

PART G

USE OF RADIONUCLIDES IN THE HEALING ARTS

General Information

Sec. G.1 - Purpose and Scope. Part G establishes requirements and provisions for the production, preparation, compounding and use of radionuclides in the healing arts and for issuance of licenses authorizing these activities. These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects. The requirements and provisions of Part G are in addition to, and not in substitution for, others in these regulations unless specifically exempted.

Sec. G.2 - Definitions.

“Address of use” means the building or buildings that are identified on the license and where radioactive material may be produced, prepared, received, used, or stored.

“Area of use” means a portion of an address of use that has been set aside for the purpose of receiving, using, or storing radioactive material.

“Associate Radiation Safety Officer” (ARSO) means an individual who:

- a. Meets the requirements in G.50 and G.59; and
- b. Is currently identified as an ARSO for the types of use of radioactive material for which the individual has been assigned duties and tasks by the Radiation Safety Officer on:
 - i. A specific medical use license issued by the Agency, Nuclear Regulatory Commission, or an Agreement State; or
 - ii. A medical use permit issued by an NRC master material licensee.

“Authorized medical physicist” (AMP) means an individual who:

- a. Meets the requirements in G.51 and G.59; or
- b. Is identified as an authorized medical physicist or teletherapy physicist on:
 - i. A specific medical use license issued by the Agency, Nuclear Regulatory Commission, or Agreement State; or
 - ii. A medical use permit issued by an NRC master material licensee.
 - iii. A permit issued by an Agency, NRC, or Agreement State broad scope medical

use licensee; or

- iv. A permit issued by an NRC master material broad scope medical use permittee.

“Authorized nuclear pharmacist” (ANP) means a pharmacist who:

- a. Meets the requirements in G.55a. or G.59; or
- b. Is identified as an authorized nuclear pharmacist on:
 - i. A specific license issued by the Agency, Nuclear Regulatory Commission, or Agreement State that authorizes medical use or the practice of nuclear pharmacy;
 - ii. A permit issued by an NRC master material licensee that authorizes medical use or the practice of nuclear pharmacy;
 - iii. A permit issued by an Agency, NRC, or Agreement State broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or
 - iv. A permit issued by an NRC master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or
- c. Is identified as an ANP by a commercial nuclear pharmacy that has been authorized to identify ANPs; or
- d. Is designated as an ANP in accordance with C.28j.(ii)(4) of these regulations

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

- a. Meets the requirements in G.59 and G.190a., G.290a., G.390a., G.392a., G.394a., G.490a., G.590a., or G.690a.; or
- b. Is identified as an authorized user on:
 - i. An Agency, Nuclear Regulatory Commission, or Agreement State license that authorizes the medical use of radioactive materials;
 - 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 Agency, NRC, or Agreement State license 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 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 jobsite for the purpose of providing mobile medical service in accordance with G.80.

“Cyclotron” means a particle accelerator in which the charged particles travel in an outward spiral or circular path. A cyclotron accelerates charged particles at energies usually in excess of 10 megaelectron volts and is commonly used for production of short half-life radionuclides for medical use.

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

“Dentist” means an individual licensed to practice dentistry by the state in which the Agency is located.

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

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

“Low dose-rate remote afterloader” (LDR), as used in Part G, means a device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the point or surface where the dose is prescribed.

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

“Manual brachytherapy,” as used in Part G, means a type of therapy in which brachytherapy sources are manually placed topically on or inserted either into the body cavities that are near a treatment site or directly into the tissue volume.

“Medical Event” means an event that meets the criteria in G.3045a. or G.3045b.

“Medical institution” means an organization in which more than one medical discipline is practiced.

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

“Medium dose-rate remote afterloader” (MDR), as used in Part G, means a device that remotely delivers a dose rate of greater than 2 gray (200 rads), but less than, or equal to, 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

“Mobile medical service” means the transportation of radioactive material to and its medical use at the client's address.

“Ophthalmic Physicist” means an individual who:

- a. Meets the requirements in G.433a.ii. and G.59; and
- b. Is identified as an ophthalmic physicist on a:
 - i. Specific medical use license issued by the Agency, Nuclear Regulatory Commission, or an Agreement State;
 - ii. Permit issued by an Agency, NRC or Agreement State broad scope medical use licensee;
 - iii. Medical use permit issued by an NRC master material licensee; or
 - iv. Permit issued by an NRC master material licensee broad scope medical use permittee.

“Output” means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a brachytherapy source, or a teletherapy, remote afterloader, or gamma stereotactic radiosurgery unit for a specified set of exposure conditions.

“Patient intervention” means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

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

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

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

“Positron Emission Tomography (PET) radionuclide production facility” is defined as a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

“Preceptor” means an individual who provides directs, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear

pharmacist, a Radiation Safety Officer, or an Associate Radiation Safety Officer.

“Prescribed dosage” means the specified activity or range of activity of unsealed radioactive material as documented:

- a. In a written directive as specified in G.40; or
- b. In accordance with the directions of the authorized user for procedures performed pursuant to G.100 and G.200.

“Prescribed dose” means:

- a. For gamma stereotactic radiosurgery, the total dose as documented in the written directive;
- b. For teletherapy, the total dose and dose per fraction as documented in the written directive;
- c. For manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or
- d. For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

“Pulsed dose-rate remote afterloader” (PDR) means a special type of remote afterloading brachytherapy device that uses a single source capable of delivering dose rates in the “high dose-rate” range, but:

- a. Is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and
- b. Is used to simulate the radiobiology of a low dose rate treatment by inserting the source for a given fraction of each hour.

“Radiation Safety Officer” (RSO) means an individual who:

- a. Meets the requirements in G.50a., or G.50c.i. and G.59; or
- b. Is identified as a Radiation Safety Officer on:
 - i. A specific medical use license issued by the Agency, a Nuclear Regulatory Commission, or an Agreement State; or
 - ii. A medical use permit issued by an NRC master material licensee.

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

radiopharmaceutical is used interchangeably with radioactive drug and means the same thing.

“Sealed source” means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

“Sealed Source and Device Registry” means the national registry that contains the registration certificates generated by both the Agreement States and the Nuclear Regulatory Commission, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

“Stereotactic radiosurgery” means the use of external radiation in conjunction with a stereotactic guidance device to deliver very precisely a therapeutic dose to a tissue volume.

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

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

“Temporary jobsite” as used in this Part, means a location where mobile medical services are conducted other than the location(s) of use authorized on the license.

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

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

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

“Type of use” means use of radioactive material as specified under G.100, G.200, G.300, G.400, G.500, G.600 or G.1000.

“Unit dosage” means a dosage prepared for medical use for administration as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

“Written directive” means an authorized user's written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in G.40

Sec. G.5 - Maintenance of Records. Each record required by Part G shall be legible throughout the retention period. The record may be the original, a reproduced copy, or a microform if the copy or microform is authenticated by authorized personnel and the microform can produce a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications shall include all pertinent information such as

stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

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;
 - i. Obtain review and approval of the research from an "Institutional Review Board" as defined and described in the Federal Policy; and
 - ii. 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 approval of a specific amendment to its Agency medical license. The amendment request shall include a written commitment that the licensee will, before conducting research:
 - i. Obtain review and approval of the research from an "Institutional Review Board" as defined and described in the Federal Policy; and
 - ii. Obtain "informed consent," as defined and described in the Federal Policy, from the human research subject'
- d. Nothing in G.6 relieves licensees from complying with the other requirements in Part G.

Sec. G.7 - U.S. Food and Drug Administration, Federal, and State Requirements. Nothing in Part G relieves the licensee from complying with applicable U.S. Food and Drug Administration, other Federal, and State requirements governing radioactive drugs or devices.

Sec. G.10 - Implementation.

- a. A licensee shall implement the provisions in Part G on [insert effective date of the rule].
- b. [Reserved]
- c. [Reserved]
- d. If a license condition exempted a licensee from a provision of Part G on [insert effective date of the rules], then the license condition continues to exempt the licensee from the corresponding provision in G.1 through G.3204.

- e. When a requirement in Part G differs from the requirement in an existing license condition, the requirement in Part G shall govern.
- f. A licensee shall continue to comply with any license condition that requires it to implement procedures required by G.610, G.642, G.643 and G.645 until there is a license amendment or renewal that modifies the license condition.
- [g. If a license condition cites provisions in Part G that will be deleted on [insert effective date of the rule], then the license condition remains in effect until there is a license amendment or license renewal that modifies or removes this condition.]

Sec. G.11 - License Required.

- a. A person shall manufacture, produce, prepare, acquire, receive, possess, use, or transfer radioactive material for medical use only in accordance with a specific license issued by the Agency, the Nuclear Regulatory Commission or an Agreement State, or as allowed in G.11b. or G.11c.
- b. A specific license is not needed for an individual who:
 - i. Receives, possesses, uses, or transfers radioactive material in accordance with the regulations in Part G under the supervision of an authorized user as provided in G.27, unless prohibited by license condition.
 - ii. Prepares unsealed radioactive material for medical use in accordance with the regulations in Part G under the supervision of an authorized nuclear pharmacist or authorized user as provided in G.27, unless prohibited by license condition.
- c. [Reserved]

Sec. G.12 - Application for License, Amendment, or Renewal.

- a. An application shall be signed by the applicant's or licensee's management.
- b. An application for a license for medical use of radioactive material as described in G.100, G.200, G.300, G.400, G.500, G.600 or G.1000 shall be made by:
 - i. Filing an original of [insert Agency application form name], that includes the facility diagram, equipment, and training and experience qualifications of the Radiation Safety Officer, Associate Radiation Safety Officer(s), authorized user(s), authorized medical physicist(s), ophthalmic physicist(s) and authorized nuclear pharmacist(s); and
 - ii. Submitting procedures required by sections [G.41, G.62,] G.610, G.642, G.643 and G.645, as applicable.
- c. A request for a license amendment or renewal shall be made by:

- i. Submitting an original of either:
 - (1) [Insert Agency application form name]; or
 - (2) A letter containing all information required by [Insert Agency application form name]; and
 - ii. Submitting procedures required by sections [G.41, G.62,] G.610, G.642, G.643 and G.645, as applicable.
- d. In addition to the requirements in G.12b. and G.12c., an application for a license or amendment for medical use of radioactive material as described in G.1000 shall also include:
- i. Any additional aspects of the medical use of the material that are applicable to radiation safety that are not addressed in G.1 through G.92, and G.2024 through G.3204;
 - ii. Identification of and commitment to follow the applicable radiation safety program requirements in G.100 through G.690 that are appropriate for the specific G.1000 medical use;
 - iii. Any additional specific information on:
 - (1) Radiation safety precautions and instructions;
 - (2) Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and
 - (3) Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety; and
 - (4) Any other information requested by the Agency in its review of the application; and
 - [(5) Training and experience for proposed users.]
- e. An applicant that satisfies the requirements specified in C.27b. may apply for a Type A specific license of broad scope.

Sec. G.13 - License Amendments. A licensee shall apply for and shall receive a license amendment:

- a. Before it receives, prepares or uses radioactive material for a type of use that is permitted under Part G, but that is not authorized on the licensee's current license issued pursuant to Part G;
 - i. [Reserved]
 - ii. [Reserved]

- b. Before it permits anyone to work as an authorized user, authorized nuclear pharmacist, ophthalmic physicist or authorized medical physicist under the license, except:
 - i. For an authorized user, an individual who meets the requirements in G.59 and G.190a., G.290a., G.390a., G.392a., G.394a., G.490a., G.590a., and G.690a.;
 - ii. For an authorized nuclear pharmacist, an individual who meets the requirements in G.55a. and G.59;
 - iii. For an authorized medical physicist, an individual who meets the requirements in G.51a. and G.59;
 - iv. An individual who is identified as an authorized user, an authorized nuclear pharmacist, authorized medical physicist or an ophthalmic physicist:
 - (1) On an Agency, a Nuclear Regulatory Commission or an Agreement State license or other equivalent permit or license recognized by the Agency that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy;
 - (2) On a permit issued by an Agency, a Nuclear Regulatory Commission or an Agreement State specific licensee of broad scope that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy;
 - (3) On a permit issued by a Nuclear Regulatory Commission master material licensee that is authorized to permit the use of byproduct material in medical use or in the practice of nuclear pharmacy; or
 - (4) By a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists;
- c. Before it changes Radiation Safety Officers, except as provided in G.24c.;
- d. Before it permits anyone to work as an Associate Radiation Safety Officer, or before the Radiation Safety Officer assigns duties and tasks to an ARSO that differ from those for which this individual is authorized on the license;
- e. Before it receives radioactive material in excess of the amount, or in a different form or receives a different radionuclide than is authorized on the license;
- f. Before it adds to or changes the areas of use identified in the application or on the license, including areas used in accordance with either G.100 or G.200 if the change includes addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide/PET radioactive drug production area. Other areas of use where radioactive material is used only in accordance with either G.100 or G.200 are exempt;
- g. Before it changes the address(es) of use identified in the application or on the license;

- h. Before it revises procedures required by G.610, G.642, G.643, and G.645, as applicable, where such revision reduces radiation safety; and
- i. Before it receives a sealed source from a different manufacturer or of a different model number than authorized by its license unless the sealed source is used for manual brachytherapy, is listed in the Sealed Source and Device Registry, and is in a quantity and for an isotope authorized by the license.

Sec. G.14 - Notifications.

- a. A licensee shall provide the Agency no later than 30 days after the date that the licensee permits an individual to work under the provisions of G.13b. as an authorized user, an authorized nuclear pharmacist, an authorized medical physicist, or an ophthalmic physicist:
 - i. A copy of the board certification and , as appropriate, verification of completion of:
 - (1) Training for the authorized medical physicist under G.51c.;
 - (2) Any additional case experience required in G.390b.i.(2)(g) for an authorized user under G.390; or
 - (3) Device specific training in G.690c. for the authorized user under G.600; or
 - ii. [Reserved]
- b. A licensee shall notify the Agency, in writing, no later than 30 days after
 - i. An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer an Associate Radiation Safety Officer, an authorized medical physicist, or ophthalmic physicist permanently discontinues performance of duties under the license or has a name change;
 - ii. The licensee permits 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 in accordance with G.24c.;
 - iii. The licensee's mailing address changes;
 - iv. The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in Part C.31b. of these regulations;
 - v. The licensee has added to or changed the areas of use identified in the application or on the license where radioactive material is used in accordance with either G.100 and G.200 if the change does not include addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide/PET radioactive drug production area, or

- vi. The licensee obtains a sealed source for use in manual brachytherapy from a different manufacturer or with a different model number than authorized by its license for which it did not require a license amendment as provided in G.13i. The notification shall include the manufacturer and model number of the sealed source, the isotope, and the quantity per sealed source.
- c. The licensee shall send the documents required in G.14 to the appropriate address identified in A.12. of these regulations.

Sec. G.15 - Exemptions Regarding Type A Specific Licenses of Broad Scope. A licensee possessing a Type A specific license of broad scope for medical use, issued under Part C of these regulations, is exempt from:

- a. The provisions of G.12d. regarding the need to file an amendment to the license for medical uses of radioactive material as described in G.1000;
- b. The provisions of G.13b.;
- c. The provisions of G.13f. regarding additions to or changes in the areas of use at the addresses identified in the application or on the license;
- d. The provisions of G.14a.;
- e. The provisions of G.14b.i. for an authorized user, an authorized nuclear pharmacist, an authorized medical physicist, or an ophthalmic physicist;
- f. The provisions of G.14b.v.;
- g. The provisions of G.49a.

Sec. G.18 - License Issuance.

- a. The Agency shall issue a license for the medical use of radioactive material if:
 - i. The applicant has filed [insert name of proper Agency license application or form ID] in accordance with the instructions in G.12;
 - ii. The applicant has paid any applicable fee as provided in [insert Agency's rule reference to Agency's fee table];
 - iii. The Agency finds the applicant equipped and committed to observe the safety standards established by the Agency in the requirements applicable to licensed radioactive materials found in Parts A through Z of these regulations for the protection of the public health and safety.
 - iv. The applicant meets the requirements of Part C of these regulations.

- b. The Agency shall issue a license for mobile services if the applicant:
 - i. Meets the requirements in G.18a.; and
 - ii. Assures that individuals or human research subjects to whom unsealed radioactive material or radiation from implants containing radioactive material will be administered, may be released following treatment in accordance with G.75.

Sec. G.19 - Specific Exemptions. The Agency may, upon application of any interested person or upon its own initiative, grant such exemptions from the regulations in Part G as it determines are authorized by law and will not endanger life or property and are otherwise in the public interest.

General Administrative Requirements

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

- a. In addition to the radiation protection program requirements of D.1101 of these regulations, a licensee's management shall approve in writing:
 - i. Requests for license application, renewal, or amendment(s) before submittal to the Agency;
 - ii. Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist or authorized medical physicist; and
 - iii. Radiation protection program changes that do not require a license amendment and are permitted under G.26.
- 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. A licensee's management may appoint, in writing, one or more Associate Radiation Safety Officers to support the Radiation Safety Officer. The Radiation Safety Officer, with written agreement of the licensee's management, shall assign the specific duties and tasks to each Associate Radiation Safety Officer. These duties and tasks are restricted to the types of use for which the Associate Radiation Officer is listed on a license. The Radiation Safety Officer may delegate duties and tasks to the Associate Radiation Safety Officer but shall not delegate the authority or responsibilities for implementing the radiation protection program.
- c. For up to 60 days each year, a licensee may permit 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.24g., if the licensee takes the actions required in G.24b., G.24e., G.24g. and G.24h. and notifies the Agency in accordance with G.14b.

- d. A licensee may simultaneously appoint more than one temporary RSO in accordance with G.24c., if needed to ensure that the licensee has a temporary RSO that satisfies the requirements to be an RSO 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. Licensees that are authorized for two or more different types of uses of radioactive material under G.300 through G.396, G.400 through G.491, and G.600 through G.690, or two or more types of units under G.600 through G.690, shall establish a Radiation Safety Committee to oversee all uses of radioactive material permitted by the license. The Committee shall include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. The Committee may include other members the licensee considers appropriate.
- g. A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative, to:
 - i. Identify radiation safety problems;
 - ii. Initiate, recommend, or provide corrective actions;
 - iii. Stop unsafe operations; and,
 - iv. Verify implementation of corrective actions.
- h. A licensee shall retain a record of actions taken under G.24a., G.24b. and G.24e. in accordance with G.2024.
- [i. A licensee's Radiation Safety Committee shall meet as necessary, but at a minimum shall meet at intervals not to exceed 12 [6] months. The licensee shall maintain minutes of each meeting in accordance with G.2024d.]

Sec. G.26 - Radiation Protection Program Changes.

- a. A licensee may revise its radiation protection program without Agency approval if:
 - i. The revision does not require an amendment under G.13;
 - ii. The revision is in compliance with the regulations and the license;
 - iii. The revision has been reviewed and approved by the Radiation Safety Officer, licensee management and licensee's Radiation Safety Committee, if applicable; and

- iv. The affected individuals are instructed on the revised program before the changes are implemented.
- b. A licensee shall retain a record of each change in accordance with G.2026.

Sec. G.27 - Supervision.

- a. A licensee that permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user, as allowed by G.11b.i. shall:
 - i. In addition to the requirements in J.12 of these regulations, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, in the requirements applicable to licensed radioactive materials found in Parts A through Z of these regulations, and license conditions with respect to the use of radioactive material; and
 - ii. 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, requirements applicable to licensed radioactive materials found in Parts A through Z of these regulations, 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.11b.ii., shall:
 - i. In addition to the requirements in J.12 of these regulations instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and
 - ii. 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 requirements applicable to licensed radioactive materials found in Parts A through Z of these regulations, and license conditions.
- c. A licensee that permits supervised activities under G.21a. and G.21b. is responsible for the acts and omissions of the supervised individual.
- [d. Unless physical presence as described in other sections of Part G is required, a licensee who permits supervised activities under G.27a. and G.27b. shall require an authorized user to be immediately available by telephone or other means to communicate with the supervised individual, within one hour of notification.]

[Sec. G.30 - Duties of Authorized User and Authorized Medical Physicist.

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

- i. Prescribe the radiopharmaceutical dosage and/or radiation dose to be administered through the issuance of a written directive or reference to the diagnostic clinical procedures manual; and
 - ii. Direct, as specified in G.27 and G.40, or in license conditions, the administration of radioactive material for medical use to patients or human research subjects;
 - iii. Prepare and administer, or supervise the preparation and administration of radioactive material for medical use, in accordance with G.11b., G.11c. and G.27;
- b. A licensee shall assure that only authorized medical physicists perform full calibration measurements as described in G.632, G.633, and G.635;
- c. A licensee shall assure that only authorized medical physicists or their designee perform, as applicable:
- i. Periodic spot checks as described in G.642, G.643, and G.645; and
 - ii. Radiation surveys as described in G.652.

Sec. G.40 - Written Directives.

- a. A written directive shall be dated and signed by an authorized user before administration of I-131 sodium iodide greater than 1.11 megabecquerels (30 μ Ci), any therapeutic dosage of unsealed radioactive material or any therapeutic dose of radiation from radioactive material.
- i. 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 shall be documented as soon as possible in writing in the patient's record. A written directive shall be prepared within 48 hours of the oral directive.
- b. The written directive shall contain the patient or human research subject's name and the following information:
- i. For any administration of quantities greater than 1.11 megabecquerels (30 μ Ci) of sodium iodide I-131: The dosage;
 - ii. 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;
 - iii. For gamma stereotactic radiosurgery: The total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;
 - iv. For teletherapy: The total dose, dose per fraction, number of fractions, and treatment site;

- v. For high dose rate remote afterloading brachytherapy: The radionuclide, treatment site, dose per fraction, number of fractions, and total dose;
- vi. For permanent implant brachytherapy:
 - (1) Before implantation: The treatment site, the radionuclide, and the total source strength; and
 - (2) After implantation but before the patient leaves the post-treatment recovery area: The treatment site, the number of sources implanted, the total source strength implanted, and the date; or
- vii. For all other brachytherapy including low, medium, and pulsed dose rate afterloaders:
 - (1) Before implantation: The treatment site, radionuclide, and dose; and
 - (2) After implantation but before completion of the procedure: The radionuclide treatment site, number of sources, either the total source strength and exposure time or the total dose, and date.
- c.
 - i. 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.
 - ii. 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 shall be documented as soon as possible in the patient's record. A revised written directive shall be signed by the authorized user within 48 hours of the oral revision.
- d. The licensee shall retain 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:
 - i. The patient's or human research subject's identity is verified before each administration; and
 - ii. Each administration is in accordance with the written directive.
- b. At a minimum, the procedures required by G.41a. shall address the following items that are applicable to the licensee's use of radioactive material:

- i. Verifying the identity of the patient or human research subject;
 - ii. Verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;
 - iii. Checking both manual and computer-generated dose calculations;
 - iv. Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by G.600 or G.1000;
 - v. Determining if a medical event, as defined in G.3045, has occurred; and
 - vi. Determining, for permanent implant brachytherapy, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented.
- c. A licensee shall retain a copy of the procedures required under G.41 a. in accordance with G.2041.

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 pursuant to Part C of these regulations or the equivalent requirements of the Nuclear Regulatory Commission, or an Agreement State;
- b. Sealed sources or devices noncommercially transferred from a Part G licensee or a Nuclear Regulatory Commission or Agreement State medical use licensee.
- c. Teletherapy sources manufactured and distributed in accordance with a license issued under Part C of these regulations or equivalent requirements of the Nuclear Regulatory Commission, or 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 (RSO) or an individual assigned duties and tasks as an Associate Radiation Safety Officer (ARSO) 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 Agency, the Nuclear Regulatory Commission or an Agreement State and who meets the requirements in G.50d. The names of board certifications that have been recognized by the Agency, the Nuclear Regulatory Commission or an Agreement State are posted on the Nuclear Regulatory Commission's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to :

- i.
 - (1) Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;
 - (2) Have five or more years of professional experience in health physics (graduate training may be substituted for no more than two years of the required experience) including at least three years in applied health physics; and
 - (3) Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or
- ii.
 - (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 two 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 Agency, the Nuclear Regulatory Commission, or an Agreement State; or
 - (b) In clinical nuclear medicine facilities providing diagnostic or therapeutic services under the direction of physicians who meet the requirements for authorized users in G.57, G.290, or G.390; and
 - (3) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or
- b.
 - i. Has completed a structured educational program consisting of both:
 - (1) 200 hours of classroom and laboratory training in the following areas:
 - (a) Radiation physics and instrumentation;
 - (b) Radiation protection;
 - (c) Mathematics pertaining to the use and measurement of radioactivity;
 - (d) Radiation biology; and
 - (e) Radiation dosimetry; and
 - (2) One year of full-time radiation safety experience under the supervision of the

individual identified as the RSO on an Agency, a Nuclear Regulatory Commission or an Agreement State license or permit issued by a Nuclear Regulatory Commission master material license that authorizes similar type(s) of use(s) of radioactive material. An ARSO may provide supervision for those areas for which the ARSO is authorized on an Agency, a Nuclear Regulatory Commission or an Agreement State license or permit issued by a Nuclear Regulatory Commission master material licensee. The full-time radiation safety experience shall involve the following:

- (a) Shipping, receiving, and performing related radiation surveys;
 - (b) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;
 - (c) Securing and controlling radioactive material;
 - (d) Using administrative controls to avoid mistakes in the administration of radioactive material;
 - (e) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;
 - (f) Using emergency procedures to control radioactive material; and
 - (g) Disposing of radioactive material; and
- ii. This individual shall obtain a written attestation, signed by a preceptor RSO, or ARSO who has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual is seeking approval as an RSO or an ARSO. The written attestation shall state, that the individual has satisfactorily completed the requirements in G.50b.i. and G.50d., and is able to independently fulfill the radiation safety-related duties as an RSO or as an ARSO for a medical use license; or
- c.
 - i. Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Agency, the Nuclear Regulatory Commission or an Agreement State under G.51a., has experience with the radiation safety aspects of similar types of use of radioactive material for which the licensee seeks the approval of the individual as RSO or ARSO, and meets the requirements in G.50d.; or
 - ii. Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on an Agency, a Nuclear Regulatory Commission or Agreement State license, a permit issued by a Nuclear Regulatory Commission master material licensee, a permit issued by an Agency, Nuclear Regulatory Commission, or Agreement State licensee of broad scope, or a permit issued by a Nuclear Regulatory Commission master material license broad scope permittee, has experience with the radiation safety aspects of similar types of use of radioactive material for which the licensee seeks the approval of the

individual as the RSO or ARSO and meets the requirements in G.50d.; or

- iii. Has experience with the radiation safety aspects of the types of use of radioactive material for which the individual is seeking simultaneous approval both as the RSO and the authorized user on the same new medical use license or new medical use permit issued by a Nuclear Regulatory Commission master material licensee. The individual shall also meet the requirements in G.50d.
- d. Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by an RSO, an ARSO, 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 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 recognized by the Nuclear Regulatory Commission or an Agreement State and who meets the requirements in G.51c. The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State are posted on the Nuclear Regulatory Commission's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:
 - i. Hold a master's or doctor's degree in physics, medical physics, or other physical science, engineering, or applied mathematics from an accredited college or university;
 - ii. Have two years of full-time practical training and/or supervised experience in medical physics:
 - (1) Under the supervision of a medical physicist who is certified in medical physics by a specialty board whose certification process has been recognized under G.51 by the Agency, an Agreement State or the Nuclear Regulatory Commission; or
 - (2) In clinical radiation facilities providing high-energy, external beam therapy using photons and electrons with energies greater than or equal to one million electron volts and brachytherapy services under the direction of physicians who meet the requirements in G.57, G.490, or G.690; and
 - iii. 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. i. 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 one 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 shall be conducted in clinical radiation facilities that provide high-energy, external beam therapy using photons and electrons with energies greater than or equal to one million electron volts and brachytherapy services and shall include:

- (1) Performing sealed source leak tests and inventories;
 - (2) Performing decay corrections;
 - (3) Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and
 - (4) Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and
- ii. Has obtained written attestation that the individual has satisfactorily completed the requirements in G.51b.i. and G.51c. and is able to independently fulfill the radiation safety-related duties as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation shall be signed by a preceptor authorized medical physicist who meets the requirements in G.51, G.57, or equivalent Nuclear Regulatory Commission or Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.
- 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.

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 Agency, the Nuclear Regulatory Commission or an Agreement State. The names of board certifications that have been recognized by the Agency, the Nuclear Regulatory Commission or an Agreement State are posted on the Nuclear Regulatory Commission's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:
 - i. Have graduated from a pharmacy program accredited by the Accreditation Council for

Pharmacy Education^{1/} (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

- ii. Hold a current, active license to practice pharmacy;
 - iii. 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
 - iv. 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. i. Has completed 700 hours in a structured educational program consisting of both:
- (1) 200 hours of classroom and laboratory training in the following areas:
 - (a) Radiation physics and instrumentation;
 - (b) Radiation protection;
 - (c) Mathematics pertaining to the use and measurement of radioactivity;
 - (d) Chemistry of radioactive material for medical use; and
 - (e) Radiation biology; and
 - (2) Supervised practical experience in 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 medical events in the administration of radioactive material; and
 - (e) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

^{1/} previously named the American Council on Pharmaceutical Education.

- ii. Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in G.55b.i. and is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist.

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.
 - i. An individual identified on an Agency, a Nuclear Regulatory Commission, or an Agreement State license or a permit issued by an Agency, a Nuclear Regulatory Commission or Agreement State broad scope licensee or an NRC master material license permit or by an NRC master material license permittee of broad scope as a Radiation Safety Officer, a teletherapy or medical physicist, an authorized medical physicist, a nuclear pharmacist or an authorized nuclear pharmacist on or before January 14, 2019 need not comply with the training requirements of G.50, G.51 and G.55, respectively, except the Radiation Safety Officers and authorized medical physicists identified in G.57a. shall meet the training requirements in G.50d. or G.51c., as appropriate, for any material or uses for which they were not authorized prior to this date.
 - ii. An individual certified by the American Board of Health Physics in Comprehensive Health Physics; American Board of Radiology; American Board of Nuclear Medicine; American Board of Science in Nuclear Medicine; Board of Pharmaceutical Specialties in Nuclear Pharmacy; American Board of Medical Physics in radiation oncology physics; Royal College of Physicians and Surgeons of Canada in nuclear medicine; American Osteopathic Board of Radiology, or American Osteopathic Board of Nuclear Medicine on or before October 24, 2005, need not comply with the training requirements of G.50 to be identified as a Radiation Safety Officer or as an Associate Radiation Safety Officer on an Agency, a Nuclear Regulatory Commission or an Agreement State license or a Nuclear Regulatory Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005.
 - iii. Any individual certified by the American Board of Radiology in therapeutic radiological physics, Roentgen ray and gamma ray physics, x-ray and radium physics, or radiological physics, or certified by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2005, need not comply with the training requirements for an authorized medical physicist described in G.51, for those materials and uses that these individuals performed on or before October 24, 2005.
 - iv. [Reserved]
- b.
 - i. Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by an Agency, a Nuclear Regulatory Commission or an Agreement State, a permit issued by a Nuclear Regulatory Commission master material licensee, a permit issued by an Agency, a Nuclear Regulatory Commission or an Agreement State broad scope licensee, or a permit issued by a Nuclear Regulatory Commission master material license broad scope permittee on or before January 14, 2019

who perform only those medical uses for which they were authorized on or before that date need not comply with the training requirements of G.100 through G.690.

- ii. Physicians, dentists, or podiatrists not identified as authorized users for the medical use of radioactive material on a license issued by the Agency, the Nuclear Regulatory Commission or an Agreement State, a permit issued by a Nuclear Regulatory Commission master material licensee, a permit issued by an Agency, a Nuclear Regulatory Commission or Agreement State broad scope licensee, or a permit issued in accordance with a Nuclear Regulatory Commission master material broad scope license on or before October 24, 2005, need not comply with the training requirements of G.100 through G.690 for those materials and uses that these individuals performed on or before October 24, 2005, as follows:
 - (1) For uses authorized under G.100 or G.200, or oral administration of sodium iodide I-131 requiring a written directive for imaging and localization purposes, a physician who was certified on or before October 24, 2005, in nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology by the American Board of Radiology; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or American Osteopathic Board of Nuclear Medicine in nuclear medicine;
 - (2) For uses authorized under G.300, a physician who was certified on or before October 24, 2005, by the American Board of Nuclear Medicine; the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or the American Osteopathic Board of Radiology after 1984;
 - (3) For uses authorized under G.400 or G.600, a physician who was certified on or before October 24, 2005, in radiology, therapeutic radiology or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and
 - (4) For uses authorized under G.500, a physician who was certified on or before October 24, 2005, in radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.
- iii. [Reserved]
- c. Individuals who need not comply with training requirements as described in G.57 may serve as preceptors for, and supervisors of, applicants seeking authorization on Agency licenses for the

same uses for which these individuals are authorized.

Sec. G.59 - Recentness of Training. The training and experience specified in G.24 through G.59, and G.100 through G.690 shall have been obtained within the seven years preceding the date of application or the individual shall have had related continuing education and experience since the required training and experience was completed.

General Technical Requirements

Sec. G.60 - Possession, Use, Calibration and Testing of Instruments to Measure the Activity of Unsealed Radioactive Materials.

- a. For direct measurements performed in accordance with G.63, a licensee shall possess and use instrumentation to measure the activity of unsealed radioactive materials before it is administered to each patient or human research subject.
- b. A licensee shall test and calibrate the instrumentation required in G.60a. in accordance with nationally recognized standards or the manufacturer's instructions.
- c. A licensee shall retain a record of each instrument test and calibration required in G.60 in accordance with G.2060.
- [d. The tests required in G.60b. shall, at a minimum, include tests for constancy and linearity as appropriate to demonstrate proper operation of the instrument.
- e. The calibrations required in G.60b. shall, at a minimum. include accuracy and geometric dependence, as appropriate, to demonstrate proper operation of the instrument.]

Sec. G.61 - Calibration of Survey Instruments.

- a. A licensee shall ensure that the survey instruments used to show compliance with Part G and Part D of these regulations have been calibrated before first use, annually, and following any repair that will affect the calibration. The licensee shall:
 - i. Calibrate all scales with readings up to 10 millisieverts (1000 mrem) per hour with a radiation source;
 - ii. Calibrate two separated readings on each scale or decade that will be used to show compliance; and
 - iii. Conspicuously note on the instrument the date of calibration.
- b. The licensee shall not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than 20 percent.
- c. The licensee shall retain a record of each survey instrument calibration in accordance with

G.2061.

- [d. The licensee shall check each survey instrument for consistent response with a dedicated check source before each day of use. The licensee is not required to keep records of these checks.]

[Sec. G-62 - Quality Control of Diagnostic Equipment. Each licensee shall establish written quality control procedures for all diagnostic equipment used for radionuclide studies. As a minimum, quality control procedures and frequencies shall be those recommended by equipment manufacturers or procedures which have been approved by the Agency. The licensee shall conduct quality control procedures in accordance with written procedures.]

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. [For photon-emitting radioactive material, this determination shall be within 30 minutes before medical use. For all other radioactive material, this determination shall be within the period before medical use that is no greater than 10 percent of the physical half-life of the radioactive material.]
- b. For a unit dosage, this determination shall be made by:
- i. Direct measurement of radioactivity; or
 - ii. A decay correction, based on the activity or activity concentration determined by:
 - (1) A manufacturer or preparer licensed pursuant to C.28j. of these regulations or equivalent Nuclear Regulatory Commission or Agreement State requirements; or
 - (2) An Agency, Nuclear Regulatory Commission, or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by the U.S. Food and Drug Administration; or
 - (3) A PET radioactive drug producer licensed under C.24h. of these regulations or equivalent Nuclear Regulatory or Agreement State requirements.
- c. For other than unit dosages, this determination shall be made by:
- i. Direct measurement of radioactivity;
 - ii. Combination of measurements of radioactivity and mathematical calculations; or
 - iii. Combination of volumetric measurements and mathematical calculations, based on the measurement made by:
 - (1) A manufacturer or preparer licensed under C.28j. of these regulations or equivalent Nuclear Regulatory Commission, or Agreement State requirements.

- (2) A PET radioactive drug producer licensed under C.24h. of these regulations or equivalent Nuclear Regulatory Commission or Agreement State requirements.
- d. Unless otherwise directed by the authorized user, a licensee shall 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.63 in accordance with G.2063.

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 the following radioactive material for check, calibration and reference use:

- a.
 - i. Sealed sources, not exceeding 1.11 gigabecquerels (30 mCi) each, manufactured and distributed by persons specifically licensed pursuant to Part C.28k. of these regulations or equivalent Nuclear Regulatory Commission or Agreement State requirements;
 - ii. Sealed Sources not exceeding 1.11 gigabecquerels (30 mCi) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under Part C.28k. of these regulations or equivalent Nuclear Regulatory Commission 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; Any radioactive material with a half-life of not longer then 120 days in individual amounts not to exceed 0.56 gigabecquerels (15 mCi);
 - iii. Any radioactive material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 7.4 megabecquerels (200 μ Ci) or 1000 times the quantities in Appendix A of Part S of these regulations; or
 - v. Technetium-99m in amounts as needed.
- b. Radioactive material in sealed sources authorized by G.65 shall not be:
 - i. Used for medical use as defined in G.2 except in accordance with the requirements in G.500; or
 - ii. Bundled, aggregated, or otherwise combined to create an activity greater than the maximum activity of any single sealed source authorized under G.65.
- c. A licensee using calibration, transmission, and reference sources in accordance with the requirements in G.65a. or G.65b. need not list these sources on a specific medical use license.

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[or equivalent instructions approved by the Agency].

- b. A licensee in possession of a sealed source shall:
 - i. Test the source for leakage before its first use unless the licensee has a certificate from the supplier indicating the source was tested within six months before transfer to the licensee; and
 - ii. Test the source for leakage at intervals not to exceed six months or at other intervals approved by the Agency, an Agreement State, or the Nuclear Regulatory Commission in the Sealed Source and Device Registry.
- c. To satisfy the leak test requirements of G.67, the licensee shall measure the sample so that the leak test can detect the presence of 185 becquerels (0.005 μCi) or more of radioactive material in the sample.
- d. A licensee shall retain leak test records in accordance with G.2067a.
- e. If the leak test reveals the presence of 185 becquerels (0.005 μCi) or more of removable contamination, the licensee shall:
 - i. Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements in Parts C and D of these regulations;
 - ii. File a report with the Agency within five days of receiving the leak tests results in accordance with G.3067.
- f. A licensee need not perform a leak test on the following sources:
 - i. Sources containing only radioactive material with a half-life of less than 30 days;
 - ii. Sources containing only radioactive material as a gas;
 - iii. Sources containing 3.7 megabecquerels (100 μCi) or less of beta or gamma-emitting material or 0.37 megabecquerels (10 μCi) or less of alpha-emitting material;
 - iv. Seeds of iridium-192 encased in nylon ribbon; and
 - v. 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 six months before the date of use or transfer.
- g. A licensee in possession of a sealed source or brachytherapy source, except for gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such sources. The licensee shall retain each inventory record in accordance with G.2067b.

Sec. G.69 - Labeling and Shielding of Vials and Syringes.

- a. Each syringe and vial that contains unsealed radioactive material shall be labeled to identify the radioactive drug. Each syringe shield and vial shield shall also be labeled unless the label on the syringe or vial is visible when shielded.
- [b. A licensee shall require each individual preparing or handling a vial that contains a radioactive drug to keep the vial in a vial radiation shield.]

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

- a. Except as provided in G.70b., in addition to the surveys required by Part D of these regulations, a licensee shall survey with a radiation detection survey instrument at the end of each day of use. A licensee shall survey all areas where unsealed radioactive material requiring a written directive was prepared for use or administered.
- b. A licensee does not need to perform the surveys required by G.70a. in area(s) where patients or human research subjects are confined when they cannot be released under G.75.
- c. A licensee shall retain a record of each survey in accordance with G.2070.
- [d. A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radioactive drugs or radioactive wastes are stored, unless conditions have not changed.]
- [e. A licensee shall conduct the surveys required by G.70a. and G.70b. to be able to measure dose rates as low as 1 microsievert (0.1 mrem) per hour.]
- [f. A licensee shall establish dose rate action levels for the surveys required by G.70a. and G.70b. and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if a dose rate exceeds an action level.]
- [g. A licensee shall survey for removable contamination each day of use all areas where generators and bulk radioactive drugs are prepared for use or administered and each week where radioactive materials are stored.
- [h. A licensee shall conduct the surveys required by G.70e. to be able to detect contamination on each wipe sample of 33.3 becquerels (2000 dpm).]
- [i. A licensee shall establish removable contamination action levels for the surveys required by G.70e. and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds action levels.]

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 materials or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisievert (0.5 rem).^{2/}
- b. A licensee shall provide the released individual, or the individual's parent or guardian, with instructions, including oral and written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 millisievert (0.1 rem). If the total effective dose equivalent to a breast-feeding infant or child could exceed 1 millisievert (0.1 rem) assuming there was no interruption of breast-feeding, the instructions shall also include:
 - i. Guidance on the interruption or discontinuation of breast-feeding; and
 - ii. Information on the potential consequences, if any, of failure to follow the guidance.
- c. The licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with G.2075a.
- d. The licensee shall maintain a record of instructions provided to breast-feeding women in accordance with G.2075b.
- [e. Notwithstanding G.75a., the licensee may be held responsible for the proper disposal of any individual's radioactive waste discovered in a solid waste stream that can be traced to the licensee.]

Sec. G.80 - Provision of Mobile Medical Service.

- a. A licensee providing mobile medical services shall:
 - i. 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 of use and clearly delineates the authority and responsibility of both the client and the mobile medical service. [If the client is licensed, the letter shall document procedures for notification, receipt, storage, and documentation of transfer of radioactive material delivered to the client's address for use by the mobile medical service.];
 - ii. 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 G.80a, shall include a constancy check;

^{2/} The current revision of NREG-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).

- iii. Check survey instruments for proper operation with a dedicated check source before use at each client's address;
- iv. Before leaving a client's address, survey all areas of use to ensure compliance with Part D of these regulations;
- [v. Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at a client's address; and]
- [vi. Use radioactive gases only in areas of use and under conditions which have been evaluated and approved by the Agency for compliance with airborne release standards.]
- b. A mobile medical service shall not have radioactive material delivered directly from the manufacturer or the distributor to the client, unless the client has a license allowing possession of the radioactive material. Radioactive material delivered to the client shall be received and handled in conformance with the client's license.
- c. A licensee providing mobile medical services shall retain the letter required in G.80a.i. and the record of each survey required in G.80a.iv. in accordance with G.2080a. and G.2080b., respectively.
- [d. Use radioactive gases only in areas of use and under conditions which have been evaluated and approved by the Agency for compliance with airborne release standards;]
- [e. A mobile medical service licensee shall, at a minimum, maintain or have access to the following documents on each mobile unit:
 - i. The current operating and emergency procedures;
 - ii. A copy of the license;
 - iii. Copies of the letter required by G.80a.i.;
 - iv. Copies of and/or access to electronic records with proper signatures of:
 - (1) Current calibration records for each survey instrument and diagnostic equipment or dose delivery device in use; and
 - (2) Survey records covering uses associated with the mobile unit during, at a minimum, the preceding [insert number of calendar days determined by Agency].
- [f. A mobile medical service licensee shall maintain all records required by Parts D and G of these regulations at a location within the Agency's jurisdiction identified on the license. For purposes of inspection, these records shall be available to the Agency at all reasonable hours of operation at:

- i. A single address of use; or
- ii. When no address of use is identified on the license for records retention, the mobile unit identified in the license.]

[Sec. G.85 - Storage and Control of Volatiles and Gases.

- a. A licensee shall store volatile radioactive materials and radioactive gases in a radiation shield and container.
- b. A licensee shall store and use a multi-dose container in a properly functioning fume hood.
- c. A licensee who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed in Part D of these regulations.
- d. The system shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.
- e. A licensee shall check the operation of collection systems monthly. Records of these checks shall be maintained for three years.]

Sec. G.92 - Decay-in-Storage.

- a. A licensee may hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:
 - i. Monitors radioactive material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey instrument set on its most sensitive scale and with no interposed shielding;
 - ii. Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee; and
 - [iii. Separates and monitors each generator column individually with all radiation shielding removed to ensure that its contents have decayed to background radiation level before disposal.]
- b. A licensee shall retain a record of each disposal permitted under G.92a. in accordance with G.2092.

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

Sec. G.100 - Use of Unsealed Radioactive Material for Uptake, Dilution, or Excretion Studies for which a Written Directive is Not Required. Except for quantities that require a written directive under

G.40b., a licensee may use any unsealed radioactive material, prepared for medical use for uptake, dilution, or excretion studies that is:

- a. Obtained from:
 - i. A manufacturer or preparer licensed pursuant to C.28j of these regulations or equivalent Agreement State or Nuclear Regulatory Commission requirements; or
 - ii. A PET radioactive drug producer licensed under C.24h of these regulations, or equivalent Agreement State or Nuclear Regulatory Commission requirements; or
- b. Excluding production of PET radionuclides, prepared by:
 - i. An authorized nuclear pharmacist;
 - ii. A physician who is an authorized user and who meets the requirements specified in G.290, or G.390 and G.290c.i.(2)(g); or
 - iii. An individual under the supervision, as specified in G.27, of the authorized nuclear pharmacist in G.100b.i. or the physician who is an authorized user in G.100b.ii.; or
- c. Obtained from and prepared by an Agency, Nuclear Regulatory Commission, or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or
- 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.

Sec. G.190 - Training for Uptake, Dilution, and Excretion Studies. Except as provided in G.57, the licensee shall require an authorized user of an 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 Agency, the Nuclear Regulatory Commission, or an Agreement State. The names of board certifications which have been recognized by the Agency, the Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolbox web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:
 - i. Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies as described in G.190c.i.(1) through G.190c.i.(2)(f); and
 - ii. 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 or G.390, or equivalent Nuclear Regulatory Commission or Agreement State requirements; or
- c. i. Has completed 60 hours of training and experience, including a minimum of eight 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 shall include:
 - (1) Classroom and laboratory training in the following areas:
 - (a) Radiation physics and instrumentation;
 - (b) Radiation protection;
 - (c) Mathematics pertaining to the use and measurement of radioactivity;
 - (d) Chemistry of radioactive material for medical use; and
 - (e) Radiation biology; and
 - (2) Work experience, under the supervision of an authorized user who meets the requirements in G.57, G.190, G.290, G.390 or equivalent Agreement State or Nuclear Regulatory Commission requirements, involving:
 - (a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - (b) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
 - (c) Calculating, measuring, and safely preparing patient or human research subject dosages;
 - (d) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
 - (e) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
 - (f) Administering dosages of radioactive drugs to patients or human research subjects; and
- ii. Has obtained written attestation that the individual has satisfactorily completed the requirements in G.190c.i. and is able to independently fulfill the radiation safety-related

duties as an authorized user for the medical uses authorized under G.100. The attestation shall be obtained from either:

- (1) A preceptor authorized user who meets the requirements in G.57, G.190, G.290, G.390, or equivalent Nuclear Regulatory Commission or Agreement State requirements; or
- (2) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in G.57, G.190, G.290, G.390, or equivalent Nuclear Regulatory Commission or Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training shall be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and shall include training and experience specified in G.190c.i.

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

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 shall use, for imaging and localization studies, any radioactive material prepared for medical use that is:

- a. Obtained from:
 - i. A manufacturer or preparer licensed under C.28j. of these regulations or equivalent Agreement State or Nuclear Regulatory Commission requirements; or
 - ii. A PET radioactive drug producer licensed under C.28h. of these regulations, or equivalent Nuclear Regulatory Commission or Agreement State requirements; or
- b. Excluding production of PET radionuclides, prepared by:
 - i. An authorized nuclear pharmacist;
 - ii. A physician who is an authorized user and who meets the requirements specified in G.290, or G.390 and G.290c.i.(2)(g); or
 - iii. An individual under the supervision, as specified in G.27, of the authorized nuclear pharmacist in G.290b.i. or the physician who is an authorized user in G.290b.ii.; or
- c. Obtained from and prepared by an Agency, Nuclear Regulatory Commission, or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-

- approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or
- 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.
- [e. Provided the conditions of G.85 are met, a licensee shall use radioactive aerosols or gases only if specific application is made to and approved by the Agency.]

Sec. G.204 - Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations.

- a. A licensee shall not administer to humans a radiopharmaceutical containing:
- i. More than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 μ Ci of Mo-99 per mCi of Tc-99m); or
 - ii. More than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 μ Ci of Sr-82 per mCi of Rb-82 chloride); or
 - iii. More than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 μ Ci of Sr-85 per mCi of Rb-82).
- b. A licensee that uses molybdenum-99/technetium-99 generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in each eluate from a generator to demonstrate compliance with G.204.a.
- c. A licensee that uses a strontium-82/rubidium-82 generator for preparing a rubidium-82 radiopharmaceutical shall, before the first patient use of the day, measure the concentration of radionuclides strontium-82 and strontium-85 to demonstrate compliance with G.204a.
- d. If a licensee is required to measure the molybdenum-99 concentration or strontium-82 and strontium-85 concentrations, the licensee shall retain a record of each measurement in accordance with G.2204.
- e. A licensee shall report any measurement that exceeds the limits in G.204a at the time of generator elution, in accordance with G.3204s.

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

- i. Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for imaging and localization studies as described in G.290c.i.(1) through G.290c.i.(2)(g); and
 - ii. 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, or equivalent Agreement State, or Nuclear Regulatory Commission requirements; or
- c. i. Has completed 700 hours of training and experience including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience shall include, at a minimum:
- (1) Classroom and laboratory training in the following areas:
 - (a) Radiation physics and instrumentation;
 - (b) Radiation protection;
 - (c) Mathematics pertaining to the use and measurement of radioactivity;
 - (d) Chemistry of radioactive material for medical use;
 - (e) Radiation biology; and
 - (2) Work experience, under the supervision of an authorized user, who meets the requirements in G.57, G.290, or G.390 and G.290c.i.(2)(g) or equivalent Agreement State or Nuclear Regulatory Commission requirements. An authorized nuclear pharmacist who meets the requirements in G.55 or G.57 may provide the supervised work experience for G.290c.i.(2)(g). Work experience shall involve:
 - (a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - (b) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
 - (c) Calculating, measuring, and safely preparing patient or human research subject dosages;
 - (d) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

- (e) Using procedures to safely contain spilled radioactive material 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 radionuclide purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and
- ii. Has obtained written attestation that the individual has satisfactorily completed the requirements in G.290c.i. and is able to fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under G.100 and G.200. The attestation shall be obtained from either:
- (1) A preceptor authorized user who meets the requirements in G.57, G.290, or G.390 and G.290c.i.(2)(g), or equivalent Nuclear Regulatory Commission or Agreement State requirements; or
 - (2) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in G.57, G.290, or G.390 and G.290c.i.(2)(g), or equivalent Nuclear Regulatory Commission or Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training shall be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and shall include training and experience specified in G.290c.i.

Specific Requirements for the Use of 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 identified in G.390b.i.(2)(g) prepared for medical use for which a written directive is required that is:

- a. Obtained from:
 - i. A manufacturer or preparer licensed in accordance with C.28j. of these regulations or equivalent Nuclear Regulatory Commission or Agreement State regulations; or
 - ii. A PET radioactive drug producer licensed under C.24h. of these regulations or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

- b. Excluding production of PET radionuclides prepared by:
 - i. An authorized nuclear pharmacist;
 - ii. A physician who is an authorized user and who meets the requirements specified in G.290, G.390; or
 - iii. An individual under the supervision, as specified in G.27, of the authorized nuclear pharmacist in G.300b.i. or the physician who is an authorized user in G.300b.ii.; or
- c. Obtained from and prepared by an Agency, Nuclear Regulatory Commission, or Agreement State licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by the FDA; or
- d. Prepared by the licensee for use in research in accordance with an IND protocol accepted by FDA.

Sec. G.310 - Safety Instruction. In addition to the requirements of J.12 of these regulations:

- a. A licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects that cannot be released under G.75. To satisfy this agreement, the instruction shall be appropriate with the duties of the personnel and include the following:
 - i. Patient or human research subject control;
 - ii. Visitor control including:
 - (1) Routine visitation to hospitalized individuals in accordance with Part D.1301a.i. of these regulations.
 - (2) Visitation authorized in accordance with Part D.1301c. of these regulations.
 - iii. Contamination control;
 - iv. Waste control; and
 - v. Notification of the RSO, or their designee, and an authorized user for the type of radioactive materials used in the treatment if the patient or the human research subject dies or has a medical emergency.
- b. A licensee shall retain a record of individuals receiving instruction in accordance with G.2310.

Sec. G.315 - Safety Precautions.

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

- i. Quarter the patient or the human research subject either in:
 - (1) A private room with a private sanitary facility; or
 - (2) A room, with a private sanitary facility, with another individual who also has received similar radiopharmaceutical therapy and who cannot be released under G.75; and,
 - ii. Visibly post the patient's or the human research subject's room with a “Radioactive Materials” sign;
 - iii. 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
 - iv. Either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding or handle such material and items as radioactive waste.
- b. A licensee shall notify the Radiation Safety Officer, or their designee, and an authorized user approved for the use of the type of radioactive materials used in the treatment as soon as possible if the patient or human research subject has a has a medical emergency or dies.

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 Agency, an Agreement State or the Nuclear Regulatory Commission and who meets the requirements in G.390b.i.(2)(g). The names of board certifications that have been recognized by the Agency, the Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses License Toolkit web page. To be recognized, a specialty board shall require all candidates for certification to:
 - i. 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 shall include 700 hours of training and experience as described in G.390b.i.(1) through G.390b.i.(2)(e). Eligible training programs shall be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Council on Postdoctoral Training of the American Osteopathic Association; and
 - ii. 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. i. 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 shall include:
- (1) Classroom and laboratory training in the following areas:
 - (a) Radiation physics and instrumentation;
 - (b) Radiation protection;
 - (c) Mathematics pertaining to the use and measurement of radioactivity;
 - (d) Chemistry of radioactive material for medical use; and
 - (e) Radiation biology; and
 - (2) Work experience, under the supervision of an authorized user who meets the requirements in G.57, G.390, or equivalent Agreement State or Nuclear Regulatory Commission requirements. A supervising authorized user, who meets the requirements in G.390b. shall have experience in administering dosages in the same dosage category or categories listed in G.390b.ii.(2)(g) as the individual requesting authorized user status. The work experience shall involve:
 - (a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - (b) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;
 - (c) Calculating, measuring, and safely preparing patient or human research subject dosages;
 - (d) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
 - (e) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
 - (f) [Reserved]
 - (g) Administering dosages of radioactive drugs to patients or human research subjects from the three categories in G.390b.i.(2)(g). Radioactive drugs containing radionuclides not included in G.390b.i.(2)(g) are regulated under G.1000. This work experience shall involve a minimum of three

cases in each of the following categories for which the individual is requesting authorized user status:

- (i) Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for which a written directive is required;
 - (ii) Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131;^{3/}
 - (iii) Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy less than 150 keV, for which a written directive is required; and
- ii. Has obtained written attestation that the individual has satisfactorily completed the requirements in G.392b.i. and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under G.300 for which the authorized user is requesting authorized user status. The written attestation shall be obtained from either:
- (1) A preceptor authorized user who meets the requirements in G.57, G.390 or equivalent Nuclear Regulatory Commission or Agreement State requirements and has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status; or
 - (2) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in G.57, G.390 or equivalent Nuclear Regulatory Commission or Agreement State requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training shall be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and shall include training and experience specified in G.390b.i.

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

^{3/} Experience with at least three cases in category G.390b.i.(2)(g)(ii) also satisfies the requirement in category G.390b.i.(2)(g)(i).

- a. Is certified by a medical specialty board whose certification process includes all of the requirements in G.392c.i. and G.392c.ii. and whose certification process has been recognized by the Agency, an Agreement State or the Nuclear Regulatory Commission. The names of board certifications whose certification has been recognized by the Agency, Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page.); or
- b. Is an authorized user under G.390, for uses listed in G.390b.i.(2)(g)(i) or G.390b.i.(2)(g)(ii), G.394 or equivalent Agreement State or Nuclear Regulatory Commission requirements; or
- c.
 - i. Has successfully completed 80 hours classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training shall include:
 - (1) Radiation physics and instrumentation;
 - (2) Radiation protection;
 - (3) Mathematics pertaining to the use and measurement of radioactivity;
 - (4) Chemistry of radioactive material for medical use; and
 - (5) Radiation biology; and
 - ii. Has work experience under the supervision of an authorized user who meets the requirements in G.57, G.390, G.392, G.394, or equivalent Agreement State, or Nuclear Regulatory Commission requirements. A supervising authorized user who meets the requirements of G.390b. shall also have experience in administering dosages as specified in G.390b.i.(2)(g)(i) or G.390b.i.(2)(g)(ii). The work experience shall involve:
 - (1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - (2) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;
 - (3) Calculating, measuring, and safely preparing patient or human research subject dosages;
 - (4) Using administrative controls to prevent a medical event involving the use of radioactive material;
 - (5) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
 - (6) Administering dosages to patients or human research subjects that includes at

least three cases involving the oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

- iii. Has obtained written attestation that the individual has satisfactorily completed the requirements in G.392c.i. and G.392c.ii., and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under G.300. The attestation shall be obtained from:
 - (1) A preceptor authorized user who meets the requirements of G.57, G.390, G.392, G.394, or equivalent Agreement State or Nuclear Regulatory Commission requirements and has experience in administering dosages as specified in G.390b.i.(2)(g)(i) or G.390b.i.(2)(g)(ii); or
 - (2) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in G.57, G.390, G.392, G.394, or equivalent Nuclear Regulatory Commission or Agreement State requirements, has experience in administering dosages as specified in G.390b.i.(2)(g)(i) or G.390b.i.(2)(g)(ii), and concurs with the attestation provided by the residency program director. The residency training shall be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and shall include training and experience specified in G.392c.i. or G.392c.ii.

Sec. G.394 - Training for the Oral Administration of Sodium Iodide I-131 in Quantities Greater than 1.22 Gigabecquerels (33 millicuries) for which a Written Directive is Required. 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.394c.i. and G.394c.ii. and whose certification has been recognized by the Agency, an Agreement State or the Nuclear Regulatory Commission. The names of board certifications that have been recognized by the Agency, the Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensees Toolkit web page; or
- b. Is an authorized user under G.390 for uses listed in G.390b.i.(2)(g)(ii), or equivalent Agreement State, or Nuclear Regulatory Commission requirements; or
- c. i. Has successfully completed 80 hours classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive; the training shall include:
 - (1) Radiation physics and instrumentation;

- (2) Radiation protection;
 - (3) Mathematics pertaining to the use and measurement of radioactivity;
 - (4) Chemistry of radioactive material for medical use; and
 - (5) Radiation biology; and
- ii. Has work experience, under the supervision of an authorized user who meets the requirements in G.57, G.390, G.394, or equivalent Agreement State or Nuclear Regulatory Commission requirements. A supervising authorized user, who meets the requirements in G.390b., shall also have experience in administering dosages as specified in G.390b.i(2)(g)(ii). The work experience shall involve:
- (1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - (2) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;
 - (3) Calculating, measuring, and safely preparing patient or human research subject dosages;
 - (4) Using administrative controls to prevent a medical event involving the use of radioactive material;
 - (5) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
 - (6) Administering dosages to patients or human research subjects that includes at least three cases involving the oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and
- iii. Has obtained written attestation that the individual has satisfactorily completed the requirements in G.390c.i and G.390c.ii. and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under G.300. The attestation shall be obtained from either:
- (1) A preceptor authorized user, who meets the requirements in G.57, G.390, G.394, or equivalent Agreement State or Nuclear Regulatory Commission requirements and has experience in administering dosages as specified in G.390b.i(2)(g)(ii); or
 - (2) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in G.57, G.390, G.394, or

equivalent Nuclear Regulatory Commission or Agreement State requirements, has experience in administering dosages as specified in G.390b.i.(2)(g)(ii), and concurs with the attestation provided by the residency program director. The residency training shall be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and shall include training and experience specified in G.390c.i. and G.390c.ii.

Sec. G.396 - Training for the parenteral administration of unsealed radioactive material requiring a written directive.

- a. 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:
 - i. Is an authorized user under G.390 for uses listed in G.390b.i.(2)(g)(iii), or equivalent Nuclear Regulatory Commission or Agreement State requirements; or
 - ii. Is an authorized user under G.490, G.690, or equivalent Nuclear Regulatory Commission or Agreement State requirements, and who meets the requirements in G.396b.;
 - iii. Is certified by a medical specialty board whose certification process has been recognized by the Agency, the Nuclear Regulatory Commission, or an Agreement State under G.490 or G.690, and who meets the requirements in G.390b.
- b. The physician:
 - i. Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations listed in G.390b.i.(2)(g)(iii). The training shall include:
 - (1) Radiation physics and instrumentation;
 - (2) Radiation protection;
 - (3) Mathematics pertaining to the use and measurement of radioactivity;
 - (4) Chemistry of radioactive material for medical use; and
 - (5) Radiation biology; and
 - ii. Has work experience, under the supervision of an authorized user who meets the requirements in G.57, G.390, G.396, or equivalent Agreement State requirements, in the parenteral administrations listed in G.390b.i.(2)(g)(iii). A supervising authorized user who meets the requirements in G.390, G.396, or equivalent Nuclear Regulatory Commission or Agreement State requirements, shall have experience in administering dosages in the same category or categories as the individual requesting authorized user status. The work experience shall involve:

- (1) Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;
 - (2) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;
 - (3) Calculating, measuring, and safely preparing patient or human research subject dosages;
 - (4) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
 - (5) Using procedures to contain spilled radioactive material safely, and using proper decontamination procedures; and
 - (6) Administering dosages to patients or human research subjects, that include at least three cases of the parenteral administrations as specified in G.390b.i(2)(g)(iii); and
- iii. Has obtained written attestation that the individual has satisfactorily completed the requirements in G.396b.i. and G.396b.ii., and is able to independently fulfill the radiation safety-related duties as an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive. The attestation shall be obtained from either:
- (1) A preceptor authorized user who meets the requirements in G.57, G.390, G.396, or equivalent Nuclear Regulatory Commission or Agreement State requirements. A preceptor authorized user who meets the requirements in G.390, G.396, or equivalent Nuclear Regulatory Commission or Agreement State requirements, shall have experience in administering dosages in the same category or categories as the individual requesting authorized user status; or
 - (2) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in G.57, G.390, G.396, or equivalent Nuclear Regulatory Commission or Agreement State requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program shall be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and shall include training and experience specified in paragraphs G.396b.i. and G.396b.ii.

Manual Brachytherapy

Sec. G.400 - Use of Sealed Sources for Manual Brachytherapy. A licensee shall only use brachytherapy sources:

- a. As approved in the Sealed Source and Device Registry for manual brachytherapy medical use. The manual brachytherapy sources may be used for manual brachytherapy uses that are not explicitly listed in the Sealed Source and Device Registry, but shall be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry; or
- b. In research to deliver therapeutic doses for medical use in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of G.49a are met.

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 perform 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.404a. and G.404b. in accordance with G.2404.

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.

Sec. G.410 - Safety Instruction. In addition to the requirements of Part J.12 of these regulations:

- 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 shall be commensurate with the duties of the personnel and shall include the:
 - i. Size and appearance of the brachytherapy sources;

- ii. Safe handling and shielding instructions;
 - iii. Patient or human research subject control;
 - iv. Visitor control, including both:
 - (1) Routine visitation of hospitalized individuals in accordance with D1301a.i. of these regulations; and
 - (2) Visitation authorized in accordance with D.1301c. of these regulations; and
 - v. 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.

Sec. G.415 - Safety Precautions for Patients or Human Research Subjects Receiving Brachytherapy.

- a. For each patient or human research subject that is receiving brachytherapy and cannot be released under G.75, a licensee shall:
 - i. Not quarter the patient or human research subject in the same room as an individual who is not receiving brachytherapy;
 - ii. Visibly post the patient's or human research subject's room with a "Radioactive Materials" sign; and
 - iii. 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 emergency response equipment available near each treatment room to respond to a source:
 - i. Dislodged from the patient; or
 - ii. Lodged within the patient following removal of the source applicators.
- c. A licensee shall notify the Radiation Safety Officer, or their designee, and an authorized user for the materials involved shall be notified as soon as possible immediately if the patient or human research subject has a medical emergency or dies.

Sec. G.432 - Calibration Measurements of Brachytherapy Sealed Sources.

- a. Before the first medical use of a brachytherapy source on or after [insert effective date of the rule], a licensee shall have:
 - i. Determined the source output or activity using a dosimetry system that meets the

- requirements of G.630a.;
- ii. Determined source positioning accuracy within applicators; and
 - iii. Used published protocols currently accepted by nationally recognized bodies to meet the requirements of G.432a.i. and G.432a.ii.
- b. Instead of a licensee making its own measurements as required in G.432a., 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.432a.
 - c. A licensee shall mathematically correct the outputs or activities determined in G.432 for physical decay at intervals consistent with one percent physical decay.
 - d. A licensee shall retain a record of each calibration in accordance with G.2432.
 - [e. An authorized medical physicist shall perform or review the calculation measurements made pursuant to G.432a., G.432b., or G.432c.]
 - [f. 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 shall be based on the activity determined in accordance with paragraphs G.432a., G.432b., and G.432c.]
 - [g. A licensee shall retain a record of decay calculations required by G.432f. in accordance with G.2432]

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

- a. Licensees who use strontium-90 for ophthalmic treatments shall ensure that certain activities as specified in G.433b. are performed by either:
 - i. An authorized medical physicist; or
 - ii. An individual who:
 - (1) is identified as an ophthalmic physicist on a specific medical use license issued by the Agency, the Nuclear Regulatory Commission or an Agreement State; permit issued by an Agency, a Nuclear Regulatory Commission or Agreement State broad scope medical use licensee; medical use permit issued by a Nuclear Regulatory Commission master material licensee; or permit issued by a Nuclear Regulatory Commission master material licensee broad scope medical use permittee; and
 - (2) holds a master's or doctor's degree in physics, medical physics, other physical sciences, engineering, or applied mathematics from an accredited college or university; and

- (3) has successfully completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of a medical physicist; and
 - (4) Has documented training in:
 - (i) The creation, modification, and completion of written directives;
 - (ii) Procedures for administrations requiring a written directive; and
 - (iii) Performing the calibration measurements of brachytherapy sources as detailed in G.432.
- b. The individuals who are identified in G.433a. shall:
- i. Calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay shall be based on the activity determined under G.432; and
 - ii. Assist the licensee in developing, implementing, and maintaining written procedures, to provide high confidence that the administration is in accordance with the written directive. These procedures shall include the frequencies that the individual meeting the requirements in G.433a. will observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the administrations were in accordance with the written directives.
- c. Licensees shall retain a record of the activity of each strontium-90 source in accordance with G.2433.

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 shall 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.

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 Agency, an Agreement State or the Nuclear Regulatory Commission. The names of board certifications that have been recognized by the Agency, the Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:
 - i. Successfully complete a minimum of three years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association; and
 - ii. 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. i. Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:
 - (1) 200 hours of classroom and laboratory training in the following areas:
 - (a) Radiation physics and instrumentation;
 - (b) Radiation protection;
 - (c) Mathematics pertaining to the use and measurement of radioactivity; and
 - (d) Radiation biology; and
 - (2) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in G.57, G.490, or equivalent Agreement State, or Nuclear Regulatory Commission requirements at a medical facility authorized to use radioactive materials under G.400, involving:
 - (a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - (b) Checking survey meters for proper operation;
 - (c) Preparing, implanting, and removing brachytherapy sources;
 - (d) Maintaining running inventories of material on hand;
 - (e) Using administrative controls to prevent a medical event involving the use of radioactive material;

- (f) Using emergency procedures to control radioactive material; and
- ii. Has completed three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in G.57, G.490. or equivalent Agreement State or Nuclear Regulatory Commission requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada, or the Council on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by G.490b.i.(2); and
- iii. Has obtained written attestation that the individual has satisfactorily completed the requirements in G.490b.i. and G.490b.ii. and is able to independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy sources for the medical uses authorized under G.400. The attestation shall be obtain from either:
 - (1) A preceptor authorized user who meets the requirements in G.57, G.490, or equivalent Nuclear Regulatory Commission or Agreement State requirements; or
 - (2) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in G.57, G.490, or equivalent Nuclear Regulatory Commission or Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program shall be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and shall include training and experience specified in G.490b.i and G.490b.ii.

Sec. G.491 - Training for ophthalmic use of strontium-90. Except as provided in G.57, the licensee shall require an authorized user of a strontium-90 source for ophthalmic radiotherapy to be a physician who:

- a. Is an authorized user under G.490 or equivalent Agreement State or Nuclear Regulatory Commission requirements; or,
- b. i. Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training shall include:
 - (1) Radiation physics and instrumentation;
 - (2) Radiation protection;
 - (3) Mathematics pertaining to the use and measurement of radioactivity; and,
 - (4) Radiation biology; and,

- ii. 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 shall involve:
 - (1) Examination of each individual to be treated;
 - (2) Calculation of the dose to be administered;
 - (3) Administration of the dose; and,
 - (4) Follow-up and review of each individual's case history; and,
- iii. Has obtained written attestation, signed by a preceptor authorized user, who meets the requirements in G.57, G.490, G.491, or equivalent Agreement State or Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in G.491b.i. and G.491b.ii. and is able to independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.

Sealed Sources For Diagnosis

Sec. G.500 - Use of Sealed Sources and Medical Devices for Diagnosis.

- a. A licensee shall only use sealed sources that are not in medical devices for diagnostic medical uses if the sealed sources are approved in the Sealed Source and Device Registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but shall be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.
- b. A licensee shall only use medical devices containing sealed sources for diagnostic medical uses if both the sealed sources and medical devices are approved in the Sealed Source and Device Registry for diagnostic medical uses. The diagnostic medical devices may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but shall be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.
- c. Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of G.49a. are met.

Sec. G.590 - Training for Use of Sealed Sources and Medical Devices for Diagnosis. Except as provided in G.57, the licensee shall require the authorized user of a diagnostic sealed source or 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.590c. and G.590d. and whose certification has been recognized by the Agency, an Agreement State or the Nuclear Regulatory Commission (The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page.); or

- b. Is an authorized user for uses listed in G.200 or equivalent Nuclear Regulatory Commission or Agreement State requirements; or
- c. Has had eight hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training shall include:
 - i. Radiation physics and instrumentation;
 - ii. Radiation protection;
 - iii. Mathematics pertaining to the use and measurement of radioactivity; and
 - iv. Radiation biology; and
- d. Has completed training in the use of the device for the uses requested.

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

Sec. G.600 - Use of Sealed Sources in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit.

- a. A licensee shall only use sealed sources:
 - i. Approved and as provided for in the Sealed Source and Device Registry in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units to deliver therapeutic doses for medical uses; or
 - ii. In research involving photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of G.49a. are met.
- b. A licensee shall use photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units:
 - i. Approved in the Sealed Source and Device Registry to deliver a therapeutic dose for medical use. These devices may be used for therapeutic medical treatments that are not explicitly provided for in the Sealed Source and Device Registry, but shall be used in accordance with radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

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

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 the surveys in accordance with G.2404.

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

- a. Only a person specifically licensed by the Agency, the Nuclear Regulatory Commission or an Agreement State shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).
- b. Except for low dose-rate remote afterloader units, only a person specifically licensed by the Agency, an Agreement State, or the Nuclear Regulatory Commission shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.
- c. For a low dose-rate remote afterloader unit, only a person specifically licensed by the Agency, an Agreement State, or the Nuclear Regulatory Commission, or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.
- 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.

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

- a. A licensee shall:
 - i. Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;
 - ii. 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);

- iii. Prevent dual operation of more than one radiation producing device in a treatment room, if applicable; and
- iv. Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. This procedure shall include:
 - (1) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;
 - (2) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and
 - (3) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.
- b. A copy of the procedures required by G.610a.iv. shall be physically located at the unit console.
- c. A licensee shall post instructions at the unit console to inform the operator of:
 - i. The location of the procedures required by G.610a.iv.; and
 - ii. 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.
 - i. Prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit, a licensee shall ensure that vendor operational and safety training is provided to all individuals who will operate the unit. The vendor operational and safety training shall be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training.
 - ii. A licensee shall provide operational and safety instructions, initially and at least annually, to all individuals who operate the unit at the facility, as appropriate to the individual's assigned duties. The instructions shall include instruction in:
 - (1) The procedures identified in G.610a.iv.; 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.610d., in accordance with G.2310.
- g. A licensee shall retain a copy of the procedures required by G.610a.iv. and G.610d.ii. in accordance with G.2610.

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:
 - i. Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;
 - ii. Cause the source(s) to be shielded when an entrance door is opened; and
 - iii. 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 G.615a. through G.615e., a licensee shall:
 - i. For [low dose-rate,] medium dose-rate, and pulsed dose-rate remote afterloader units, require:
 - (1) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and
 - (2) An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be

- immediately available during continuation of all patient treatments involving the unit.
- ii. For high dose-rate remote afterloader units, require:
 - (1) An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and
 - (2) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.
 - iii. 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.
 - iv. Notify the Radiation Safety Officer, or their designee, and an authorized user as soon as possible, if the patient or human research subject has a medical emergency or if dies.
- g. A licensee shall have applicable emergency response equipment available near each treatment room, to respond to a source:
- i. Remaining in the unshielded position; or
 - ii. Lodged within the patient following completion of the treatment.

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 shall be met.
 - i. The system shall have been calibrated using a system or source traceable to the National Institute of Standards and Technology (NIST) and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration shall have been performed within the previous two years and after any servicing that may have affected system calibration; or
 - ii. The system shall have been calibrated within the previous four years; 18 to 30 months after that calibration, the system shall have been intercompared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison shall have indicated that the calibration factor of the licensee's system had not changed by more than two percent. The licensee shall not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating

sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.

- b. The licensee shall have available for use a dosimetry system 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.630a. This comparison shall have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in G.630a.
- c. The licensee shall retain a record of each calibration, intercomparison, and comparison in accordance with G.2630.

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:
 - i. Before the first medical use of the unit; and
 - ii. Before medical use under the following conditions:
 - (1) Whenever spot-check measurements indicate that the output differs by more than five percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;
 - (2) Following replacement of the source or following reinstallation of the teletherapy unit in a new location;
 - (3) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and
 - iii. At intervals not exceeding one year.
- b. To satisfy the requirement of G.632a., full calibration measurements shall include determination of:
 - i. The output within 3 percent for the range of field sizes and for the distance or range of distances used for medical use;
 - ii. The coincidence of the radiation field and the field indicated by the light beam localizing device;
 - iii. The uniformity of the radiation field and its dependence on the orientation of the useful beam;

- iv. Timer accuracy and linearity over the range of use;
 - v. On-off error; and
 - vi. The accuracy of all distance measuring and localization devices in medical use.
- c. A licensee shall use the dosimetry system described in G.630a. to measure the output for one set of exposure conditions. The remaining radiation measurements required in G632b.i. may be made using a dosimetry system that indicates relative dose rates.
- d. A licensee shall make full calibration measurements required by G.632a. in accordance with published protocols accepted by nationally recognized bodies.
- e. A licensee shall mathematically correct the outputs determined in G.632b.i. for physical decay for intervals not exceeding one month for cobalt-60, six months for cesium-137, or at intervals consistent with one percent decay for all other nuclides.
- f. Full calibration measurements required by G.632a. and physical decay corrections required by G.632e shall be performed by the authorized medical physicist.
- g. A licensee shall retain 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:
- i. Before the first medical use of the unit;
 - ii. Before medical use under the following conditions:
 - (1) Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and
 - (2) Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and
 - iii. At intervals not exceeding one quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and
 - iv. At intervals not exceeding one year for low dose-rate remote afterloader units.
- b. To satisfy the requirement of G.633a., full calibration measurements shall include, as applicable, determination of:
- i. The output within five percent;

- ii. Source positioning accuracy to within one millimeter;
 - iii. Source retraction with backup battery upon power failure;
 - iv. Length of the source transfer tubes;
 - v. Timer accuracy and linearity over the typical range of use;
 - vi. Length of the applicators; and
 - vii. Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.
- c. A licensee shall use the dosimetry system described in G.630a. to measure the output.
 - d. A licensee shall make full calibration measurements required by G.630a. 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.633b., a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding one 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.633a. through G.633e.
 - g. A licensee shall mathematically correct the outputs determined in G.633b.i. for physical decay at intervals consistent with one percent physical decay.
 - h. Full calibration measurements required by G.633a. and physical decay corrections required by G.633g. shall be performed by the authorized medical physicist.
 - i. A licensee shall retain a record of each calibration in accordance with G.2632.

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:
 - i. Before the first medical use of the unit;
 - ii. Before medical use under the following conditions:
 - (1) Whenever spot-check measurements indicate that the output differs by more than five percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;
 - (2) Following replacement of the sources or following reinstallation of the gamma

stereotactic radiosurgery unit in a new location; and

- (3) Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and
 - iii. At intervals not exceeding one 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.635a., full calibration measurements shall include determination of [the following items, if applicable]:
- i. The output within three percent;
 - ii. Relative helmet factors;
 - iii. Isocenter coincidence;
 - iv. Timer accuracy and linearity over the range of use;
 - v. On-off error;
 - vi. Trunnion centricity;
 - vii. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;
 - viii. Helmet microswitches;
 - ix. Emergency timing circuits; and
 - x. Stereotactic frames and localizing devices (trunnions).
- c. A licensee shall use the dosimetry system described in G.630a. to measure the output for one set of exposure conditions. The remaining radiation measurements required in G.635b.i. may be made using a dosimetry system that indicates relative dose rates.
- d. A licensee shall make full calibration measurements required by G.635a. in accordance with published protocols accepted by nationally recognized bodies.
- e. A licensee shall mathematically correct the outputs determined in G.635b.i. at intervals not exceeding one month for cobalt-60 and at intervals consistent with one percent physical decay for all other radionuclides.
- f. Full calibration measurements required by G.635a. and physical decay corrections required by G.635e. shall be performed by the authorized medical physicist.

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

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:
- i. Timer accuracy, and timer linearity over the range of use;
 - ii. On-off error;
 - iii. The coincidence of the radiation field and the field indicated by the light beam localizing device;
 - iv. The accuracy of all distance measuring and localization devices used for medical use;
 - v. The output for one typical set of operating conditions measured with the dosimetry system described in G.630b.; and
 - vi. The difference between the measurement made in G.642a.v. and the anticipated output, expressed as a percentage of the anticipated output or the value obtained at last full calibration corrected mathematically for physical decay.
- b. A licensee shall perform measurements required by G.642a. in accordance with written procedures established by the authorized medical physicist. The authorized medical physicist 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:
- i. Electrical interlocks at each teletherapy room entrance;
 - ii. Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation^{4/};
 - iii. Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;

^{4/} Some examples of stops installed to limit use of primary beam of radiation are: restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism.

- iv. Viewing and intercom systems;
 - v. Treatment room doors from inside and outside the treatment room; and
 - vi. Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.
- e. If the results of the checks required in G.642d. 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 spot-check required by G.642a. and G.642d., and a copy of the procedures required by G.642b., in accordance with G.2642.

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

- a. A licensee authorized to use remote afterloader units for medical use shall perform spot-checks of each remote afterloader facility and on each unit:
- i. Before the first use of a high dose-rate, medium dose-rate or pulsed dose-rate remote afterloader unit on a given day;
 - ii. Before each patient treatment with a low dose-rate remote afterloader unit; and
 - iii. After each source installation.
- b. A licensee shall perform the measurements required by G.643a. in accordance with written procedures established by the authorized medical physicist. The authorized medical physicist 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.643a., spot-checks shall, at a minimum, assure proper operation of:
- i. Electrical interlocks at each remote afterloader unit room entrance;
 - ii. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
 - iii. Viewing and intercom systems in each high dose-rate, medium dose-rate and pulsed dose-rate remote afterloader facility;
 - iv. Emergency response equipment;

- v. Radiation monitors used to indicate the source position;
 - vi. Timer accuracy;
 - vii. Clock (date and time) in the unit's computer; and
 - viii. Decayed source(s) activity in the unit's computer.
- e. If the results of the checks required in G.643d. 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.643d., and a copy of the procedures required by G.643b. in accordance with G.2643.

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:
- i. Monthly;
 - ii. Before the first use of the unit on a given day; and
 - iii. After each source installation.
- b. The licensee shall:
- i. Perform the measurements required by G.645a. in accordance with written procedures established by the authorized medical physicist. The authorized medical physicist need not actually perform the spot-check measurements.
 - ii. Have the authorized medical physicist review the results of each spot-check required by G.645a.i. 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.645a.i., spot-checks shall, at a minimum:
- i. Assure proper operation, if applicable, of:
 - (1) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;
 - (2) Helmet microswitches;
 - (3) Emergency timing circuits; and

- (4) Stereotactic frames and localizing devices (trunnions).
- ii. Determine :
 - (1) The output for one typical set of operating conditions measured with the dosimetry system described in G.630b.;
 - (2) The difference between the measurement made in G.645c.ii.(1) and the anticipated output, expressed as a percentage of the anticipated output or the value obtained at last full calibration corrected mathematically for physical decay;
 - (3) Source output against computer calculation;
 - (4) Timer accuracy and linearity over the range of use;
 - (5) On-off error; and
 - (6) Trunnion centricity.
- d. To satisfy the requirements of G.645a.ii. and G.645a.iii., spot-checks shall assure proper operation of:
 - i. Electrical interlocks at each gamma stereotactic radiosurgery room entrance;
 - ii. Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;
 - iii. Viewing and intercom systems;
 - iv. Timer termination;
 - v. Radiation monitors used to indicate room exposures; and
 - vi. Emergency off buttons.
- e. A licensee shall arrange for the repair of any system identified in G.645c. that is not operating properly as soon as possible.
- f. If the results of the checks required in G.645d. 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.645c. and G.645d. and a copy of the procedures requires by G.645b. in accordance with G.2645.

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

- a. A licensee providing mobile remote afterloader service shall:

- i. Check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and
 - ii. 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 shall be made to verify the operation of :
 - i. Electrical interlocks on treatment area access points;
 - ii. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
 - iii. Viewing and intercom systems;
 - iv. Applicators, source transfer tubes, and transfer tube-applicator interfaces;
 - v. Radiation monitors used to indicate room exposures;
 - vi. Source positioning (accuracy); and
 - vii. 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.647b., 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.647b. 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.647b. in accordance with G.2647.

Sec. G.652 - Radiation Surveys.

- a. In addition to the survey requirements in D.1501 of these regulations, a person licensed under G.600 through G.690 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.652a. 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.652a. in accordance with G.2652.

Sec. G.655 - Full-Inspection Servicing 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 to assure proper functioning of the source exposure mechanism and other safety components. The interval between each full-inspection servicing shall not exceed five years for each teletherapy unit and shall not exceed seven years for each gamma stereotactic radiosurgery unit.
- b. This inspection and servicing may only be performed by persons specifically licensed to do so by the Agency, an Agreement State, or the Nuclear Regulatory Commission.
- c. A licensee shall keep a record of the inspection and servicing in accordance with G.2655.

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 shall 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.

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 Agency, an Agreement State or the Nuclear Regulatory Commission. The names of board certifications that have been recognized by the Agency, the Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:
 - i. Successfully complete a minimum of three years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and

Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association; and

- ii. 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. i. Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes:
 - (1) 200 hours of classroom and laboratory training in the following areas:
 - (a) Radiation physics and instrumentation;
 - (b) Radiation protection;
 - (c) Mathematics pertaining to the use and measurement of radioactivity; and
 - (d) Radiation biology; and
 - ii. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in G.57, G.690, or equivalent Agreement State or Nuclear Regulatory Commission requirements at a medical facility that is authorized to use radioactive materials in § 35.600, involving:
 - (1) Reviewing full calibration measurements and periodic spot checks;
 - (2) Preparing treatment plans and calculating treatment doses and times;
 - (3) Using administrative controls to prevent a medical event involving the use of radioactive material;
 - (4) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;
 - (5) Checking and using survey meters; and
 - (6) Selecting the proper dose and how it is to be administered; and
 - iii. Has completed three years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in G.57, G.690 or equivalent Agreement State or Nuclear Regulatory requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work

experience required by G.690b.i.(2); and

- iv. Has obtained written attestation that the individual has satisfactorily completed the requirements in G.690b.i., G.690b.ii. and G.690c. and is able to independently fulfill the radiation safety-related duties as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The attestation must be obtained from either:
 - (1) A preceptor authorized user who meets the requirements in G.57, G.690, or equivalent Nuclear Regulatory Commission or Agreement State requirements for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status; or
 - (2) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in G.57, G.690, or equivalent Nuclear Regulatory Commission or Agreement State requirements, for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program shall be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and shall include training and experience specified in G.690b.i. and G.690b.ii.
- 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.

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 that is not specifically addressed in G.100 through G.690 if:

- a. The applicant or licensee has submitted the information required by G.12b., G.12c. and G.12d.; and
- b. The applicant or licensee has received written approval from the Agency, the NRC, or an Agreement State, in a license or license amendment and uses the material in accordance with the regulations and specific conditions the Agency, the NRC, or Agreement State, considers necessary for the medical use of the material.

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.24a. for five years. The record shall include a summary of the actions taken and a signature of licensee management.
- b. The licensee shall retain a current copy of both the authority, and the duties and responsibilities of the Radiation Safety Officer as required by G.24e., and a signed copy of each Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by G.24b. for the duration of the license. The record shall include the signature of the Radiation Safety Officer and licensee management.
- c. For each Associate Radiation Safety Officer appointed under G.24b., the licensee shall retain, for five years after the Associate Radiation Safety Officer is removed from the license, a copy of the written document appointing the Associate Radiation Safety Officer signed by the licensee's management.
- [d. The minutes of each Radiation Safety Committee meeting held in accordance with G.24i. shall include:
 - i. The date of the meeting;
 - ii. Members present;
 - iii. Members absent; and
 - iv. Summary of deliberations and discussions.]

Sec. G.2026 - Records of Radiation Protection Program Safety Changes. A licensee shall retain a record of each radiation protection program change made in accordance with G.26a. for five years. The record shall include a copy of the old and new procedures; the effective date of the change; and the signature of the licensee management that reviewed and approved the change.

Sec. G.2040 - Records of Written Directives. A licensee shall retain a copy of each written directive as required by G.40 for three 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.41a. for the duration of the license.

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 for three years. The records shall 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 Survey Instrument Calibrations. A licensee shall maintain a record of survey

instrument calibrations required by G.61 for three years. The record shall 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.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 three years.
- b. The record shall contain:
 - i. The radiopharmaceutical;
 - ii. The patient's or human research subject's name, or identification number if one has been assigned;
 - iii. The prescribed dosage; the determined dosage, or a notation that the total activity is less than 1.1 megabecquerel (30 μ Ci);
 - iv. The date and time of the dosage determination; and
 - v. The name of the individual who determined the dosage.

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.67b. for three years. The records shall 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.67g. for three years. The inventory record shall 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.

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 three years. The record shall 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.

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:
 - i. Using the retained activity rather than the activity administered;

- ii. Using an occupancy factor less than 0.25 at 1 meter;
 - iii. Using the biological or effective half-life; or
 - iv. Considering the shielding by tissue.
- b. A licensee shall retain a record that the instructions required by G.75b. were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 millisieverts (0.5 rem) [1 millisievert (0.1 rem)].
- c. The records required by G.2075a. and G.2075b. shall be retained for three years after the date of release of the individual.

Sec. G.2080 - Records of Mobile Services.

- a. A licensee shall retain a copy of each letter that permits the use of radioactive material at a client's address of use, as required by G.80a.i. Each letter shall clearly delineate the authority and responsibility of the licensee and the client and shall be retained for three years after the last provision of service.
- b. A licensee shall retain the record of each survey required by G.80a.iv for three years. The record shall 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.

Sec. G.2092 - Records of Decay-in-Storage. A licensee shall maintain records of the disposal of licensed materials, as required by G.92, for three years. The record shall include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.

Sec. G.2204 - Records of Molybdenum-99, Strontium-82, and Strontium-85 Concentrations. A licensee shall maintain a record of the molybdenum-99 concentration or strontium-82 and strontium-85 radionuclide concentration tests required by G.204b and G.204c for three years. The record shall include:

- a. For each measured elution of technetium-99m, the ratio of the measures expressed as kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (or microcuries of molybdenum per millicurie of technetium), the time and date of the measurement, and the name of the individual who made the measurement; or
- b. For each measured elution of rubidium-82, the ratio of the measures expressed as kilobecquerel of strontium-82 per megabecquerel of rubidium-82 (or microcuries of strontium-82 per millicurie of rubidium), kilobecquerel of strontium-85 per megabecquerel of rubidium-82 (or microcuries of strontium-85 per millicurie of rubidium), the time and date of the measurement, and the name of the individual who made the measurement.

Sec. G.2310 - Records of Safety Instruction. A licensee shall maintain a record of safety instructions required by G.310 and G.410 and the operational and safety instructions required by G.610 for three years. The record shall 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.

Sec. G.2404 - Records of Radiation Surveys After Source Implant and Removal. A licensee shall maintain a record of the surveys required by G.404 and G.604 for three years. Each record shall include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

Sec. G.2406 - Records of Brachytherapy Source Accountability.

- a. A licensee shall maintain a record of brachytherapy source accountability required by G.406 for three years.
- b. For temporary implants, the record shall include:
 - i. 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
 - ii. 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 shall include:
 - i. 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;
 - ii. 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
 - iii. The number and activity of sources permanently implanted in the patient or human research subject.

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 three years after the last use of the source.
- b. The record shall include:
 - i. The date of the calibration;
 - ii. The manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source;

- iii. The source output or activity;
- iv. The source positioning accuracy within the applicators; and
- v. 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. The 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 shall include:
 - i. The date and initial activity of the source as determined under G.432; and
 - ii. For each decay calculation, the date, and the source activity as determined under G.433.

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 three years. For each installation, maintenance, adjustment and repair, the record shall include the date, description of the service, and name(s) of the individual(s) who performed the work.

Sec. G.2610 - Records of Safety Procedures. A licensee shall retain a copy of the procedures required by G.610a.iv and G.610d.ii until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.

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 shall include:
 - i. The date;
 - ii. The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by G.630a. and G.630b.;
 - iii. The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and
 - iv. The names of the individuals who performed the calibration, intercomparison, or comparison.

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

- a. A licensee shall maintain a record of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations required by G.632, G.633 and G.635 for three years.
- b. The record shall include:
 - i. The date of the calibration;
 - ii. The manufacturer's name, model number, and serial number for the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit(s), the source(s), and instruments used to calibrate the unit;
 - iii. The results and assessments of the full calibrations;
 - iv. The results of the autoradiograph required for low dose-rate remote afterloader units; and
 - v. The signature of the authorized medical physicist who performed the full calibration.

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 three years.
- b. The record shall include:
 - i. The date of the spot-check;
 - ii. The manufacturer's name, model number, and serial number for the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;
 - iii. An assessment of timer linearity and constancy;
 - iv. The calculated on-off error;
 - v. A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;
 - vi. The determined accuracy of each distance measuring and localization device;
 - vii. The difference between the anticipated output and the measured output;
 - viii. 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

- ix. 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.642b. 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 three years.
- b. The record shall include, as applicable:
 - i. The date of the spot-check;
 - ii. The manufacturer's name, model number, and serial number for the remote afterloader unit and source;
 - iii. An assessment of timer accuracy;
 - iv. 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
 - v. 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.643b. until the licensee no longer possesses the remote afterloader unit.

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 three years.
- b. The record shall include:
 - i. The date of the spot-check;
 - ii. 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;
 - iii. An assessment of timer linearity and accuracy;
 - iv. The calculated on-off error;

- v. A determination of trunnion centricity;
 - vi. The difference between the anticipated output and the measured output;
 - vii. An assessment of source output against computer calculations;
 - viii. 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
 - ix. 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.645b until the licensee no longer possesses the gamma stereotactic radiosurgery unit.

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 three years.
- b. The record shall include:
 - i. The date of the check;
 - ii. The manufacturer's name, model number, and serial number of the remote afterloader unit;
 - iii. Notations accounting for all sources before the licensee departs from a facility;
 - iv. Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators, source transfer tubes, transfer tube applicator interfaces, and source positioning accuracy; and
 - v. The signature of the individual who performed the check.

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 shall include:
 - i. The date of the measurements;

- ii. The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;
- iii. Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and
- iv. The signature of the individual who performed the test.

Sec. G.2655 - Records of Full Inspection Servicing for Teletherapy and Gamma Stereotactic Surgery Units.

- a. A licensee shall maintain a record of the full inspection servicing for teletherapy and gamma stereotactic radiosurgery units required by G.655 for the duration of use of the unit.
- b. The record shall contain:
 - i. The inspector's radioactive materials license number;
 - ii. The date of inspection;
 - iii. The manufacturer's name and model number and serial number of both the treatment unit and source;
 - iv. A list of components inspected and serviced, and the type of service; and
 - v. The signature of the inspector.

Reports

Sec.G.3045 - Reports and Notifications of a Medical Event.

- a. A licensee shall report any event as a medical event, except for an event that results from patient intervention, in which:
 - i. The administration of radioactive material or radiation from radioactive material, except permanent implant brachytherapy, results in:
 - (1) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sievert (5 rem) effective dose equivalent, 0.5 Sievert (50 rem) to an organ or tissue, or 0.5 Sievert (50 rem) shallow dose equivalent to the skin; and
 - (a) The total dose delivered differs from the prescribed dose by 20 percent or more;
 - (b) The total dosage delivered differs from the prescribed dosage by 20

- percent or more or falls outside the prescribed dosage range; or
- (c) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.
- (2) A dose that exceeds 0.05 Sievert (5 rem) effective dose equivalent, 0.5 Sievert (50 rem) to an organ or tissue, or 0.5 Sievert (50 rem) shallow dose equivalent to the skin from any of the following:
 - (a) An administration of a wrong radioactive drug containing radioactive material or the wrong radionuclide for a brachytherapy procedure;
 - (b) An administration of a radioactive drug containing radioactive material by the wrong route of administration;
 - (c) An administration of a dose or dosage to the wrong individual or human research subject;
 - (d) An administration of a dose or dosage delivered by the wrong mode of treatment; or
 - (e) A leaking sealed source.
 - (3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by:
 - (a) 0.5 Sievert (50 rem) or more of the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and
 - (b) 50 percent or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.
- ii. For permanent implant brachytherapy, the administration of radioactive material or radiation from radioactive material, excluding sources that were implanted in the correct site but migrated outside the treatment site, that results in:
- (1) The total source strength administered outside of the treatment site differing by 20 percent or more from the total source strength documented in the post-implantation portion of the written directive; or
 - (2) The total source strength administered outside of the treatment site exceeding 20 percent of the total source strength documented in the post-implantation portion of the written directive; or
 - (3) An administration that includes any of the following:

- (a) The wrong radionuclide;
 - (b) The wrong individual or human research subject;
 - (c) Sealed source(s) implanted directly into a location discontinuous from the treatment site, as documented in the post-implantation portion of the written directive; or
 - (d) A leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue.
- b. A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results, or will result in, unintended permanent functional damage to an organ or a physiological system, as determined by a physician.
- c. The licensee shall notify the Agency by telephone no later than the next calendar day after discovery of the medical event.^{5/}
- d. The licensee shall submit a written report to the Agency within 15 days after discovery of the medical event.
- i. The written report shall include:
 - (1) The licensee's name;
 - (2) The name of the prescribing physician;
 - (3) A brief description of the event;
 - (4) Why the event occurred;
 - (5) The effect, if any, on the individual(s) who received the administration;
 - (6) What actions, if any, have been taken, or are planned, to prevent recurrence; and
 - (7) Certification that the licensee notified the individual or the individual's responsible relative or guardian, and if not, why not.
 - ii. The report may not contain the individual's name or any other information that could lead to identification of the individual.
- e. The licensee shall provide notification of the medical event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its

^{5/} The Agency's telephone number is (XXX) XXX-XXXX

discovery, unless the referring physician personally informs the licensee either that they will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

- f. Aside from the notification requirement, nothing in G.3045 affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.
- g. A licensee shall:
 - i. Annotate a copy of the report provided to the Agency with the:
 - (1) Name of the individual who is the subject of the event; and
 - (2) Identification number or if no other identification number is available, the social security number of the individual who is the subject of the event; and
 - ii. Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

Sec. G.3047 - Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child.

- a. A licensee shall report any dose to an embryo/fetus that is greater than 50 mSv (5 rem) [5 millisievert (500 mrem)] dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.
- b. A licensee shall report any dose to a nursing child, that was not specifically approved, in advance, by the authorized user, that is a result of an administration of radioactive material to a breast feeding individual that:
 - i. Is greater than 50 mSv (5 rem) [5 millisievert (500 mrem)] total effective dose equivalent; or
 - ii. Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.
- c. The licensee shall notify by telephone the Agency no later than the next calendar day after

discovery of a dose to the embryo/fetus or nursing child that requires a report in G.3047a. or G.3047b.

- d. The licensee shall submit a written report to the Agency within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in G.3047a. or G.3047b.
 - i. The written report shall include:
 - (1) The licensee's name;
 - (2) The name of the prescribing physician
 - (3) A brief description of the event;
 - (4) Why the event occurred;
 - (5) The effect on the embryo/fetus or the nursing child;
 - (6) What actions, if any, have been taken, or are planned, to prevent recurrence; and
 - (7) Certification that the licensee notified the pregnant individual or mother or the mother's or child's responsible relative or guardian, and if not, why not.
 - ii. The report shall not contain the individual's or child's name or any other information that could lead to identification of the individual or child.
- e. The licensee shall notify the referring physician of the event and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under G.3047a. or G.3047b., unless the referring physician personally informs the licensee either that they will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of G.3047e., the notification may be made to the mother's or child's responsible relative or guardian instead of the mother, when appropriate. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.
- f. A licensee shall:
 - i. Annotate a copy of the report provided to the Agency with the:
 - (1) Name of the pregnant individual or the nursing child who is the subject of the

event; and

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

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

[g. A licensee shall retain a record of a dose to an embryo/fetus or a nursing child reported in accordance with G.3047d. for three years. The licensee's records shall include the information reported in accordance with G.3047d. and a copy of the annotated report made in accordance with G.3047f.i.]

Sec. G.3067 - Reports of Leaking Sources. A licensee shall file a report with the Agency within five days if a leakage test required by G.67 reveals the presence of 185 becquerel (0.005 μCi) or more of removable contamination. The written report shall include the model number and serial number if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken.

Sec. 3204 - Report and notification for an eluate exceeding permissible molybdenum-99, strontium-82, and strontium-85 concentrations.

- a. The licensee shall notify by telephone the Agency and the distributor of the generator within seven calendar days after discovery that an eluate exceeded the permissible concentration listed in Part G.204a. of these regulations at the time of generator elution. The telephone report to the Agency shall include the manufacturer, model number, and serial number or lot number of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects, when the distributor was notified, and the action taken.
- b. By an appropriate method listed in A.12 of these regulations, the licensee shall submit a written report to the Agency within 30 calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report shall include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; and the probable cause and an assessment of failure in the licensee's equipment, procedures or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination; and the information in the telephone report as required by G.3204a.

2023 Rationale

PART G

USE OF RADIONUCLIDES IN THE HEALING ARTS

Introduction.

Part G was modified in its entirety in the 2023 version to update Part G with all modifications to 10 CFR Part 35 made by the U.S. Nuclear Regulatory Commission (NRC) through December 31, 2022 (NRC RATS #2022-2). The purpose of the revision was to update Part G to meet the compatibility requirements of the NRC. All sections in Part G contain some modifications.

As in other parts of the SSRs, requirements or wording contained within brackets are optional to adopt and are not required to meet NRC compatibility requirements; however, the adoption of bracketed requirements or wording is recommended to enhance the health and safety protections of NRC requirements.

In addition to updating Part G requirements to meet NRC's compatibility requirements, a major revision to Part G was to reformat the Part in its entirety to make it easier to find corresponding requirements for 10 CFR Part 35 in Part G. Over the years many individuals have commented that it would be easier to compare Part G with 10 CFR Part 35 if both documents followed the same numbering format. To address this comment, the Committee decided to reformat Part G to follow the format used by the U.S. Nuclear Regulatory Commission (NRC) in 10 CFR Part 35 as closely as possible. This required the repositioning of some Part G sections and some requirements contained in within sections of Part G to parallel their locations within the corresponding 10 CFR Part 35 sections. Additionally, some Part G sections were combined which required repositioning of combined sections to correspond to the locations of the section's 10 CFR Part 35 counterpart and the removal of the Part G sections replaced by the combined section.

References to requirements in other Parts of the SSRs were updated to reflect the current reference locations. During the review, it was noted that substitutions made in Part G to replace the 10 CFR Part 35 references to "regulations of this chapter" or similar phrases were incorrect. "Part G" was commonly used to substitute for the references to "regulations of this chapter" or similar phrases. In these cases, "chapter" refers to NRC's Chapter I (Parts 1-199). The Committee determined that this was an incorrect substitution since by using only "Part G" as the substitution, effectively, the regulations in 10 CFR Part 35 were being used to replace all of the regulations found in 10 CFR Part 1 through Part 199. This changed the meaning of the requirement by requiring the licensee to comply only with the regulations in Part G and not the additional requirements found in the SSR equivalents to Parts 1 through include leaving out all regulations other than those found in 10 CFR Part 35. To correct this issue, in instances where NRC's Chapter I is referenced, the Committee substituted, "requirements applicable to licensed radioactive materials found in Parts A through Z of these regulations" instead of using "Part G."

This modification requires licensees to comply with all applicable requirements found in the SSRs which meets the intent of the NRC's references to "regulations of this chapter" or similar wording.

Specific Provisions.

As stated above, all sections in Part G contain some modifications. To further address the reformatting of Part G, all Sections were renumbered to reflect their 10 CFR Part 35 section counterparts. Other than simple renumbering and text changes, the following specific changes were made for the reasons noted:

Section G.9. - Mobile Medical Service Administrative Requirements. was combined with Section G.41 - Mobile Medical Service Technical Requirements. to create Section G.80 - Provision of Mobile Medical Service. The requirements were relocated within G.80 to allow the numbering format from 10 CFR Part 35 to be maintained.

Section G.20 - Duties of Authorized Users and Authorized Medical Physicists. Although there are no equivalent NRC requirements for the requirements in this section, the requirements were maintained, renumbered as G.30, and moved to the proper location within Part G

Section G.28 - Training and Technical Requirements for Nuclear Medicine Technologists and Radiation Therapists. was removed from Part G. This information is now addressed in Part Z - Medical Credentialing.; therefore, this section was removed from Part G.

Section G.31 - Quality Control of Diagnostic Equipment. was maintained, renumbered Section G.62 - Quality Control of Diagnostic Equipment., and moved to the proper location within Part G.

Section G.37 - Labels. was combined with Section G.38 - Vial Shields and renumbered as Section G.69 - Labeling and Shielding of Vials and Syringes. and moved to the proper location within Part G.

Section G.42 - Storage and Control of Volatiles and Gases. was maintained, renumbered as Section G.85 - Storage and Control of Volatiles and Gases., and moved to the proper location within Part G.

Section G.122 - Reports of Patient Departure Prior to Authorized Release.

Section G.122 was reviewed and the requirements within the section were found to be unnecessary. If patients treated with radioactive materials leave the licensee's facility before released in accordance with G.75, Agency personnel have no authority to obtain patient information, locate patients, and require patients to return to the licensee's facility or otherwise restrict patients. Therefore, the Committee determined that although a report could be made, since no actions could be taken by Agency personnel as a result of the report, the requirements to report these instances are not necessary and were removed.

Section G.123 - Notification of Deceased Patients or Human Research Subjects Containing Radioactive Material.

Section G.123 was reviewed and the requirements in this section, like those in Section G.122, were determined to be unnecessary. If a licensee is required to report death patients treated using radioactive materials, what actions would Agency personnel take with that information? The decedents would be under the control of the licensee if not released from the licensee's facility in accordance with the requirements in G.75 and the licensee would be required to take appropriate actions regarding exposures to employees and members of the public. If the decedent was released in accordance with G.75 prior to death, the licensee may not be informed that the patient died if the physician treating the decedent was not an Authorized User (AU) at the licensee's facility. Even if the decedent was treated by an AU at the licensee's facility and the death was reported to the licensee, if the decedent was released in accordance with requirements in G.75 prior to death, neither licensee nor Agency personnel would have the authority to require the decedent's body to be returned to the licensee's facility to be held until radioactive materials decay further. Therefore, the Committee determined that although a report could be made, since no actions could be taken by Agency personnel as a result of the report, the requirements to report these instances are not necessary and were removed.

Section G.3047 - Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child.

The rules in Section G.3047 (corresponding to 10 CFR 35.3047) describe the record and reporting requirements for licensees should an embryo/fetus or nursing child receive a dose equivalent greater than 50 millisievert (5 rem). The NRC included this provision to reduce the number of reports that licensees must submit as result of a nursing child exceeding dose limits specified in 10 CFR Part 20 (5 millisieverts or 500 mrem) when a nursing individual receives a diagnostic dosage, and to include embryo/fetuses in the reporting requirements. NRC's rule does not specifically approve doses of 5 rem TEDE to an embryo/fetus or nursing infant and is not intended to be an exception to Part 20 dose limits.

Embryos and fetuses are not considered members of the public. Therefore, except for dose limits specified for embryos/fetuses of a declared pregnant woman, there are no dose limits specified in NRC requirements for embryos/fetuses. The dose limit for an embryo/fetus of a declared pregnant woman is specified in 10 CFR 20.1208 and is 5 millisieverts (500 mrem) to the embryo/fetus over the entire term of the pregnancy. Because there is no dose limit specified for an embryo/fetus of a non-occupationally exposed woman, the dose limit has effectively been set at the reporting requirement set in 10 CFR 35.3047 which is 50 millisievert or 5000 mrem. Unfortunately, this exception to the reporting requirements also appears to give tacit approval for such exposures to nursing children. The NRC requirements in 10 CFR 35.3047 appear to add to the confusing collection of dose limits and reporting requirements specified in 10 CFR Part 20.

While the committee agrees, in part, with the intent of this rule, the members of the Committee believe that accidental exposures above 5 millisievert (500 mrem) to an embryo/fetus or nursing child should be reported. The radiosensitivity of the embryo/fetus or developing child warrants the use of lower dose reporting limit requirements. Therefore, the Committee recommends adopting the bracketed level of 5 millisievert (500 mrem) in these requirements.

The NRC designated 10 CFR 35.3047 as a compatibility category C; therefore, Agreement States can be more restrictive than the NRC. The Committee included rule G.3047, but has included a lowered reporting level of 5 millisievert (500 mrem) in brackets. Doses exceeding 5 millisievert (500 mrem) to a nursing child should not occur if the patient is properly questioned and instructed. It should be noted that Part D rules allow a trained authorized user to knowingly approve any amount of exposure to the embryo/fetus if, through the use of their medical and radiation safety knowledge, they decide the risk is justified.

The following sections were determined to be redundant and were deleted from Part G:

Section G.45 - Possession of Survey Instruments.;

Section G.50 - Possession of Survey Instruments.;

Section G.55 - Possession of Survey Instruments.;

Section G.66 - Possession of Survey Instruments.;

Section G.87 - Possession of Survey Instruments.

Matters for Future Consideration:

1. From January 1, 2020 through December 31, 2022, the requirements in 10 CFR Part 35 were modified a number of times. The modifications were both substantive and non-substantive in nature. There are a number of changes to 10 CFR Part 35 presently under consideration by the NRC. Inevitably, 10 CFR Part 35 will be modified a number of times in the next few years and consideration will need to be given to when Part G should be opened to address the resulting changes.
2. Given the length of time that it takes the NRC to write specific requirements for emerging technologies. Consideration should be given to creating specific requirements for some of the emerging technologies that have been in use for quite some time, but are still addressed through the use of license guidance documents and the addition of specific license conditions. Since these technologies have not been addressed by NRC in rulemaking, this should not cause an issue with compatibility with NRC requirements.