shall--

(1) Obtain a letter signed by the management of each client for which services are rendered that permits the use of radioactive material at the client's address and clearly delineates the authority and responsibility of the licensee and the client;

(2) 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 required by this paragraph must include a constancy check;

(3) Check survey instruments for proper operation with a dedicated check source before use at each client's address; and

(4) Before leaving a client's address, survey all areas of use to ensure compliance with the requirements in COMAR 26.12.01.01 Part D.

(b) A mobile medical service may not have radioactive material delivered from the manufacturer or the distributor to the client unless the client has a license allowing possession of the radioactive material. Radioactive material delivered to the client must be received and handled in conformance with the client's license.

(c) A licensee providing mobile medical services shall retain the letter required in G.80(a)(1) and the record of each survey required in G.80(a)(4) in accordance with G.2080(a) and (b), respectively.

Secs. G.81 – G.99 Reserved.

Unsealed Radioactive Material—Written Directive Not Required

Sec. G.100 Use of Unsealed Radioactive Material for Uptake, Dilution, and Excretion Studies for which a Written Directive is Not Required.

Except for quantities that require a written directive under G.40(b), a licensee may use any unsealed radioactive material prepared for medical use for uptake, dilution, or excretion studies that is—

(a) Obtained from a manufacturer or preparer licensed by the Agency pursuant to C.28(j), or licensed by the NRC or any other Agreement State pursuant to provisions equivalent to C.28(j); or

(b) Prepared by an authorized nuclear pharmacist; a physician who is an authorized user and who meets the requirements specified in G.290, or G.390 and G.290(c)(1)(ii)(g); or an individual under the supervision of either as specified in G.27; or

(c) Obtained from and prepared by an NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(d) 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.

Secs. G.101 – G.189 Reserved.

Sec. G.190 Training for Uptake, Dilution, and Excretion Studies.

Except as provided in G.57, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under G.100 to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in G.190(c)(2). (The names of board certifications which have been recognized by the NRC or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

> (1) Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies that includes the topics listed in G.190(c)(1)(i) and G.190(c)(1)(ii); and

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

(b) Is an authorized user under G.290, G.390, or equivalent NRC requirements; or

(c) Has completed the following:

(1) 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:

(i) Classroom and laboratory training in the following areas:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

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

(e) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in G.190, G.290, G.390, or equivalent NRC or Agreement State requirements, involving:

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

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

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

(d) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;

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

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

(2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in G.190, G.290, G.390, or equivalent NRC or Agreement State requirements, that the individual has satisfactorily completed the requirements in G.190(a)(1) or G.190(c)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under G.100.

Secs. G.191 – G.199 Reserved.

Sec. G.200 Use of Unsealed Radioactive Material for Imaging and Localization Studies for Which a Written Directive is Not Required.

Except for quantities that require a written directive under G.40(b), a licensee may use any unsealed radioactive material prepared for medical use for imaging and localization studies that is:

(a) Obtained from a manufacturer or preparer licensed under Sec. C.28(j) or equivalent Agreement State or NRC requirements; or

(b) Prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements specified in G.290, or G.390 and G.290(c)(1)(ii)(g); or

(3) An individual under the supervision, as specified in G.27, of the authorized nuclear pharmacist in G.200(b)(1) or the physician who is an authorized user in G.200(b)(2);

(c) Obtained from and prepared by an Agreement State licensee or NRC 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

(d) 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.

Secs. G.201 – G.203 Reserved.

Sec. G.204 Permissible Molybdenum-99 Concentration.

(a) A licensee may not administer to humans a radiopharmaceutical that contains more than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m).

(b) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration of the first eluate after receipt of a generator to demonstrate compliance with G.204(a).

(c) If a licensee is required to measure the molybdenum-99 concentration, the licensee shall retain a record of each measurement in accordance with G.2204.

Secs. G.205 – G.289 Reserved.

Sec. G.290 Training for Imaging and Localization Studies.

Except as provided in G.57, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under G.200 to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by an Agreement State or the NRC and who meets the requirements in G.290(c)(2). (The names of board certifications which have been recognized by the NRC or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for imaging and localization studies that includes the topics listed in G.290(c)(1)(i) and G.290(c)(1)(ii); and

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

(b) Is an authorized user under G.390 and meets the requirements in G.290(c)(1)(ii)(g), or equivalent Agreement State or NRC requirements; or

(c) Has completed the following:

(1) 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:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

(d) Chemistry of radioactive material for medical use;

(e) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user, who meets the requirements in G.290, or G.290(c)(1)(ii)(g) and G.390, or equivalent Agreement State or NRC requirements, involving:

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

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

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

(d) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;

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

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

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

(2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in G.290 or G.390 and G.290(c)(1)(ii)(g), or equivalent Agreement State or NRC requirements, that the individual has satisfactorily completed the requirements in G.290(a)(1) or G.290(c)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under G.100 and G.200.

Secs. G.291 – G.299 Reserved.

Unsealed Radioactive Material—Written Directive Required

Sec. G.300 Use of Unsealed Radioactive Material for Which a Written Directive is Required.

A licensee may use any unsealed radioactive material prepared for medical use and for which a written directive is required that is:

(a) Obtained from a manufacturer or preparer licensed under Sec. C.28(j) or equivalent NRC or Agreement State requirements; or

(b) Prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements specified in G.290 and G.390; or

(3) An individual under the supervision, as specified in G.27, of the authorized nuclear pharmacist in G.300(b)(1) or the physician who is an authorized user in G.300(b)(2); or

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

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

Secs. G.301 – G.309 Reserved.

Sec. G.310 Safety Instruction.

In addition to the requirements of Sec. J.12:

(a) A licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who cannot be released under G.75. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include:

(1) Patient or human research subject control;

(2) Visitor control, including:

(i) Routine visitation to hospitalized individuals in accordance with Sec. D.301(a)(1); and

(ii) Visitation authorized in accordance with Sec. D.301(d);

(3) Contamination control;

(4) Waste control; and

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

(b) A licensee shall retain a record of individuals receiving instruction in accordance with G.2310.

Secs. G.311 – G.314 Reserved.

Sec. G.315 Safety Precautions.

(a) For each patient or human research subject who cannot be released under G.75, a licensee shall:

(1) 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 therapy with unsealed radioactive material and who also cannot be released under G.75;

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

(3) Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room; and

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

(b) A licensee shall notify the Radiation Safety Officer, or his or her designee, and the authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

Secs. G.316 – G.389 Reserved.

Sec. G.390 Training for Use of Unsealed Radioactive Material for Which a Written Directive is Required.

Except as provided in G.57, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under G.300 to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in G.390(b)(1)(ii)(g) and G.390(b)(2). (Specialty boards whose certification processes have been recognized by the NRC or an Agreement State will be posted on the NRC's Web page.) To be recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in G.390(b)(1)(i) through G.390(b)(1)(ii)(e). Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(2) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed radioactive material for which a written directive is required; or

(b) (1) Has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience must include:

(i) Classroom and laboratory training in the following areas:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

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

(e) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in G.390, or equivalent Agreement State or NRC requirements. A supervising authorized user, who meets the requirements in G.390(b), must also have experience in administering dosages in the same dosage category or categories (i.e., G.390(b)(1)(ii)(g)) as the individual requesting authorized user status. The work experience must involve:

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

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

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

(d) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;

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

(f) [Reserved]

(g) 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;[2]

(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

[2] Experience with at least 3 cases in G.390(b)(1)(ii)(g)(*2*) also satisfies the requirement in Category G.390(b)(1)(ii)(g)(*1*)

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

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in G.390(a)(1) and G.390(b)(1)(ii)(g) or G.390(b)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under G.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in G.390 or equivalent Agreement State or NRC requirements. The preceptor authorized user, who meets the requirements in G.390(b), must have experience in administering dosages in the same dosage category or categories (i.e., G.390(b)(1)(ii)(g)) as the individual requesting authorized user status.

Sec. G.391 Reserved.

Sec. G.392 Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Less than or Equal to 1.22 Gigabecquerels (33 millicuries).

Except as provided in G.57, 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:

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in G.392(c)(1) and G.392(c)(2) and whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in G.392(c)(3) (the names of board certifications which have been recognized by the NRC or an Agreement State will be posted on the NRC's Web page); or

(b) Is an authorized user under G.390 for uses listed in G.390(b)(1)(ii)(g)(1) or (2), G.394, or equivalent Agreement State or NRC requirements; or

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

(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

(2) Has work experience, under the supervision of an authorized user who meets the requirements in G.390, G.392, G.394, or equivalent Agreement State or NRC requirements. A supervising authorized user who meets the requirements in G.390(b) must also have experience in administering dosages as specified in G.390(b)(1)(ii)(g)(*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

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in G.392(c)(1) and G.392(c)(2), and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under G.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in G.390, G.392, or G.394, or equivalent Agreement State or NRC requirements. A preceptor authorized user, who meets the requirement in G.390(b), must also have experience in administering dosages as specified in G.390(b)(1)(ii)(g)(*1*) or (*2*).

Sec. G.393 Reserved.

Sec. G.394 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 G.57, 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:

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in G.394(c)(1) and G.394(c)(2), and whose certification has been recognized by the NRC or an Agreement State, and who meets the requirements in paragraph G.394(c)(3) (the names of board certifications which have been recognized by the NRC or an Agreement State will be posted on the NRC's Web page); or

(b) Is an authorized user under G.390 for uses listed in G.390(b)(1)(ii)(g)(2) or equivalent Agreement State or NRC requirements; or

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

(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

(2) Has work experience, under the supervision of an authorized user who meets the requirements in G.390, G.394, or equivalent Agreement State or NRC requirements. A supervising authorized user, who meets the requirements in G.390(b), must also have experience in administering dosages as specified in G.390(b)(1)(ii)(g)(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 greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in G.394(c)(1) and G.394(c)(2), and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under G.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in G.390 or G.394, or equivalent Agreement State or NRC requirements. A preceptor authorized user, who meets the requirements in G.390(b), must also have experience in administering dosages as specified in G.390(b)(1)(ii)(g)(2).

Sec. G.395 Reserved.

Sec. G.396 Training for the Parenteral Administration of Unsealed Radioactive Material Requiring a Written Directive.

Except as provided in G.57, the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who:

(a) Is an authorized user under G.390 for uses listed in G.390(b)(1)(ii)(g)(3) or G.390(b)(1)(ii)(g)(4), or equivalent Agreement State or NRC requirements; or

(b) Is an authorized user under G.490 or G.690, or equivalent Agreement State or NRC requirements and who meets the requirements in G.396(d); or

(c) Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State under G.490 or G.690, and who meets the requirements in G.396(d).

(d) (1) 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

(2) Has work experience, under the supervision of an authorized user who meets the requirements in G.390 or G.396, or equivalent Agreement State or NRC requirements, in the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in G.390 must have experience in administering dosages as specified in G.390(b)(1)(ii)(g)(3) and/or G.390(b)(1)(ii)(g)(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

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in G.396(b) or (c), 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 G.390, G.396, or equivalent Agreement State or NRC requirements. A preceptor authorized user, who meets the requirements in G.390, must have experience in administering dosages as specified in G.390(b)(1)(ii)(g)(3) and/or G.390(b)(1)(ii)(g)(4).

Secs. G.397 – G.399 Reserved.

Manual Brachytherapy

Sec. G.400 Use of Sources for Manual Brachytherapy. A licensee shall use only brachytherapy sources for therapeutic medical uses:

(a) As approved in the Sealed Source and Device Registry; or

(b) In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of G.49(a) are met.

Secs. G.401 – G.403 Reserved.

Sec. G.404 Surveys after Source Implant and Removal.

(a) Immediately after implanting sources in a patient or a human research subject, the licensee shall make a survey to locate and account for all sources that have not been implanted.

(b) Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed.

(c) A licensee shall retain a record of the surveys required by G.404(a) and G.404(b) in accordance with G.2404.

Sec. G.405 Reserved.

Sec. G.406 Brachytherapy Sources Accountability.

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

(b) As soon as possible after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.

(c) A licensee shall maintain a record of the brachytherapy source accountability in accordance with G.2406.

Secs. G.407 – G.409 Reserved.

Sec. G.410 Safety Instruction. In addition to the requirements of Sec. J.12,

(a) The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who are receiving brachytherapy and cannot be released under G.75. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include the:

(1) Size and appearance of the brachytherapy sources;

(2) Safe handling and shielding instructions;

(3) Patient or human research subject control;

(4) Visitor control, including both:

(i) Routine visitation of hospitalized individuals in accordance with Sec. D.301(a)(1); and

(ii) Visitation authorized in accordance with Sec. D.301(d); and

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

(b) A licensee shall retain a record of individuals receiving instruction in accordance with G.2310.

Secs. G.411 – G.414 Reserved.

Sec. G.415 Safety Precautions.

(a) For each patient or human research subject who is receiving brachytherapy and cannot be released under G.75, a licensee shall:

(1) Not quarter the patient or the human research subject in the same room as an individual who is not receiving brachytherapy;

(2) Visibly post the patient's or human research subject's room with a "Radioactive Materials" sign; and

(3) Note on the door or in 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.

(b) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source:

(1) Dislodged from the patient; and

(2) Lodged within the patient following removal of the source applicators.

(c) A licensee shall 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 or dies.

Secs. G.416 – G.431 Reserved.

Sec. G.432 Calibration Measurements of Brachytherapy Sources.

(a) Before the first medical use of a brachytherapy source on or after the effective date of these regulations, a licensee shall have:

(1) Determined the source output or activity using a dosimetry system that meets the requirements of G.630(a);

(2) Determined source positioning accuracy within applicators; and

(3) Used published protocols currently accepted by nationally recognized bodies to meet the requirements of G.432(a)(1) and G.432(a)(2).

(b) Instead of a licensee making its own measurements as required in G.432(a), the licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with G.432(a).

(c) A licensee shall mathematically correct the outputs or activities determined in G.432(a) for physical decay at intervals consistent with 1 percent physical decay.

(d) A licensee shall retain a record of each calibration in accordance with G.2432.

Sec. G.433 Decay of Strontium-90 Sources for Ophthalmic Treatments.

(a) 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 under G.432.

(b) A licensee shall retain a record of the activity of each strontium-90 source in accordance with G.2433.

Secs. G.434 – G.456 Reserved.

Sec. G.457 Therapy-related Computer Systems.

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

(a) The source-specific input parameters required by the dose calculation algorithm;

(b) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(c) The accuracy of isodose plots and graphic displays; and

(d) The accuracy of the software used to determine sealed source positions from radiographic images.

Secs. G.458 – G.489 Reserved.

Sec. G.490 Training for Use of Manual Brachytherapy Sources.

Except as provided in G.57, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under G.400 to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State, and who meets the requirements in G.490(b)(3). (The names of board certifications which have been recognized by the NRC or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

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

(2) Pass an examination, administered by 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

(b) (1) 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:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

(d) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in G.490 or equivalent Agreement State or NRC requirements at a medical institution, involving:

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

(b) Checking survey meters for proper operation;

(c) Preparing, implanting, and removing brachytherapy sources;

(d) Maintaining running inventories of material on hand;

(e) Using administrative controls to prevent a misadministration involving the use of radioactive material;

(f) Using emergency procedures to control radioactive material; and

(2) Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in G.490 or equivalent Agreement State or NRC requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by G.490(b)(1)(ii); and

(3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in G.490 or equivalent Agreement State or NRC requirements, that the individual has satisfactorily completed the requirements in G.490(a)(1), or G.490(b)(1) and G.490(b)(2) and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under G.400.

Sec. G.491 Training for Ophthalmic Use of Strontium-90.

Except as provided in G.57, the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who:

(a) Is an authorized user under G.490 or equivalent NRC or Agreement State requirements; or

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

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

(iv) Radiation biology; and

(2) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve:

(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

(3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in G.490 or G.491, or equivalent Agreement State or NRC requirements, that the individual has satisfactorily completed the requirements in G.491(a) and G.491(b) and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

Secs. G.492 – G.499 Reserved.

Sealed Sources for Diagnosis

Sec. G.500 Use of Sealed Sources for Diagnosis.

A licensee shall use only sealed sources for diagnostic medical uses as approved in the Sealed Source and Device Registry.

Secs. G.501 – G.589 Reserved.

Sec. G.590 Training for Use of Sealed Sources for Diagnosis.

Except as provided in G.57, the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under G.500 to be a physician, dentist, or podiatrist who:

(a) Is certified by a specialty board whose certification process includes all of the requirements in G.590(b) and G.590(c) and whose certification has been recognized by the NRC or an Agreement State (the names of board certifications which have been recognized by the NRC or an Agreement State will be posted on the NRC's Web page); or

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

(1) Radiation physics and instrumentation;

(2) Radiation protection;

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

(4) Radiation biology; and

(c) Has completed training in the use of the device for the uses requested.

Sections G.591 – G.599 Reserved.

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

Sec. G.600 Use of a Sealed Source 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:

(a) As approved in the Sealed Source and Device Registry; or

(b) In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of G.49(a) are met.

Sections G.601 – G.603 Reserved.

Sec. G.604 Surveys of Patients and Human Research Subjects Treated with a Remote Afterloader Unit.

(a) Before releasing a patient or a human research subject from licensee control, a licensee shall survey 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.

(b) A licensee shall retain a record of these surveys in accordance with G.2404.

Sec. G.605 Installation, Maintenance, Adjustment and Repair.

(a) Only a person specifically licensed by the NRC 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).

(b) Except for low dose-rate remote afterloader units, only a person specifically licensed by the NRC or an Agreement State shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

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

(d) A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with G.2605.

Secs. G.606 – G.609 Reserved.

Sec. G.610 Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.

(a) A licensee shall:

(1) Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;

(2) 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);

(3) Prevent dual operation of more than one radiation producing device in a treatment room if applicable; and

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

(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.

(b) A copy of the procedures required by G.610(a)(4) must be physically located at the unit console.

(c) A licensee shall post instructions at the unit console to inform the operator of:

(1) The location of the procedures required by G.610(a)(4); and

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

(d) 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:

(1) The procedures identified in G.610(a)(4); and

(2) The operating procedures for the unit.

(e) A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

(f) A licensee shall retain a record of individuals receiving instruction required by G.610(d) in accordance with G.2310.

(g) A licensee shall retain a copy of the procedures required by G.610(a)(4) and G.610(d)(2) in accordance with G.2610.

Secs. G.611 – G.614 Reserved.

Sec. G.615 Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.

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

(b) A licensee shall equip each entrance to the treatment room with an electrical interlock system that will:

(1) Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

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

(3) Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.

(c) A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.

(d) 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.

(e) 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.

(f) In addition to the requirements specified in paragraphs (a) through (e) of this section, a licensee shall:

(1) 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.

(2) 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.

(3) For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.

(4) Notify the Radiation Safety Officer, or his/her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

(g) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source:

(1) Remaining in the unshielded position; or

(2) Lodged within the patient following completion of the treatment.

Secs. G.616 – G.629 Reserved.

Sec. G.630 Dosimetry Equipment.

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

(1) The system must 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 must have been performed within the previous 2 years and after any servicing that may have affected system calibration; or

(2) The system must have been calibrated within the previous 4 years. Eighteen to thirty months after that calibration, the system must have been intercompared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison must indicate that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee may 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.

(b) The licensee shall have a dosimetry system available for use for spot-check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with G.630(a). This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in G.630(a).

(c) The licensee shall retain a record of each calibration, intercomparison, and comparison in accordance with G.2630.

Sec. G.631 Reserved.

Sec. G.632 Full Calibration Measurements on Teletherapy Units.

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

(1) Before the first medical use of the unit; and

(2) 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;

(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

(3) At intervals not exceeding 1 year.

(b) To satisfy the requirement of G.632(a), full calibration measurements must include determination of:

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

(2) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(3) The uniformity of the radiation field and its dependence on the orientation of the useful beam;

(4) Timer accuracy and linearity over the range of use;

(5) On-off error; and

(6) The accuracy of all distance measuring and localization devices in medical use.

(c) A licensee shall use the dosimetry system described in G.630(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in G.632(b)(1) may be made using a dosimetry system that indicates relative dose rates.

(d) A licensee shall make full calibration measurements required by G.632(a) in accordance with published protocols accepted by nationally recognized bodies.

(e) A licensee shall mathematically correct the outputs determined in G.632(b)(1) for physical decay for intervals not exceeding 1 month for cobalt-60, 6 months for cesium-137, or at intervals consistent with 1 percent decay for all other nuclides.

(f) Full calibration measurements required by G.632(a) and physical decay corrections required by G.632(e) must be performed by the authorized medical physicist.

(g) A licensee shall maintain a record of each calibration in accordance with G.2632.

Sec. G.633 Full Calibration Measurements on Remote Afterloader Units.

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

(1) Before the first medical use of the unit;

(2) 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

(3) 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

(4) At intervals not exceeding 1 year for low dose-rate remote afterloader units.

(b) To satisfy the requirement of G.633(a), full calibration measurements must include, as applicable, determination of:

(1) The output within +/- 5 percent;

(2) Source positioning accuracy to within +/- 1 millimeter;

(3) Source retraction with backup battery upon power failure;

(4) Length of the source transfer tubes;

(5) Timer accuracy and linearity over the typical range of use;

(6) Length of the applicators; and

(7) Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

(c) A licensee shall use the dosimetry system described in G.630(a) to measure the output.

(d) A licensee shall make full calibration measurements required by G.633(a) in accordance with published protocols accepted by nationally recognized bodies.

(e) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in G.633(b), a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding 1 quarter.

(f) For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with G.633(a) through G.633(e).

(g) A licensee shall mathematically correct the outputs determined in G.633(b)(1) for physical decay at intervals consistent with 1 percent physical decay.

(h) Full calibration measurements required by G.633(a) and physical decay corrections required by paragraph G.633(g) must be performed by the authorized medical physicist.

(i) A licensee shall retain a record of each calibration in accordance with G.2632.

Sec. G.634 Reserved.

Sec. G.635 Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units.

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

(1) Before the first medical use of the unit;

(2) 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

(3) At intervals not exceeding 1 year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

(b) To satisfy the requirement of G.635(a), full calibration measurements must include determination of:

(1) The output within +/-3 percent;

(2) Relative helmet factors;

(3) Isocenter coincidence;

(4) Timer accuracy and linearity over the range of use;

(5) On-off error;

(6) Trunnion centricity;

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

(8) Helmet microswitches;

(9) Emergency timing circuits; and

(10) Stereotactic frames and localizing devices (trunnions).

(c) A licensee shall use the dosimetry system described in G.630(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in G.635(b)(1) may be made using a dosimetry system that indicates relative dose rates.

(d) A licensee shall make full calibration measurements required by G.635(a) in accordance with published protocols accepted by nationally recognized bodies.

(e) A licensee shall mathematically correct the outputs determined in G.635(b)(1) at intervals not exceeding 1 month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.

(f) Full calibration measurements required by G.635(a) and physical decay corrections required by G.635(e) must be performed by the authorized medical physicist.

(g) A licensee shall retain a record of each calibration in accordance with G.2632.

Secs. G.636 – G.641 Reserved.

Sec. G.642 Periodic Spot–checks for Teletherapy Units.

(a) A licensee authorized to use teletherapy units for medical use shall perform output spot checks on each teletherapy unit once in each calendar month that include determination of:

(1) Timer accuracy, and timer linearity over the range of use;

(2) On-off error;

(3) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(4) The accuracy of all distance measuring and localization devices used for medical use;

(5) The output for one typical set of operating conditions measured with the dosimetry system described in G.630(b); and

(6) The difference between the measurement made in G.642(a)(5) and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

(b) A licensee shall perform measurements required by G.642(a) in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.

(c) 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.

(d) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot checks of each teletherapy facility once in each calendar month and after each source installation to assure proper operation of:

(1) Electrical interlocks at each teletherapy room entrance;

(2) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);

(3) Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;

(4) Viewing and intercom systems;

(5) Treatment room doors from inside and outside the treatment room; and

(6) Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

(e) If the results of the checks required in G.642(d) 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.

(f) A licensee shall maintain a record of each spot check required by G.642(a) and G.642(d), and a copy of the procedures required by G.642(b), in accordance with G.2642.

Sec. G.643 Periodic Spot-checks for Remote Afterloader Units.

(a) A licensee authorized to use a remote afterloader unit for medical use shall perform spot-checks of each remote afterloader facility and on each unit:

(1) Before the first use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit on a given day;

(2) Before each patient treatment with a low dose-rate remote afterloader unit; and

(3) After each source installation.

(b) A licensee shall perform the measurements required by G.643(a) in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

(c) 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.

(d) To satisfy the requirements of G.643(a), spot-checks must, at a minimum, assure proper operation of:

(1) Electrical interlocks at each remote afterloader unit room entrance;

(2) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(3) Viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;

(4) Emergency response equipment;

(5) Radiation monitors used to indicate the source position;

(6) Timer accuracy;

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

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

(e) If the results of the checks required in G.643(d) 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.

(f) A licensee shall retain a record of each check required by G.643(d) and a copy of the procedures required by G.643(b) in accordance with G.2643.

Sec. G.644 Reserved.

Sec. G.645 Periodic Spot-checks for Gamma Stereotactic Radiosurgery Units.

(a) 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:

(1) Monthly;

(2) Before the first use of the unit on a given day; and

(3) After each source installation.

(b) A licensee shall:

(1) Perform the measurements required by G.645(a) in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

(2) Have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(c) To satisfy the requirements of G.645(a)(1), spot-checks must, at a minimum:

(1) 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).

(2) Determine:

(i) The output for one typical set of operating conditions measured with the dosimetry system described in G.630(b);

(ii) The difference between the measurement made in G.645(c)(2)(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.

(d) To satisfy the requirements of G.645(a)(2) and G.645(a)(3), spot-checks must assure proper operation of:

(1) Electrical interlocks at each gamma stereotactic radiosurgery room entrance;

(2) Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;

(3) Viewing and intercom systems;

(4) Timer termination;

(5) Radiation monitors used to indicate room exposures; and

(6) Emergency off buttons.

(e) A licensee shall arrange for the repair of any system identified in G.645(c) that is not operating properly as soon as possible.

(f) If the results of the checks required in G.645(d) 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.

(g) A licensee shall retain a record of each check required by G.645(c) and G.645(d) and a copy of the procedures required by G.645(b) in accordance with G.2645.

Sec. G.646 Reserved.

Sec. G.647 Additional Technical Requirements for Mobile Remote Afterloader Units.

(a) A licensee providing mobile remote afterloader service shall:

(1) Check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and

(2) Account for all sources before departure from a client's address of use.

(b) In addition to the periodic spot-checks required by G.643, 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:

(1) Electrical interlocks on treatment area access points;

(2) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(3) Viewing and intercom systems;

(4) Applicators, source transfer tubes, and transfer tube-applicator interfaces;

(5) Radiation monitors used to indicate room exposures;

(6) Source positioning (accuracy); and

(7) Radiation monitors used to indicate whether the source has returned to a safe shielded position.

(c) In addition to the requirements for checks in G.647(b), 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.

(d) If the results of the checks required in G.647(b) 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.

(e) A licensee shall retain a record of each check required by G.647(b) in accordance with G.2647.

Secs. G.648 – G.650 Reserved.

Sec. G.651 Availability of Survey Instrument. A licensee authorized to use radioactive material as a sealed source for diagnostic purposes shall have available for use a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem (1 μSv) per hour to 100 millirems (1000 μSv) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem (10 μSv) per hour to 1000 millirems (10 mSv) per hour. The instrument shall be operable and calibrated in accordance with G.61.

Sec. G.652 Radiation Surveys.

(a) In addition to the survey requirement in Sec. D.501, a person licensed under this part 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 do not exceed the levels stated in the Sealed Source and Device Registry.

(b) The licensee shall make the survey required by G.652(a) 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).

(c) A licensee shall retain a record of the radiation surveys required by G.652(a) in accordance with G.2652.

Secs. G.653 – G.654 Reserved.

Sec. G.655 Five-Year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units.

(a) 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.

(b) This inspection and servicing shall only be performed by persons specifically licensed to do so by the Agency, an Agreement State, or the U.S. Nuclear Regulatory Commission.

(c) A licensee shall keep a record of the inspection and servicing in accordance with G.2655.

Sec. G.656 Reserved.

Sec. G.657 Therapy-Related Computer Systems.

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

(a) The source-specific input parameters required by the dose calculation algorithm;

(b) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(c) The accuracy of isodose plots and graphic displays;

(d) The accuracy of the software used to determine sealed source positions from radiographic images; and

(e) The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

Secs. G.658 – G.689 Reserved.

Sec. G.690 Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.

Except as provided in G.57, the licensee shall require an authorized user of a sealed source for a use authorized under G.600 to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in G.690(b)(3) and G.690(c). (The names of board certifications which have been recognized by the NRC or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

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

(2) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy; or

(b) (1) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes:

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

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

(d) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in G.690, or NRC or equivalent Agreement State requirements at a medical institution, involving:

(a) Reviewing full calibration measurements and periodic spot-checks;

(b) Preparing treatment plans and calculating treatment doses and times;

(c) Using administrative controls to prevent a misadministration involving the use of radioactive material;

(d) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

(e) Checking and using survey meters; and

(f) Selecting the proper dose and how it is to be administered; and

(2) Has completed 3 years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in G.690, or NRC or equivalent 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 G.690(b)(1)(ii); and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in G.690(a)(1) or G.690(b)(1) and G.690(b)(2), and G.690(c), 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 G.690, or NRC or equivalent Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and

(c) 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.

Secs. G.691 – G.999 Reserved.

Other Medical Uses of Radioactive Material or Radiation From Radioactive Material

Sec. G.1000 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 which is not specifically addressed in G.100 through G.690 if:

(a) The applicant or licensee has submitted the information required by G.12(a)(2) through G.12(b); and

(b) The applicant or licensee has received written approval from the Agency in a license or license amendment and uses the material in accordance with the regulations and specific conditions the Agency considers necessary for the medical use of the material.

Secs. G.1001 – G.2023 Reserved.

Records

Sec. G.2024 Records of Authority and Responsibilities for Radiation Protection Programs.

(a) A licensee shall retain a record of actions taken by the licensee's management in accordance with G.24(a) for 5 years. The record must include a summary of the actions taken and a signature of licensee management.

(b) The licensee shall retain a copy of both authority, duties, and responsibilities of the Radiation Safety Officer as required by G.24(e), and a signed copy of each Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by G.24(b), for the duration of the license. The records must include the signature of the Radiation Safety Officer and licensee management.

Secs. G.2025 – G.2039 Reserved.

Sec. G.2040 Records of Written Directives.

A licensee shall retain a copy of each written directive as required by G.40 for 3 years.

Sec. G.2041 Records for Procedures for Administrations Requiring a Written Directive.

A licensee shall retain a copy of the procedures required by G.41(a) for the duration of the license.

Secs. G.2042 – G.2059 Reserved.

Sec. G.2060 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 G.60.A and G.60.B 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.

Sec. G.2061 Records of Radiation Survey Instrument Calibrations.

A licensee shall maintain a record of radiation survey instrument calibrations required by G.61 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.

Sec. G.2062 Reserved.

Sec. G.2063 Records of Dosages of Unsealed Radioactive Material for Medical Use.

(a) A licensee shall maintain a record of dosage determinations required by G.63 for 3 years.

(b) The record must contain:

(1) The radiopharmaceutical;

(2) The patient's or human research subject's name, or identification number if one has been assigned;

(3) The prescribed dosage, the determined dosage, or a notation that the total activity is less than 1.1 MBq (30 μCi);

(4) The date and time of the dosage determination; and

(5) The name of the individual who determined the dosage.

Secs. G.2064 – G.2066 Reserved.

Sec. G.2067 Records of Leak Tests and Inventory of Sealed Sources and Brachytherapy Sources.

(a) A licensee shall retain records of leak tests required by G.67(b) for 3 years. The records must include the model number, and serial number if one has been assigned, of each source tested; the identity of each source by radionuclide and its estimated activity; the results of the test; the date of the test; and the name of the individual who performed the test.

(b) A licensee shall retain records of the semi-annual physical inventory of sealed sources and brachytherapy sources required by G.67(g) for 3 years. The inventory records must contain the model number of each source, and serial number if one has been assigned, the identity of each source by radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

Secs. G.2068 – G.2069 Reserved.

Sec. G.2070 Records of Surveys for Ambient Radiation Exposure Rate.

A licensee shall retain a record of each survey required by G.70 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.

Secs. G.2071 – G.2074 Reserved.

Sec. G.2075 Records of the Release of Individuals Containing Unsealed Radioactive Material or Implants Containing Radioactive Material.

(a) A licensee shall retain a record of the basis for authorizing the release of an individual in accordance with G.75, if the total effective dose equivalent is calculated by:

(1) Using the retained activity rather than the activity administered;

(2) Using an occupancy factor less than 0.25 at 1 meter;

(3) Using the biological or effective half-life; or

(4) Considering the shielding by tissue.

(b) A licensee shall retain a record that the instructions required by G.75(b) were provided to a breast-feeding female if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 mSv (0.5 rem).

(c) The records required by G.2075(a) and G.2075(b) must be retained for 3 years after the date of release of the individual.

Secs. G.2076 – G.2079 Reserved.

Sec. G.2080 Records of Mobile Medical Services.

(a) A licensee shall retain a copy of each letter that permits the use of radioactive material at a client's address, as required by G.80(a)(1). Each letter must clearly delineate the authority and responsibility of the licensee and the client and must be retained for 3 years after the last provision of service.

(b) A licensee shall retain the record of each survey required by G.80(a)(4) 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.

Secs. G.2081 – G.2203 Reserved.

Sec. G.2204 Records of Molybdenum-99 Concentrations.

A licensee shall maintain a record of the molybdenum-99 concentration tests required by G.204(b) for 3 years. The record must include, for each measured elution of technetium-99m, the ratio of the measures expressed as kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (or microcuries of molybdenum per millicurie of technetium), the time and date of the measurement, and the name of the individual who made the measurement.

Secs. G.2205 – G.2309 Reserved.

Sec. G.2310 Records of Safety Instruction.

A licensee shall maintain a record of safety instructions required by G.310, G.410, and G.610 for 3 years. The record must include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

Secs. G.2311 – G.2403 Reserved.

Sec. G.2404 Records of Surveys after Source Implant and Removal.

A licensee shall maintain a record of the surveys required by G.404 and G.604 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.

Sec. G.2405 Reserved.

Sec. G.2406 Records of Brachytherapy Source Accountability.

(a) A licensee shall maintain a record of brachytherapy source accountability required by G.406 for 3 years.

(b) For temporary implants, the record must include:

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

(2) The number and activity of sources returned to storage, the time and date they were returned to storage, and the name of the individual who returned them to storage.

(c) For permanent implants, the record must include:

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

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

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

Secs. G.2407 – G.2431 Reserved.

Sec. G.2432 Records of Calibration Measurements of Brachytherapy Sources.

(a) A licensee shall maintain a record of the calibrations of brachytherapy sources required by G.432 for 3 years after the last use of the source.

(b) The record must include:

(1) The date of the calibration;

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

(3) The source output or activity;

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

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

Sec. G.2433 Records of Decay of Strontium-90 Sources for Ophthalmic Treatments.

(a) A licensee shall maintain a record of the activity of a strontium-90 source required by G.433 for the life of the source.

(b) The record must include:

(1) The date and initial activity of the source as determined under G.432; and

(2) For each decay calculation, the date and the source activity as determined under G.433.

Secs. G.2434 – G.2604 Reserved.

Sec. G.2605 Records of Installation, Maintenance, Adjustment, and Repair of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.

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 G.605 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.

Secs. G.2606 – G.2609 Reserved.

Sec. G.2610 Records of Safety Procedures.

A licensee shall retain a copy of the procedures required by G.610(a)(4) and G.610(d)(2) until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.

Secs. G.2611 – G.2629 Reserved.

Sec. G.2630 Records of Dosimetry Equipment used with Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.

(a) A licensee shall retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with G.630 for the duration of the license.

(b) For each calibration, intercomparison, or comparison, the record must include:

(1) The date;

(2) The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by G.630(a) and G.630(b);

(3) The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and

(4) The names of the individuals who performed the calibration, intercomparison, or comparison.

Sec. G.2631 Reserved.

Sec. G.2632 Records of Teletherapy, Remote Afterloader, and Gamma Stereotactic Radiosurgery full Calibrations.

(a) A licensee shall maintain a record of the teletherapy unit, remote afterloader unit, and gamma stereotactic radiosurgery unit full calibrations required by G.632, G.633, and G.635 for 3 years.

(b) The record must include:

(1) The date of the calibration;

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

(3) The results and an assessment of the full calibrations;

(4) The results of the autoradiograph required for low dose-rate remote afterloader units; and

(5) The signature of the authorized medical physicist who performed the full calibration.

Secs. G.2633 – G.2641 Reserved.

Sec. G.2642 Records of Periodic Spot-checks for Teletherapy Units.

(a) A licensee shall retain a record of each periodic spot-check for teletherapy units required by G.642 for 3 years.

(b) The record must include:

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number of the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;

(3) An assessment of timer linearity and constancy;

(4) The calculated on-off error;

(5) A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

(6) The determined accuracy of each distance measuring and localization device;

(7) The difference between the anticipated output and the measured output;

(8) Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and

(9) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(c) A licensee shall retain a copy of the procedures required by G.642(b) until the licensee no longer possesses the teletherapy unit.

Sec. G.2643 Records of Periodic Spot-checks for Remote Afterloader Units.

(a) A licensee shall retain a record of each spot-check for remote afterloader units required by G.643 for 3 years.

(b) The record must include, as applicable:

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number for the remote afterloader unit and source;

(3) An assessment of timer accuracy;

(4) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and

(5) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(c) A licensee shall retain a copy of the procedures required by G.643(b) until the licensee no longer possesses the remote afterloader unit.

Sec. G.2644 Reserved.

Sec. G.2645 Records of Periodic Spot-checks for Gamma Stereotactic Radiosurgery Units.

(a) A licensee shall retain a record of each spot-check for gamma stereotactic radiosurgery units required by G.645 for 3 years.

(b) The record must include:

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;

(3) An assessment of timer linearity and accuracy;

(4) The calculated on-off error;

(5) A determination of trunnion centricity;

(6) The difference between the anticipated output and the measured output;

(7) An assessment of source output against computer calculations;

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

(9) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(c) A licensee shall retain a copy of the procedures required by G.645(b) until the licensee no longer possesses the gamma stereotactic radiosurgery unit.

Sec. G.2646 Reserved.

Sec. G.2647 Records of Additional Technical Requirements for Mobile Remote Afterloader Units.

(a) A licensee shall retain a record of each check for mobile remote afterloader units required by G.647 for 3 years.

(b) The record must include:

(1) The date of the check;

(2) The manufacturer's name, model number, and serial number of the remote afterloader unit;

(3) Notations accounting for all sources before the licensee departs from a facility;

(4) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators, source transfer tubes, and transfer tube applicator interfaces, and source positioning accuracy; and

(5) The signature of the individual who performed the check.

Secs. G.2648 – G.2651 Reserved.

Sec. G.2652 Records of Surveys of Therapeutic Treatment Units.

(a) A licensee shall maintain a record of radiation surveys of treatment units made in accordance with G.652 for the duration of use of the unit.

(b) The record must include:

(1) The date of the measurements;

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

(3) Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and

(4) The signature of the individual who performed the test.

Secs. G.2653 – G.2654 Reserved.

Sec. G.2655 Records of 5-year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units.

(a) A licensee shall maintain a record of the 5-year inspections for teletherapy and gamma stereotactic radiosurgery units required by G.655 for the duration of use of the unit.

(b) The record must contain:

(1) The inspector's radioactive materials license number;

(2) The date of inspection;

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

(4) A list of components inspected and serviced, and the type of service; and

(5) The signature of the inspector.

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