PART G

MEDICAL USE OF RADIOACTIVE MATERIAL

SUBPART A – GENERAL INFORMATION

1. **Purpose and Scope.** This part contains the requirements and provisions for the medical use of radioactive material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects. The requirements and provisions of this part are in addition to, and not in substitution for, others in these regulations. The requirements and provisions of these regulations apply to applicants and licensees subject to this part unless specifically exempted.

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

Authorized Medical Physicist means an individual who --

(1) Meets the requirements in G.51.A and G.59; or

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

(a) A specific medical use license or equivalent permit issued by the Agency, the Nuclear Regulatory Commission or an Agreement State;

(b) A medical use permit issued by a Nuclear Regulatory Commission master material licensee;

(c) A permit issued by an Agency, Nuclear Regulatory Commission or an Agreement State broad scope medical use licensee; or

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

Authorized Nuclear Pharmacist means a pharmacist who --

(1) Meets the requirements in G.55.A and G.59; or

(2) Is identified as an authorized nuclear pharmacist on --

(a) A specific license or equivalent permit issued by the Agency, the Nuclear Regulatory Commission or an Agreement State, that authorizes medical use or the practice of nuclear pharmacy;

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

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

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

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

(4) Is designated as an authorized nuclear pharmacist in accordance with Part C.11.I(2)(d).

Authorized User means a physician, dentist, or podiatrist who --

(1) Meets the requirements in G.59 and G.190, G.290, G.390, G.392.A., G.394.A, G.490, G.590, G.690 or G.790; or

(2) Is identified as an authorized user on --

(a) An Agency, Nuclear Regulatory Commission or an Agreement State license that authorizes the medical use of radioactive material;

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

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

(d) A permit issued by a Nuclear Regulatory Commission master material licensee broad scope permittee that is authorized to permit the medical use of radioactive material.

Black Box means the radiopharmaceutical production purification system used in a Cyclotron/PET facility.

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

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

Client's Address means the area of use or a temporary job site for the purpose of providing mobile nuclear medicine services in accordance with G.31.

High Dose-Rate Remote Afterloader, as used in this part, means a device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the treatment site.

Low Dose-Rate Remote Afterloader, as used in this part, means a device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the treatment site.

Manual Brachytherapy as used in this part, means a type of therapy in which brachytherapy sources (e.g., seeds, ribbons) are manually applied or inserted.

Medical Event means an event that meets the criteria in G.3045.

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 there from, to patients or human research subjects under the supervision of an authorized user.

Medium Dose-Rate Remote Afterloader, as used in this part, means a brachytherapy device that remotely delivers a dose rate of greater than 2 gray (200 rads), but less than 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

Mobile Nuclear Medicine Service means the transportation of radioactive material to and its medical use at the client's address.

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

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

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

Prescribed Dosage means the specified activity or range of activity of unsealed radioactive material as documented --

(1) In a written directive as specified in G.40; or

(2) In accordance with the directions of the authorized user for procedures performed pursuant to G.100, G.200, and G.300.

Prescribed Dose means --

(1) For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

(2) For teletherapy, the total dose and dose per fraction as documented in the written directive;

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

(4) For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

Pulsed Dose-Rate Remote Afterloader, as used in this part, 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 --

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

(2) Is used to simulate the radiobiology of a low dose-rate treatment by inserting the source for a given fraction of each hour.

Radiation Safety Officer for Medical Use means an individual who --

(1) Meets the requirements in G.50.A and G.59*;* or

(2) Is identified as a Radiation Safety Officer on –

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

(b) A medical use permit issued by a Nuclear Regulatory Commission master material licensee.

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

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

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.

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 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 under G.100, G.200, G.300, G.400, G.500, G.600, or G.1000.

Unit Dosage means a dosage that:

(1) is obtained and prepared in accordance with the regulations for uses described in G.100, G.200, G.300, G.400, G.500, G.600, and G.1000; and

(2) is 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.15.

5. **Maintenance of Records.** Each record required by this part must be legible throughout the specified 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 is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

6. **Provisions for the Protection of Human Research Subjects.**

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

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

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

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

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

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

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

   D. Nothing in this section relieves licensees from complying with the other requirements in this part.

7. **[reserved.]**

8. **[reserved.]**

9. **[reserved.]**

10. **Implementation.**

    A. A licensee shall implement the provisions in this part on the effective date of these rules.

    B. When a requirement in Part G differs from the requirement in an existing license condition, the requirement in this part shall govern.

    C. Any existing license condition that is not affected by a requirement in Part G remains in effect until there is a license amendment or renewal.

    D. If a license condition exempted a licensee from a provision in Part G on June 1, 2003, it will continue to exempt a licensee from the corresponding provision in Part G.

    E. If a license condition cites provisions in Part G that will be deleted on the effective date of these rules, then the license condition remains in effect until other is a license amendment or license renewal that modifies or removes the condition.

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.

11. License Required.

A. A person may manufacture, produce, acquire, receive, possess, prepare, use, or transfer radioactive material for medical use only in accordance with a specific license issued pursuant to these regulations.

B. A specific license is not needed for an individual who --

(1) Receives, possesses, uses, or transfer radioactive material in accordance with the regulations in this part under the supervision of an authorized user as provided in G.27, unless prohibited by license condition; or

(2) Prepares unsealed radioactive material for medical use in accordance with these regulations under the supervision of an authorized nuclear pharmacist or authorized user as provided in G.27, unless prohibited by license condition.

12. Application for License, Amendment, or Renewal.

A. An application must 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, and G.1000 must be made by --

(1) Filing the appropriate HHE Form 850, "Application for Radioactive Material License" that includes the facility diagram, equipment, and training and experience qualifications of the Radiation Safety Officer, authorized user(s), authorized medical physicist(s), and authorized nuclear pharmacist(s); and

(2) Submitting procedures required by G.610, G.642, G.643 and G.645, as applicable.

C. A request for a license amendment, or renewal must be made by --

(1) Submitting either the appropriate HHE Form 850, "Application for a Radioactive Material License" or a letter requesting the amendment; and

(2) Submitting procedures required by G.610, G.642, G.643, and G.645, as applicable.

D. In addition to the requirements in G.12.A, G.12.B and G.12.C, an application for a license or amendment for medical use of radioactive material as described in G.1000 must also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in Subparts A through C of Part G.

(1) The applicant shall also provide specific information on --

(a) Radiation safety precautions and instructions;

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

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

(2) The applicant or licensee shall also provide any other information requested by the Agency in its review of the application.

E. An applicant that satisfies the requirements specified in Part C.10.B may apply for a Type A specific license of broad scope.

13. License Amendments. A licensee shall apply for and must receive a license amendment --

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

B. Before it permits anyone to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license, except --

(1) For an authorized user, an individual who meets the requirements in G.190.A, G.290.A, G.390.A, G.392.A, G.394.A, G.490.A, G.590.A, G.690.A, G.690.B., and G.59;

(2) For an authorized nuclear pharmacist, an individual who meets the requirements in G.55.A and G.59;

(3) For an authorized medical physicist, an individual who meets the requirements in G.51.A and G.59;

(4) An individual who is identified as an authorized user, an authorized nuclear pharmacist, or authorized medical physicist --

(a) On an Agency, 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;

(b) On a permit issued by an Agency, Nuclear Regulatory Commission, or an Agreement State specific license of broad scope that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy;

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

(d) 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.24.C;

D. 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;

E. Before it adds to or changes the areas of use identified in the application or on the license, except for areas of use where radioactive material is used only in accordance with either G.100 or G.200;

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

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

H. Before it releases licensed facilities for unrestricted use.

14. Notifications.

A. A licensee shall provide the Agency a copy of the board certification and the Agency, Nuclear Regulatory Commission, or an Agreement State license for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist, under G.7.B(1) through G.7.B(4).

B. A licensee shall notify the Agency by letter no later than 30 days after:

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

(2) The licensee's mailing address changes;

(3) The licensee's name changes, but the name change does not constitute a transfer of control of the license; or

(4) The licensee has added to or changed the areas of use as identified in the application or on the license where radioactive material is used in accordance with either G.100 or G.200.

C. The licensee shall mail the documents required in this section to: Radiation Control Program, Division of Environmental Health, 11 State House Station, Augusta, ME, 04333-0011.

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

A. The provisions of G.12.C regarding the need to file an amendment to the license for medical use of radioactive material, as described in G.1000;

B. The provisions of G.13.B;

C. The provisions of G.13.E 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.14.A;

E. The provisions of G.14.B.1 for an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist;

F. The provisions of G.14.B.4 regarding additions to or changes in the areas of use identified in the application or on the license where radioactive material is used in accordance with G.100 or G.200; and

G. The provisions of G.49.A.

16. [reserved.]

17. [reserved.]

18. License Issuance.

A. The Agency shall issue a license for the medical use of radioactive material if --

(1) The applicant has filed HHE Form 850 "Application for a Radioactive Material License" in accordance with the instructions in G.12*;*

(2) The applicant has paid any applicable fee as provided in Part C;

(3) The Agency finds the applicant equipped and committed to observe the safety standards established by the Agency in these regulations for the protection of the public health and safety; and

(4) The applicant meets the requirements of Part C.

B. The Agency shall issue a license for mobile nuclear medicine service if the applicant:

(1) Meets the requirements in G.18.A; and

(2) 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.

19. Specific Exemptions. The Agency may, upon application of any interested person or upon its own initiative, grant exemptions from the regulations in this part that it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

SUBPART B -- GENERAL ADMINISTRATIVE REQUIREMENTS

24. Authority and Responsibilities for the Radiation Protection Program

A. In addition to the radiation protection program requirements of Part D, a licensee's management shall approve in writing --

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

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

(3) 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.

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

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

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

F. Licensees that are authorized for two or more different types of uses of radioactive material under Subparts E, F, and H of Part G, or two or more types of units under Subpart H of Part G, shall establish a Radiation Safety Committee to oversee all uses of radioactive material permitted by the license.

(1) The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. The Committee may include other members the licensee considers appropriate.

(2) A licensee's Radiation Safety Committee shall meet as necessary, but at a minimum shall meet at intervals not to exceed 12 months. The licensee shall maintain minutes of each meeting in accordance with G.2024.

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

(1) Identify radiation safety problems;

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

(3) Stop unsafe operations; and,

(4) Verify implementation of corrective actions.

H. A licensee shall retain a record of actions taken under G.24.A, G.24.B, and G.24.E in accordance with G.2024.

26. Radiation Protection Program Changes.

A. A licensee may revise its radiation protection program without Agency approval if --

(1) The revision does not require a license amendment under G.13;

(2) The revision is in compliance with the regulations and the license;

(3) The revision has been reviewed and approved by the Radiation Safety Officer, licensee management, and the Radiation Safety Committee (if applicable); and

(4) 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.

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.11.B(1) shall --

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

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

B. A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by G.11.B(2), shall --

(1) In addition to the requirements in Part J, instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and

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

C. Unless physical presence as described in other sections of Part G is required, a licensee who permits supervised activities under G.21 A. and G.27 B. shall require an authorized user to be immediately available to communicate with the supervised individual, and able to be physically present within three hours of notification; and

D. A licensee that permits supervised activities under G.27.A and G.27.B is responsible for the acts and omissions of the supervised individual.

28. Duties of Authorized User and Authorized Medical Physicist

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

(1) Prescribe the radiopharmaceutical dosage and/or dose to be administered through the issuance of a written directive or reference to the diagnostic clinical procedures manual; and

(2) 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;

(3) Prepare and administer, or supervise the preparation and administration of radioactive material for medical use, in accordance with G.11.B. and G11.C. and G.27;

(4) Perform the final interpretation of the results of tests, studies, or treatments

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

(1) Full calibration measurements as described in G.632, G.633, and G.635s;

(2) Periodic spot checks as described in G.642, G643, and G.645; and

(3) Radiation surveys as described in G.652.

29-39. [reserved.]

40. Written Directives.

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

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

B. The written directive must contain the patient or human research subject's name and the following information --

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

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

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

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

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

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

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

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

C. 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.

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

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

41. Procedures for Administrations Requiring a Written Directive.

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

(1) The patient's or human research subject's identity is verified before each administration; and

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

B. At a minimum, the procedures required by G.41.A must address the following items that are applicable to the licensee's use of radioactive material --

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

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

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

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

C. A licensee shall retain a copy of the procedures required under G.41.A in accordance with G.2041.

49. Suppliers for Radioactive Material, Sealed Sources or Devices for Medical Use. For medical use, a licensee may only use --

A. Radioactive material, sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to these regulations or the equivalent regulations of the NRC or an Agreement State.

B. Reagent kits that have been manufactured, labeled, packaged, and distributed in accordance with an approval issued by the U.S. Department of Health and Human Services, Food and Drug Administration.

C. Sealed sources or devices non-commercially transferred from a Part G licensee; or

D. Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to these regulations, or the equivalent regulations of the NRC or an Agreement State.

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

A. Is certified by a specialty board whose certification process includes all of the requirements in G.50.D and E. and whose certification has been recognized by the Agency, the Nuclear Regulatory Commission, or an Agreement State, and who meets the requirements in paragraphs D and E of this section. (Specialty Boards whose certification processes have been recognized by the Agency, the NRC or an Agreement State will be posted on the NRC's web page.) To be recognized, a specialty board shall require all candidates for certification to:

(1) (a) 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;

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

(c) Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

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

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

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

(ii) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the definition of an authorized user in Part A.2 or who meet the requirements for authorized users in G.57, G.290, or G.390; and

(c) Pass an examination, administered by diplomates of the specialty board that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

B. Has completed a structured educational program consisting of both:

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

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

(d) Radiation biology;

(e) Radiation dosimetry; and

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

C. (1) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Agency, the NRC, or an Agreement State under G.51.A. and has experience in radiation safety for similar types of use of radioactive material for which the licensee is seeking approval of the individual as Radiation Safety Officer, and who meets the requirements in paragraphs G.50.D and G.50.E; or

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

D. Has obtained written attestation, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in paragraph G.50.E and in paragraphs G.50.A(1)(a) and A(1)(b) or 50.A.(2)(a) and A.(2)(b) or G.50.B(1) or G.50.C(1) or G.50.C(2) and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; and

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

51. Training for an Authorized Medical Physicist. Except as provided in G.57, the licensee shall require the authorized medical physicist to be an individual who --

A. Is certified by a specialty board whose certification process includes all of the training and experience requirements in G.51.B and whose certification has been recognized by the Agency, the Nuclear Regulatory Commission, or an Agreement State and who meets the requirements in paragraphs G.51.B(2) and G.51.C. (The names of board certifications which have been recognized by the Agency, the NRC, or an Agreement State, will be posted on the NRC's web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

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

(2) Have two years of full-time practicable 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 NRC, or an Agreement State, or

(b) In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the definition of an authorized user in Part A.2 or who meet the requirements for authorized users in G.57, G.490 or G.690; and

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

B. (1) 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; and has completed 1 year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization. The training and work experience must be conducted in clinical radiation facilities that provide high energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services and must include:

(a) Performing sealed source leak tests and inventories;

(b) Performing decay corrections;

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

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

(2) Have obtained written certification that the individual has satisfactorily completed the requirements in G.51.C and G.51.A(1) and G.51.A(2) or G.51.B(1) and G.51.C and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written certification must 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; and

C. In addition to meeting requirements in G.57, have 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 of by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

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 as a nuclear pharmacist by a specialty board whose certification process includes all of the requirements in G.55.B and whose certification has been recognized by the Agency, the Nuclear Regulatory Commission, or an Agreement State and who meets the requirements in paragraph B.(2) of this section. (The names of board certifications which have been recognized by the Agency, the NRC, or an Agreement State will be posted on the NRC's web page.) To be recognized, a specialty board shall require all candidates for certification to:

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

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

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

(4) Pass an examination in nuclear pharmacy administered by diplomates of the specialty board, which assesses knowledge and competency in procurement compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or

B. (1) Has completed 700 hours in a structured educational program consisting of both:

(a) 200 hours of classroom and laboratory training in the following areas --

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

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

(v) Radiation biology; and

(b) Supervised practical experience in a nuclear pharmacy involving --

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

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

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

(iv) Using administrative controls to avoid medical events in the administration of radioactive material; and

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

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

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

A. (1) An individual identified as a Radiation Safety Officer, a teletherapy or medical physicist, or a nuclear pharmacist on an Agency, Nuclear Regulatory Commission, or an Agreement State license or a permit issued by a Nuclear Regulatory Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope before October 24, 2002 need not comply with the training requirements of G.50, G.51, or G.55, respectively.

(2) A Radiation Safety Officer, a medical physicist, or a nuclear pharmacist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses or in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the Agency, need not comply with the training requirements of G.50, G.51 or G.55, respectively, when performing the same uses. A nuclear pharmacist, who prepared only radioactive drugs containing accelerator-produced radioactive materials, or a medical physicist, who used only accelerator-produced radioactive materials, at the locations and time period identified in this paragraph, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates.

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

B. (1) Physicians, dentists, or podiatrists 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 a Nuclear Regulatory Commission or Agreement State broad scope licensee, or a permit issued by a Nuclear Regulatory Commission master material license broad scope permittee before December 1, 2003, who perform only those medical uses for which they were authorized on that date, need not comply with the training requirements of Subparts D through H of Part G.

(2) Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the Agency, the NRC, or Agreement State, a permit issued by a NRC master material licensee, a permit issued by a Agency, NRC, or Agreement State broad scope licensee, or a permit issued by a NRC master material license broad scope licensee, or a permit issued by a NRC master material license broad scope permittee who perform only those medical uses for which they were authorized between October 24, 2002 and April 29, 2005, need not comply with the training requirements of Subparts D through H of Part G.

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

C. Individuals who need not comply with the training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on an Agency, an Agreement State or NRC licenses for the same uses for which these individuals are authorized.

59. Recentness of Training. The training and experience specified in Subparts B, D, E, F, G, and H, of Part G must have been obtained within the 7 years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

SUBPART C -- GENERAL TECHNICAL REQUIREMENTS

60. Possession, Use, and Calibration of Instruments Used To Measure the Activity of Unsealed Radioactive Material.

A. For direct measurements performed in accordance with G.60, a licensee shall possess and use instrumentation to measure the activity of unsealed radioactive material before it is administered to each patient or human research subject.

B. A licensee shall calibrate the instrumentation required in G.60.A in accordance with nationally recognized standards or the manufacturer's instructions.

C. The tests shall at a minimum include tests for constancy, linearity, accuracy and geometry dependence, as appropriate to demonstrate proper operation of the instrument.

D. A licensee shall retain a record of each instrument calibration required by this section in accordance with G.2060.

61. Calibration of Survey Instruments.

A. A licensee shall calibrate the survey instruments used to show compliance with this Part and Part D before first use, annually, and following a repair that affects the calibration. A licensee shall --

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

(2) Have each radiation survey instrument calibrated:

(a) At energies appropriate for use and intervals not to exceed 12 months or after instrument servicing, except battery changes;

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

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

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

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

C. A licensee shall check each survey instrument for consistent response with a dedicated check source before each use.

D. A licensee shall retain a record of each survey instrument calibration in accordance with G.2061.

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.

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

A. A licensee shall determine and record the activity of each dosage within 30 minutes before medical use.

B. For a unit dosage, this determination must be made by --

(1) Direct measurement of radioactivity; or

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

(a) A manufacturer or preparer licensed under Part C or equivalent Nuclear Regulatory Commission, or Agreement State requirements;

(b) An Agency, Nuclear Regulatory Commission, or an 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 FDA; or

(c) A PET radioactive drug producer licensed under Part C of these regulations or equivalent provisions of the NRC, or an Agreement State.

C. For other than unit dosages, this determination must be made by --

(1) Direct measurement of radioactivity;

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

(3) Combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer or preparer licensed under Part C or equivalent Nuclear Regulatory Commission, or Agreement State requirements, or a PET radioactive drug producer licensed under Part C or equivalent provisions of the NRC or an Agreement State.

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

E. A licensee shall retain a record of the dosage determination required by this section in accordance with G.2063.

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

A. Sealed sources, not exceeding 1.11 GBq (30 mCi) each, manufactured and distributed by persons licensed pursuant to Part C of these regulations or equivalent Nuclear Regulatory Commission, or Agreement State regulations.

B. Sealed sources, not exceeding 1.11 GBq (30mCi) each, redistributed by a person licensed under Part C.11.K, provided the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions.

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

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

E. Technetium-99m in amounts as needed.

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

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

B. A licensee in possession of a sealed source shall --

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

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

C. To satisfy the leak test requirements of G.67.B. the licensee shall measure the sample so that the leak test can detect the presence of 185 Bq (0.005 μCi) of radioactive material in the sample.

D. A licensee shall retain leak test records in accordance with G.2067.A.

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

(1) Immediately withdraw the sealed source from use and store, dispose of, or cause it to be repaired in accordance with the requirements of these regulations; and

(2) File a report with the Agency within 5 days of the leak test in accordance with G.3067.

F. A licensee need not perform a leak test on the following sources:

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

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

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

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

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

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

69. Labeling of Vials and Syringes. Each syringe and vial that contains unsealed radioactive material must be labeled to identify the radioactive drug. Each syringe shield and vial shield must also be labeled unless the label on the syringe or vial is visible when shielded. Furthermore, 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.

70. Surveys for Ambient Radiation Dose Rate.

A. In addition to the surveys required by Part D, 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 was prepared for use or administered.

B. A licensee does not need to perform the surveys required by G.70.A in an area(s) where patients or human research subjects are confined when they cannot be released under G.75.

C. A licensee shall conduct the surveys required by G.70.A and B so as to able to measure dose rates as low as 1 microsievert (0.1 mrem) per hour.

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

E. A licensee shall survey for removable contamination each week of use all areas where radioactive materials are prepared for use, used, administered or stored.

F. A licensee shall conduct the surveys required by G.70.E so as to be able to detect contamination on each wipe sample of 33.3 becquerels (2000 dpm) for restricted areas and 3.33 becquerels (200 pdm) for unrestricted areas.

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

H. A licensee shall retain a record of each survey in accordance with G.2070.

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

A. A licensee may authorize the release from its control of any individual who has been administered unsealed radioactive material or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).[1]

B. The licensee shall provide the released individual, or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem). If the total effective dose equivalent to a nursing infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption of breast-feeding, the instructions must also include --

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

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

C. Release of the individual must be approved by a person listed as an authorized user on the Agency license, and who is approved for the type of radioactive material use for which the patient being released has received.

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

E. The licensee shall maintain a record of instructions provided to a breast-feeding female in accordance with G.2075.B.

F. The licensee shall immediately notify the Agency in accordance with G.3075.A if a patient departs prior to an authorized release.

G. The licensee shall notify the Agency in accordance with G.3075.B

(1) When it is aware that a patient containing radioactive material dies; and

(2) If it is possible that any individual could receive exposures in excess of 5 millisievert (500 mrem) as a result of the deceased's body.

80. Provision of Mobile Nuclear Medicine Service

A. A licensee providing mobile nuclear medicine service shall --

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

(2) Check instruments used to measure the activity of unsealed radioactive material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function required by this paragraph must include a constancy check;

[1] U.S. Nuclear Regulatory Commission Regulatory Guide NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Licenses," describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem).

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

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

B. A mobile nuclear medicine service shall have all radioactive material delivered directly from the manufacturer or the distributor to the mobile nuclear medicine facility. At no time may the client take receipt of any radioactive material intended for the mobile nuclear medicine service's use.

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

92. Decay-In-Storage.

A. A licensee may hold radioactive material with a physical half-life of less than 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee --

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

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

B. A licensee shall retain a record for each disposal permitted under G.92.A in accordance with G.2092.

SUBPART D – UNSEALED RADIOACTIVE MATERIAL

WRITTEN DIRECTIVE NOT REQUIRED

100. Use of Unsealed Radioactive Material for Uptake, Dilution, and Excretion Studies for Which a Written Directive Is Not Required. Except for quantities that require a written directive under G.40. a licensee may use any unsealed radioactive material, prepared for medical use for uptake, dilution, or excretion studies that is --

A. Obtained from a manufacturer or preparer licensed pursuant to Part C or equivalent Nuclear Regulatory Commission or Agreement State requirements; or from a PET radioactive drug producer licensed under Part C of these regulations or equivalent provisions of the NRC, Agreement State,

B. Excluding production of PET radionuclides prepared by;

(1) an authorized nuclear pharmacist;

(2) a physician who is an authorized user and who meets the requirements specified in G.290 or G.390, and G.290.C.(1)(b)(vii);

(3) or an individual under the supervision, as specified in Part G.27, of the authorized nuclear pharmacist in G.100.B(1) or the physician who is an authorized user in G.100.B(2); or

C. Obtained from and prepared by an Agency, Nuclear Regulatory Commission, or an 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 Food and Drug Administration (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 the Food and Drug Administration (FDA).

110. Possession of Survey Instrument. A licensee authorized to use radioactive material for uptake, dilution, and excretion studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrems) per hour. The instrument shall be operable and calibrated in accordance with G.61.

111-189. [reserved.]

190. Training for Uptake, Dilution, and Excretion Studies. Except as provided in G.57, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under G.100 to be a physician who –

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

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

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

B. Is an authorized user under G.290 or G.390 or equivalent Nuclear Regulatory Commission, or Agreement State requirements; or

C. (1) Has completed 60 hours of training and experience, including a minimum of 8 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience must include --

(a) Classroom and laboratory training in the following areas --

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

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

(v) Radiation biology; and

(b) Work experience, under the supervision of an authorized user who meets the requirements in G.57, G.190, G.290, or G.390 or equivalent Nuclear Regulatory Commission, or Agreement State requirements, involving --

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

(ii) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

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

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

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

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

(2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in G.57, G.190, G.290, or G.390 or equivalent Nuclear Regulatory Commission, or Agreement State requirements, that the individual has satisfactorily completed the requirements in G.190.A(1) or G.190.C.(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under G.100.

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, a licensee may use for any unsealed radioactive material prepared for medical use for imaging and localization studies that is --

A. Obtained from a manufacturer or preparer licensed pursuant to Part C or equivalent Nuclear Regulatory Commission or Agreement State requirements, or a PET radioactive drug producer licensed under Part C of these regulations or equivalent provisions of the NRC, Agreement State, or

B. Excluding production of PET radionuclides prepared by;

(1) an authorized nuclear pharmacist;

(2) a physician who is an authorized user and who meets the requirements specified in G.290 or G.390 and G.290.C(1)(b)(vii); or

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

C. Obtained from and prepared by an 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 Food and Drug Administration (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 the Food and Drug Administration (FDA).

204. Permissible Molybdenum-99 Concentration.

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

(1) More than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 µCi of molybdenum-99 per mCi of technetium-99m);

(2) More than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 (0.02 µCi of Sr-82 per mCi of Rb-82 chloride); or

(3) More than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 µCi of Sr-85 per 1 mCi of Rb-82).

B. To demonstrate compliance with G.204, the licensee preparing radioactive drugs from radionuclide generators shall:

(1) Measure the concentration of radionuclide contaminant in the first eluate after receipt of a molybdenum-99/technetium-99m generator; or, as applicable.

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

C. A licensee who must measure radionuclide contaminant concentration shall retain a record of each measurement in accordance with G.2204.

D. A licensee shall report immediately to the Agency each occurrence of radionuclide contaminant concentration exceeding the limits specified in G.204.

220. Possession of Survey Instrument. A licensee authorized to use radioactive material for imaging and localization studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrems) per hour, and a portable survey instrument capable of measuring dose rates over the range of 10 microsieverts (1 mrem) per hour to 10 microsieverts (1000 mrems) per hour. The instrument shall be operable and calibrated in accordance with G.61.

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

(1) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies that includes the topics listed in paragraphs G.290.C(1)(a) and G.290.C(1)(b); and

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

B. Is an authorized user under G.390 and meets the requirements in G.290.C(1)(b)(vii) or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

C. (1) Has completed 700 hours of training and experience, including a minimum of 80 hours classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience must include, at a minimum:

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

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

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

(v) Radiation biology; and

(b) Work experience, under the supervision of an authorized user who meets the definition of an authorized user in Part A.2 for the same uses, or who meets the requirements in G.57, G.290 or G.390 or equivalent Nuclear Regulatory Commission, or Agreement State requirements involving:

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

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

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

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

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

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

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

(2) Has obtained written attestation signed by a preceptor authorized user, who meets the definition of an authorized user in Part A.2 for the same uses or who meets the requirements in G.57, G.290 or G.390 or equivalent Nuclear Regulatory Commission, or Agreement State requirements, that the individual has satisfactorily completed the requirements in G.290.C(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under G.100 and G.200.

SUBPART E – UNSEALED RADIOACTIVE MATERIAL

WRITTEN DIRECTIVE REQUIRED

300. Use of Unsealed Radioactive Material For Which A Written Directive Is Required. A licensee may use any unsealed radioactive material prepared for medical use and for which a written directive is required that is --

A. Obtained from a manufacturer or preparer licensed pursuant to Part C or equivalent Nuclear Regulatory Commission or Agreement State requirements; or from a PET radioactive drug producer licensed under Part C of these regulations or equivalent provisions of the NRC, Agreement State, or

B. Excluding production of PET radionuclides prepared by;

(1) an authorized nuclear pharmacist;

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

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

C. Obtained from and prepared by an Agency, Nuclear Regulatory Commission, or an 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 Food and Drug Administration (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 the Food and Drug Administration (FDA).

310. Safety Instruction. In addition to the requirements of Part J.3.

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

(1) Patient or human research subject control;

(2) Visitor control, including --

(a) Routine visitation to hospitalized individuals in accordance with Part D.27.A(1), and

(b) Visitation authorized in accordance with Part D.27.C;

(3) Contamination control;

(4) Waste control; and

(5) Notification of the Radiation Safety Officer or his or her designee, and the authorized user if the patient or 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.

315. Safety Precautions.

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

(1) Quarter the patient or human research subject either in:

(a) A private room with a private sanitary facility; or

(b) A room, with a private sanitary facility, with another individual who also has received therapy with unsealed radioactive material and who also cannot be released under G.75.

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

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

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

B. A licensee shall notify the Radiation Safety Officer or his or her designee, and the authorized user as soon as possible if the patient or human research subject has a medical emergency or dies. The licensee shall also notify the Agency in accordance with G.3068 if it is possible that any individual could receive exposures in excess of Part D.301 of these regulations as a result from exposure to the deceased body.

320. Possession of Survey Instrument. A licensee authorized to use radioactive material for which a written directive is required shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrems) per hour, and a portable survey instrument capable of measuring dose rates over the range of 10 microsieverts (1 mrem) per hour to 10 microsieverts (1000 mrems) per hour. The instrument shall be operable and calibrated in accordance with G.61.

390. Training for use of Unsealed Radioactive Material for Which a Written Directive Is Required. Except as provided in G.21, 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, the Nuclear Regulatory Commission, or an Agreement State, and who meets the requirements in paragraphs G390.B(1)(b)(vi) and G.390.B(2). (Specialty Boards whose certification processes have been recognized by the Agency, the NRC, an Agreement State will be posted on the NRC's web page.) To be recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in G.390.B(1)(a) through G.390.B(2). Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

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

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

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

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

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

(v) Radiation biology; and

(b) Work experience under the supervision of an authorized user who meets the definition of an authorized user in Part A.2 for the same uses or who meets the requirements in G.57, G.390.A, G.390.B or equivalent Nuclear Regulatory Commission, or Agreement State requirements. A supervising authorized user who meets the requirements in G.390.B must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status. The work experience must involve --

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

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

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

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

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

(vi) Eluting generator systems, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

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

(a) 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;

(b) Oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131[1];

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

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

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in G.390.B(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under G.300. The written attestation must be signed by a preceptor authorized user who meets the definition of an authorized user in Part A.2 for the same uses or who meets the requirements in G.57, G.390.A, G.390.B, or equivalent Nuclear Regulatory Commission or Agreement State requirements. The preceptor authorized user, who meets the requirements in G.390B, must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

392. Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive In Quantities Less Than or Equal to 1.22 Gigabecquerels (33 Millicuries). Except as provided in G.21, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries), to be a physician who --

[1] Experience with at least 3 cases in Category (vii)(b) also satisfies the requirement in Category (vii)(a).

A. Is certified by a medical specialty board whose certification process includes all of the requirements in G.392.C and whose certification has been recognized by the Agency, the Nuclear Regulatory Commission or an Agreement State and meets the requirements in paragraph G.392.C.(3). (Specialty Boards whose certification processes have been recognized by the Agency, the NRC, or an Agreement State will be posted on the NRC's web page.); or

B. Is an authorized user under G.390.A and G.390.B, for uses listed in G.390.B(1)(b)(vii)(a) or (b), G.394 or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

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

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

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

(e) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the definition of an authorized user in Part A.2 for the same uses or who meets the requirements in G.57, G.390.A, G.390.B, G.392, G.394 or equivalent Nuclear Regulatory Commission or Agreement State requirements. A supervising authorized user who meets the requirements in G.390.B, must have experience in administering dosages as specified in G.390.B(1)(b)(vii)(a) or (b). The work experience must involve --

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

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

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

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

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

(f) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in G.392.C(1) and G.392.C(2) and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under G.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in G.57, G.390.A, G.390.B, G.392, G.394, or equivalent Nuclear Regulatory Commission or Agreement State requirements. A preceptor authorized user who meets the requirement in G.390.B, must have experience in administering dosages as specified in G.390.B(1)(a)(vii)(a) or (b).

394. Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive In Quantities Greater Than 1.22 Gigabecquerels (33 Millicuries). Except as provided in G.57, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries), to be a physician who:

A. Is certified by a medical specialty board whose certification process includes all of the requirements in G.394.C and whose certification has been recognized by the Agency, the Nuclear Regulatory Commission or an Agreement State and who meets the requirements in G.394.C(3) (The names of board certifications which have been recognized by the Agency, the NRC, or an Agreement State will be posted on the NRC's web page.); or

B. Is an authorized user under G.390.A and G.390.B for uses listed in G.390.B(1)(b)((vii)(b), or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

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

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

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

(e) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the definition of an authorized user in Part A.2 for the same uses or who meets the requirements in G.57, G.390.A, G.390.B, G.394, or equivalent Nuclear Regulatory Commission, or Agreement State requirements. A supervising authorized user, who meets the requirements in G.390.B must have experience in administering dosages as specified in G.390.B(1)(b)(vii)(b). The work experience must involve --

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

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

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

(f) Administering dosages to patients or human research subjects, including at least 3 cases involving the oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in G.394.C(1) and G.394.C(2) and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under G.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in G.57, G.390.A, G.390.B, G.394, or equivalent Nuclear Regulatory Commission or Agreement State requirements. A preceptor authorized user who meets the requirements in G.390.B must have experience in administering dosages as specified in G.390.B(1)(b)(vii)(b).

396. Training for the parenteral administration of unsealed byproduct material requiring a written directive.

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

A. Is an authorized user under G.390 for uses listed in G.390.B(1)(b)(vi)(c) and G.390.B(1)(b)(vi)(d) or equivalent NRC or Agreement State requirements; or

B. Is an authorized user under G.490, G.690, or equivalent NRC or Agreement State requirements and who meets the requirements in G.396.D; or

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

D. (1) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. The training must include--

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

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

(e) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the definition of an authorized user in Part A.2 for the same uses or who meets the requirements in G.57, G.390, G.396, or equivalent NRC Agreement State requirements, in the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in G.390 must have experience in administering dosages as specified in G.390.B(1)(b)(vii)(a) or (b). The work experience must involve--

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

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

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

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

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

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

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in G.396.B or G.396.C, and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in G.57, G.390, G.396, or equivalent NRC or Agreement State requirements. A preceptor authorized user, who meets the requirements in G.390 must have experience in administering dosages as specified in G.390.B(1)(b)(vii)(a) or (b).

SUBPART F – MANUAL BRACHYTHERAPY

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

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

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

404. Surveys After Source Implant And Removal.

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

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

C. A licensee shall retain a record of the surveys required by G.404.A and G.404.B in accordance with G.2404.

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.

410. Safety Instruction. In addition to the requirements of Part J.

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

(1) Size and appearance of the brachytherapy sources;

(2) Safe handling and shielding instructions;

(3) Patient and human research subject control;

(4) Visitor control, including both:

(a) Routine visitation of hospitalized individuals in accordance with Part D.1301.A(1); and

(b) Visitation authorized in accordance with Part D.1301.C; and

(5) Notification of the Radiation Safety Officer, or his or her designee, and an authorized user if the patient or human research subject has a medical emergency or dies. The licensee shall also notify the Agency in accordance with G.3068 if it is possible that any individual could receive exposures in excess of Part D.301 of these regulations as a result from exposure to the deceased body.

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

415. Safety Precautions.

A. For each patient or human research subject who is receiving brachytherapy and cannot be release under G.75, a licensee shall --

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

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

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

B. A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source --

(1) Dislodged from the patient or human research subject; and

(2) Lodged within the patient or human research subject following removal of the source applicators.

C. A licensee shall notify the Radiation Safety Officer or his or her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies. The licensee shall also notify the Agency in accordance with G.3068 if it is possible that any individual could receive exposures in excess of Part D.301 of these regulations as a result from exposure to the deceased body.

420. Possession of Survey Instrument. A licensee authorized to use manual brachytherapy sources shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrems) per hour, and a portable survey instrument capable of measuring dose rates over the range of 10 microsieverts (1 mrem) per hour to 10 microsieverts (1000 mrems) per hour. The instrument shall be operable and calibrated in accordance with G.61.

432. Calibration Measurements Of Brachytherapy Sources.

A. Before the first medical use of a brachytherapy source on or after December 1, 2003, a licensee shall have --

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

(2) Determined source positioning accuracy within applicators; and

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

B. A licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with G.432.A.

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

D. A licensee shall retain a record of each calibration in accordance with G.2432.

433. Decay Of Strontium-90 Sources For Ophthalmic Treatments.

A. Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under G.432.

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

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

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

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

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

D. The accuracy of the software used to determine sealed source positions from radiographic images.

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, the Nuclear Regulatory Commission, or an Agreement State and who meets the requirements in G.490.B(3). (The names of board certifications which have been recognized by the Agency, the NRC, or an Agreement State will be posted on the NRC's web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

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

(2) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or

B. (1) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes --

(a) 200 hours of classroom and laboratory training in the following areas --

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

(iv) Radiation biology; and

(b) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in G.57, G.490 or equivalent Nuclear Regulatory Commission or Agreement State requirements at a medical institution, involving:

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

(ii) Checking survey meters for proper operation;

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

(iv) Maintaining running inventories of material on hand;

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

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

(2) Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in G.57, G.490 or equivalent Nuclear Regulatory Commission or Agreement State, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by G.490.B(1)(b); and

(3) Has obtained written attestation, signed by a preceptor authorized user who meets the definition of an authorized user in Part A.2 for the same uses or who meets the requirements in G.57, G.490 or equivalent Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in G.490.B(1) and G.490.B(2) and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under G.400.

491. Training For Ophthalmic Use Of Strontium-90. Except as provided in G.57, the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who --

A. Is an authorized user under G.490 or equivalent Nuclear Regulatory Commission, or Agreement State requirements; or

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

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

(d) Radiation biology; and

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

(a) Examination of each individual to be treated;

(b) Calculation of the dose to be administered;

(c) Administration of the dose; and

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

(3) Has obtained written attestation, signed by a preceptor authorized user who meets the definition of an authorized user in Part A.2 for the same uses or who meets the requirements in G.57, G.490, G.491, or equivalent Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in G.491.A and G.491.B and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

SUBPART G - SEALED SOURCES FOR DIAGNOSIS

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

590. Training for Use of Sealed Sources for Diagnosis. Except as provided in G.57, the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under G.500 to be a physician, dentist, or podiatrist who –

A. Is certified by a specialty board whose certification process includes all of the requirements in G.590.B and whose certification 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 NRC, or an Agreement State will be posted on the NRC's web page.); or

B. Has had 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include --

(1) Radiation physics and instrumentation;

(2) Radiation protection;

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

(4) Radiation biology; and

(5) Training in the use of the device for the uses requested.

SUBPART H – PHOTON EMITTING REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS

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

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

B. In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the Food and Drug Administration (FDA), provided the requirements of G.49 are met.

604. Surveys of Patients and Human Research Subjects Treated With a Remote Afterloader Unit.

A. Before releasing a patient or a human research subject from licensee control, a licensee shall survey the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe shielded position.

B. A licensee shall retain a record of these surveys in accordance with G.2404.

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, the Nuclear Regulatory Commission or an Agreement State shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

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

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

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

A. A licensee shall --

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

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

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

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

(a) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

(b) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

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

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

C. A licensee shall post instructions at the unit console to inform the operator of --

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

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

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

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

(2) The operating procedures for the unit.

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

F. A licensee shall retain a record of individuals receiving instruction required by G.643.D, in accordance with G.2310.

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

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

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

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

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

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

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

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

D. Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

E. For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

F. In addition to the requirements specified in G.615.A through G.615.E, a licensee shall --

(1) For medium dose-rate and pulsed dose-rate remote afterloader units, require --

(a) 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

(b) An authorized medical physicist and either an authorized user or an individual under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.

(2) For high dose-rate remote afterloader units, require --

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

(b) An authorized medical physicist and either an authorized user or a physician under the supervision of an authorized user who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.

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

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

G. A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source --

(1) Remaining in the unshielded position;

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

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:

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

(2) The system must have been calibrated within the previous 4 years. Eighteen to thirty months after that calibration, the system must have been intercompared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison must indicate that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee may I not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.

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

C. The licensee shall maintain a record of each calibration, intercomparison, and comparison in accordance with G.2630.

632. Full Calibration Measurements on Teletherapy Units.

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

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

(2) Before medical use under the following conditions:

(a) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(b) Following replacement of the source or following reinstallation of the teletherapy unit in a new location;

(c) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(3) At intervals not exceeding 1 year.

B. To satisfy the requirement of G.632.A, full calibration measurements must include determination of-

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

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

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

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

(5) “On-off” error; and

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

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

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

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

F. Full calibration measurements required by G.632.A and physical decay corrections required by G.632.E must be performed by the authorized medical physicist.

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

633. Full Calibration Measurements on Remote Afterloader Units.

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

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

(2) Before medical use under the following conditions:

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

(b) Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

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

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

B. To satisfy the requirement of G.633.A, full calibration measurements must include, as applicable, determination of:

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

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

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

(4) Length of the source transfer tubes;

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

(6) Length of the applicators; and

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

C. A licensee shall use the dosimetry system described in G.630.A to measure the output.

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

E. In addition to the requirements for full calibrations for low dose-rate remote afterloader units in G.607.B, a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding 1 quarter.

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

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

H. Full calibration measurements required by G.633.A and physical decay corrections required by G.633.G must be performed by the authorized medical physicist.

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

635. Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units.

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

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

(2) Before medical use under the following conditions --

(a) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(b) Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and

(c) Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and

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

B. To satisfy the requirement of G.635.A, full calibration measurements must include determination of-

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

(2) Relative helmet factors;

(3) Isocenter coincidence;

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

(5) On-off error;

(6) Trunnion centricity;

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

(8) Helmet microswitches;

(9) Emergency timing circuits; and

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

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

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

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

F. Full calibration measurements required by G.635.A and physical decay corrections required by G.635.E must be performed by the authorized medical physicist.

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

642. Periodic Spot Checks for Teletherapy Units.

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

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

(2) On-off error;

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

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

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

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

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

C. A licensee shall have the authorized medical physicist review the results of each spot check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot check.

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

(1) Electrical interlocks at each teletherapy room entrance;

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

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

(4) Viewing and intercom systems;

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

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

E. If the results of the checks required in G.642.D indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

F. A licensee shall retain a record of each spot- check required by G.642.A and G.642.D, and a copy of the procedures required by G.642.B, in accordance with G.2642.

643. Periodic Spot-Checks for Remote Afterloader Units.

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

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

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

(3) After each source installation.

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

C. A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

D. To satisfy the requirements of G.643.A, spot-checks must, at a minimum, assure proper operation of --

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

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

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

(4) Emergency response equipment;

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

(6) Timer accuracy;

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

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

E. If the results of the checks required in G.643.D indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

F. A licensee shall retain a record of each check required by G.643.D and a copy of the procedures required by G.610.B in accordance with G.2643.

645. Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units.

A. A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit --

(1) Monthly;

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

(3) After each source installation.

B. A licensee shall --

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

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

C. To satisfy the requirements G.645.A(1), spot-checks must, at a minimum --

(1) Assure proper operation of --

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

(b) Helmet micro-switches;

(c) Emergency timing circuits; and

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

(2) Determine --

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

(b) The difference between the measurement made in G.645.C(2)(a) and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay);

(c) Source output against computer calculation;

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

(e) On-off error; and

(f) Trunnion centricity.

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

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

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

(3) Viewing and intercom systems;

(4) Timer termination;

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

(6) Emergency off buttons.

E. A licensee shall arrange for the repair of any system identified in G.645.C that is not operating properly as soon as possible.

F. If the results of the checks required in G.645.D indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

G. A licensee shall retain a record of each check required by G.645.C and G.645.D and a copy of the procedures required by G.645.B in accordance with G.2611.

647. Additional Technical Requirements for Mobile Remote Afterloader Units.

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

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

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

B. In addition to the periodic spot-checks required by G.643, a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the proper operation of --

(1) Electrical interlocks on treatment area access points;

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

(3) Viewing and intercom systems;

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

(5) Radiation monitors used to indicate room exposures;

(6) Source positioning (accuracy); and

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

C. In addition to the requirements for checks in G.647.B, a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

D. If the results of the checks required in G.647.B indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

E. A licensee shall retain a record of each check required by G.647.B in accordance with G.2652.

652. Radiation Surveys.

A. In addition to the survey requirement in Part D.1501, a person licensed under Part G shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry.

B. The licensee shall make the survey required by G.652.A at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

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

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

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

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

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

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

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

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

C. The accuracy of isodose plots and graphic displays;

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

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

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, the Nuclear Regulatory Commission, or an Agreement State and who meets the requirements in G.690.B.(3) and G.690.B(4). (The names of board certifications which have been recognized by the Agency, the NRC, or an Agreement State will be posted on the NRC's web page.) To be recognized, a specialty board shall require all candidates for certification to:

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

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

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

(a) 200 hours of classroom and laboratory training in the following areas --

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

(iv) Radiation biology; and

(b) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in G.57, G.690 or equivalent Nuclear Regulatory Commission, or Agreement State requirements, at a medical institution, involving --

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

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

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

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

(v) Checking and using survey meters; and

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

(2) Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in G.57, G.690 or equivalent Nuclear Regulatory Commission or Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by G.690.B(1)(a); and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in G.690.B(1) and G.642.B(2) and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user who meets the requirements in G.57, G.690 or equivalent Nuclear Regulatory Commission or Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and

(4) 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.

SUBPART I - RESERVED

SUBPART J – RESERVED

SUBPART K--OTHER MEDICAL USES OF RADIOACTIVE MATERIAL OR RADIATION FROM RADIOACTIVE MATERIAL

1000. Other Medical Uses of Radioactive Material or Radiation from Radioactive Material.

A licensee may use radioactive material or a radiation source approved for medical use which is not specifically addressed in subparts D through H of Part G if --

A. The applicant or licensee has submitted the information required by G.12.B through G.12.D*;* and

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

C. There are three modalities currently authorized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State:

(1) Yttrium 90 (Y-90) Microspheres. (e.g., MDS Nordion Y-90 TheraSphere®)

(2) Liquid Brachytherapy. (e.g., Proxima Therapeutics' GilaSite ® Radiation Therapy System)

(3) Intravascular Brachytherapy. (e.g., Cordis Checkmate™ System, Novoste Beta-Cath™ System, and Guidant Galileo™ Intravascular Radiotherapy System).

SUBPART L-- RECORDS

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

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

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

2026. Records of Radiation Protection Program Changes. A licensee shall retain a record of each radiation protection program change made in accordance with G.26.A for 5 years. The record must 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.

2031. Records of Mobile Nuclear Medicine Services.

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

B. A licensee shall retain the record of each survey required by G.80.A.4 for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

2040. Records of Written Directives. A licensee shall retain a copy of each written directive as required by G.15 for 3 years.

2041. Records for Procedures for Administrations Requiring a Written Directive. A licensee shall retain a copy of the procedures required by G.16.A for the duration of the license.

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 3 years. The records must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

2061. Records of Radiation Survey Instrument Calibrations. A licensee shall maintain a record of radiation survey instrument calibrations required by G.61 for 3 years. The record must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

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

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

B. The record must contain --

(1) The radiopharmaceutical;

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

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

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

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

2067. Records of Leaks Tests and Inventory of Sealed Sources and Brachytherapy Sources.

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

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

2070. Records of Surveys for Ambient Radiation Exposure Rate. A licensee shall retain a record of each survey required by G.29 for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

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

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

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

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

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

(4) Considering the shielding by tissue.

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

C. The records required by G.2075.A and G.2075.B must be signed by the authorized user and retained for 3 years after the date of release of the individual.

2092. Records of Decay-In-Storage. A licensee shall maintain records of the disposal of licensed materials, as required by G.32, for 3 years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.

2204. Records of Molybdenum-99 Concentrations. A licensee shall maintain a record of the molybdenum-99 concentration tests required by G.204.B for 3 years. The record must include, for each measured elution of technetium-99m, the ratio of the measures expressed as kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (or microcuries of molybdenum per millicurie of technetium), the time and date of the measurement, and the name of the individual who made the measurement.

2310. Records of Safety Instruction. A licensee shall maintain a record of safety instructions required by G.310, G.410, and G.610 for 3 years. The record must include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

2404. Records of Surveys of Patients and Human Research Subjects After Source Implant and Removal. A licensee shall maintain a record of the surveys required by G.404 and G.604 for 3 years. Each record must include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

2406. Records of Brachytherapy Source Accountability.

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

B. For temporary implants, the record must include --

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

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

C. For permanent implants, the record must include:

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

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

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

2432. Records of Calibration Measurements of Brachytherapy Sources.

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

B. The record must include --

(1) The date of the calibration;

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

(3) The source output or activity;

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

(5) The signature of the authorized medical physicist.

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

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

B. The record must include --

(1) The date and initial activity of the source as determined under G.433; and

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

2605. Records of Installation, Maintenance, Adjustment, and Repair of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units. A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by G.605 for 3 years. For each installation, maintenance, adjustment and repair, the record must include the date, description of the service, and name(s) of the individual(s) who performed the work.

2610. Records of Safety Procedures. A licensee shall retain a copy of the procedures required by G.610.A.(4) and G.610.D.(2) until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.

2630. Records of Dosimetry Equipment Used With Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.

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

B. For each calibration, intercomparison, or comparison, the record must include --

(1) The date;

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

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

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

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

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

B. The record must include --

(1) The date of the calibration;

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

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

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

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

2642. Records of Periodic Spot-Checks for Teletherapy Units.

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

B. The record must include --

(1) The date of the spot-check;

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

(3) An assessment of timer linearity and constancy;

(4) The calculated on-off error;

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

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

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

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

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

C. A licensee shall retain a copy of the procedures required by G.642.B until the licensee no longer possesses the teletherapy unit.

2643. Records of Periodic Spot-Checks for Remote Afterloader Units.

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

B. The record must include, as applicable --

(1) The date of the spot-check;

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

(3) An assessment of timer accuracy;

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

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

C. A licensee shall retain a copy of the procedures required by G.643.B until the licensee no longer possesses the remote afterloader unit.

2645. Records of Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units.

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

B. The record must include --

(1) The date of the spot-check;

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

(3) An assessment of timer linearity and accuracy;

(4) The calculated on-off error;

(5) A determination of trunnion centricity;

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

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

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

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

C. A licensee shall retain a copy of the procedures required by G.645.B until the licensee no longer possesses the gamma stereotactic radiosurgery unit.

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

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

B. The record must include --

(1) The date of the check;

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

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

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

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

2652. Records of Surveys of Therapeutic Treatment Units.

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

B. The record must include --

(1) The date of the measurements;

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

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

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

2655. Records of 5-Year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units.

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

B. The record must contain --

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

(2) The date of inspection;

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

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

(5) The signature of the inspector.

SUBPART M--REPORTS

3045. Report and Notification of a Medical Event.

A. A licensee shall report any event, except for an event that results from patient intervention, in which the administration of radioactive material or radiation from radioactive material results in --

(1) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and

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

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

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

(2) A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following --

(a) An administration of a wrong radioactive drug containing radioactive material;

(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 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

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

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

(1) The written report must include --

(a) The licensee's name;

(b) The name of the prescribing physician;

(c) A brief description of the event;

(d) Why the event occurred;

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

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

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

(2) 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 event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of G.3045.E, 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 this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.

G. A licensee shall:

(1) Annotate a copy of the report provided to the Agency with the:

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

(b) Social security number or other identification number, if one has been assigned, of the individual who is the subject of the event; and

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

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) 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 or that is a result of an administration of radioactive material to a breast-feeding individual that:

(1) Is greater than 50 mSv (5 rem) total effective dose equivalent; or

(2) 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.3047.A or G.3047.B.

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.3047.A or G.3047.B.

(1) The written report must include --

(a) The licensee's name;

(b) The name of the prescribing physician;

(c) A brief description of the event;

(d) Why the event occurred;

(e) The effect, if any, on the embryo/fetus or the nursing child;

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

(g) 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.

(2) The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

E. The licensee shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under G.3047.A or G.3047.B, unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. 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:

(1) Annotate a copy of the report provided to the U.S. Nuclear Regulatory Commission with the:

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

(b) Social security number or other identification number, if one has been assigned, of the pregnant individual or the nursing child who is the subject of the event; and

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

3067. Report of a Leaking Source. A licensee shall file a report within 5 days if a leak test required by G.67 reveals the presence of 185 Bq (0.005 µCi) or more of removable contamination. The report must be filed with the Agency. The written report must include the model number and serial number, if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken.

3075. Reports of Patient Departure Prior to Authorized Release or Patient Death.

A. The licensee shall notify the Agency by telephone immediately upon discovery that a patient or human research subject has departed from the licensee's facility without authorization under G.75.G.

(1) The licensee shall submit a written report to the Agency within 30 days after discovery of the unauthorized departure release. The written report must include:

(a) The licensee's name;

(b) The date and time of the unauthorized departure;

(c) The projected date and time when release would have occurred;

(d) The address of the patient's or human research subject's home or anticipated destination following departure;

(e) The radionuclide, chemical and physical form and calculated activity at time of release;

(f) The apparent reason(s) for the departure prior to authorized release; and

(g) A description of any changes in the licensee's patient release criteria or patient instructions that are designed to avoid a recurrence of such an event.

B. The licensee shall notify the Agency by telephone immediately upon discovery that a patient or human research subject containing radioactive material has died, and it is possible that any individual could receive exposures in excess of the limits in Part D.1301 of these regulations as a result of the deceased's body.

(1). The licensee shall submit a written report to the Agency within 30 days after discovery that the patient or human research subject referenced in G.3076.A has died. The written report must include

(a) The licensee's name;

(b) The date of death;

(c) The radionuclide, chemical and physical form and calculated activity at time of death; and

(d) The names (or titles) and address(s) of known individuals who might have received exposures exceeding 5 millisieverts (500 mrem).