DRAFT

PART G

USE OF RADIONUCLIDES IN THE HEALING ARTS

General Information

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

Sec. G.2 - Definitions.

~~["Accredited institution" means a teaching facility for nuclear medicine technology or radiation therapy technology whose standards are accepted by the United States Department of Education.]~~

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

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

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

a. Meets the requirements in G.50 and G.59; and

b. Is currently identified as an ARSO for the types of use of radioactive material for which the individual has been assigned duties and tasks by the Radiation Safety Officer on:

i. A specific medical use license issued by the Agency, Nuclear Regulatory Commission, or an Agreement State; or

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

"Authorized medical physicist" (AMP) means an individual who:

a.~~(1)~~ Meets the requirements in ~~G.26~~G.51 and~~or~~ ~~G.29~~G.59; or

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

i. A ~~a~~ specific medical use license ~~or equivalent permit~~ issued by the Agency,

Nuclear Regulatory Commission, or Agreement State or Licensing State; or

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

iii.(3) Is identified as an authorized medical physicist on aA permit issued by an Agency, NRCNuclear Regulatory Commission, or Agreement State or Licensing State specificbroad scope medical use licenseelicense; or

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

"Authorized nuclear pharmacist" (ANP) means a pharmacist who:

a.(1) Meets the requirements in G.55aG.27 or G.59G.29; or [and]

b.(2) Is identified as an authorized nuclear pharmacist on:

i. A a specific license or equivalent permit that authorizes medical use, the practice of nuclear pharmacy, commercial nuclear pharmacy or the manufacture and distribution of radiopharmaceuticals issued by the Agency, Nuclear Regulatory Commission, or Agreement State or Licensing Statethat authorizes medical use or the practice of nuclear pharmacy; or

ii.(3) AIs identified as an authorized nuclear pharmacist on a permit issued by an NRC master material licensee that authorizes medical use or the practice of nuclear pharmacy;

iii. A permit issued by an Agency, NRCNuclear Regulatory Commission, or Agreement State or Licensing State specific license of broad scope medical use licensee that is authorizes authorized to permit themedical use or the practice of nuclear pharmacy; orof radioactive material.

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

c. Is identified as an ANP by a commercial nuclear pharmacy that has been authorized to identify ANPs; or

d. Is designated as an ANP in accordance with C.28.j(ii)(4) of these regulations

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

a.(1) Meets the requirements in G.59G.30 and G.190aG.46a., G.290aG.51a., G.390aG.56a., G.392aG.57a., G.394aG.58a., G.490aG.67a., G.590aG.68, G.70a., or G.690aG.88a.; or

b.(2) Is identified as an authorized user on

i. An~~ a license or equivalent permit issued by the~~ Agency, Nuclear Regulatory Commission, or Agreement State ~~or Licensing State~~license that authorizes the medical use of radioactive materials;~~ or~~

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

iii.~~(3)~~ A~~Is identified as an authorized user on a~~ permit issued by an Agency, NRC~~Nuclear Regulatory Commission~~, or Agreement State ~~or Licensing State specific~~ license of broad scope that is authorized to permit the medical use of radioactive material; or~~.~~

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

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

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

"Client's address" means the area~~address~~ of use or a temporary jobsite for the purpose of providing mobile medical service in accordance with G.80~~G.41~~.

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

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

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

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

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

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

prescribed~~treatment site~~.

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

"Manual brachytherapy," as used in Part G, means a type of therapy in which brachytherapy sources are manually placed topically on or inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume~~applied or inserted~~.

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

"Medical institution" means an organization in which more than one~~several~~ medical discipline~~disciplines~~ is~~are~~ practiced.

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

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

~~"Misadministration" means an event that meets the criteria in G.119a.~~

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

~~["Nuclear medicine technologist" means an individual who meets the requirements of G.28a. and is under the supervision of an authorized user, to prepare or administer radioactive drugs to patients or human research subjects, or perform *in vivo* or *in vitro* measurements for medical purposes.]~~

~~["Nuclear medicine technology" means the science and art of *in vivo* and *in vitro* detection and measurement of radioactivity and the administration of radioactive drugs to patients or human research subjects for diagnostic and therapeutic purposes.]~~
"Ophthalmic Physicist" means an individual who:

a. Meets the requirements in G.433a.ii and G.59; and

b. Is identified as an ophthalmic physicist on a:

i. Specific medical use license issued by the Agency, Nuclear Regulatory Commission, or an Agreement State;

ii. Permit issued by an Agency, NRC or Agreement State broad scope medical use licensee;

iii. Medical use permit issued by an NRC master material licensee; or

iv. Permit issued by an NRC master material licensee broad scope medical use permittee.

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

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

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

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

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

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

"Preceptor" means an individual who provides ~~or~~ directs, or verifies ~~the~~ training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, ~~[nuclear medicine technologist, radiation therapy technologist] or~~ a Radiation Safety Officer, or an Associate Radiation Safety Officer.

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

a.~~(1)~~ In a written directive as specified in G.40~~G.22.~~; or

b.~~(2)~~ In accordance with the directions of the authorized user for procedures performed pursuant to G.100~~G.44, G.47~~ and G.200~~G.52~~.

"Prescribed dose" means:

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

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

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

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

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

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

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

"Radiation Safety Officer" (RSO) means an individual who:

a.(1) Meets the requirements in G.50a,G.25 or G.50c.i and G.59G.29; or

b.(2) Is identified as a Radiation Safety Officer on:

i. A specific medical use license issued by the Agency, a Nuclear Regulatory Commission or an Agreement State; orlicense or other equivalent permit or license recognized by the Agency for similar types and uses of radioactive material.

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

["Radiation therapist" means an individual who meets the requirements of G.28b. and is under the supervision of an authorized user to perform procedures and apply radiation emitted from sealed radioactive sources to human beings for therapeutic purposes.]

["Radiation therapy technology" means the science and art of applying radiation emitted from sealed radioactive sources to patients or human research subjects for therapeutic purposes.]

"Radioactive drug" or "Radiopharmaceutical" means any chemical compound containing radioactive material that may be used on or administered to patients or human research subjects as an aid in the diagnosis, treatment, or prevention of disease or other abnormal condition. The term radiopharmaceutical is used interchangeably with radioactive drug and means the same thing.

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

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

"Stereotactic radiosurgery" means the use of external radiation in conjunction with a stereotactic

guidance device to very precisely deliver a therapeutic dose to a tissue volume~~treatment site~~.

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

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

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

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

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

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

"Type of use" means use of radioactive material as specified under G.100~~G.44~~, G.200~~G.47~~, G.300~~G.52~~, G.400~~G.59~~, G.500~~G.69~~, G.600~~G.71~~ or G.1000~~G.89~~.

"Unit dosage" means a dosage ~~that:~~

~~(1) Is obtained or prepared in accordance with the regulations for uses described in G.44, G.47, or G.52; and~~

~~(2) Is to be administered~~ prepared for medical use for administration as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

"Written directive" means an authorized user's written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in G.40~~G.22.~~

Sec. G.5~~G.3~~ - Maintenance of Records. Each record required by Part G ~~must~~shall be legible throughout the retention period~~ specified by each Agency regulation~~. The record may be the original, a reproduced copy, or a microform if~~provided that~~ the copy or microform is authenticated by authorized personnel and the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications ~~must~~shall include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

Sec. G.6~~G.4~~ - Provisions for the Protection of~~Research Involving~~ Human Research Subjects.

a. A licensee may conduct research involving human research subjects only if it uses~~using~~ the radioactive materials~~material~~ specified on its license for the uses authorized on its license. ~~provided:~~

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

i. Obtain~~Otherwise, a licensee shall apply for and receive approval of a specific amendment to its Agency license before conducting such research. Both types of licensees shall, at a minimum, obtain prior informed consent from the human subjects and obtain prior~~ review and approval of the research from~~activities by~~ an "Institutional Review Board" ~~in accordance with the meaning of these terms~~ as defined and described in the Federal Policy~~ for the Protection of Human Subjects~~; and

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

c.~~b.~~ If the~~The~~ research ~~involving human subjects authorized in G.4a. shall~~will not be conducted, funded, supported, or regulated by a Federal agency that has implemented the Federal Policy, the licensee shall, before conducting research, apply for and receive approval of a specific amendment to its Agency~~ using radioactive material authorized for~~ medical ~~use in the~~ license. The amendment request shall include a written commitment that the licensee will, before conducting research:~~; and~~

i. Obtain review and approval of the research from an "Institutional Review Board" as defined and described in the Federal Policy; and

ii. Obtain "informed consent," as defined and described in the Federal Policy, from the human research subject'

d.~~c.~~ Nothing in G.6~~G.4~~ relieves licensees from complying with the other requirements in Part G.

Sec. G.7~~G.5~~ - U.S. Food and Drug Administration, Federal, and State Requirements. Nothing in Part G~~this Part~~ relieves the licensee from complying with applicable U.S. Food and Drug Administration, other Federal, and State requirements governing radioactive drugs or devices.

Sec. G.10~~G.6~~ - Implementation.

a. A licensee shall implement the provisions in Part G on [insert effective date of the rule].

b. [Reserved]

c. [Reserved]

d. If a license condition exempted a licensee from a provision of Part G on [insert effective date of the rules], then the license condition continues to exempt the licensee from the corresponding

provision in G.1 through G.3204.

e. When a requirement in Part G differs from the requirement in an existing license condition, the requirement in Part G~~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 license renewal.~~

~~d. If a license condition exempted a licensee from a provision of Part G on [insert effective date of the rule], 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 [insert effective date of the rule], then the license condition remains in effect until there is a license amendment or license renewal that modifies or removes this condition.~~

f. A licensee~~Licensees~~ shall continue to comply with any license condition that requires it to implement procedures required by G.610~~G.74~~, G.642~~G.80~~, G.643~~G.81~~ and G.645~~G.82~~ until there is a license amendment or renewal that modifies the license condition.

[g. If a license condition cites provisions in Part G that will be deleted on [insert effective date of the rule], then the license condition remains in effect until there is a license amendment or license renewal that modifies or removes this condition.]

Sec. G.11~~G.7~~ - License Required.

a. A person shall ~~only~~ manufacture, produce, prepare, acquire, receive, possess, use, or transfer radioactive material for medical use only in accordance with a specific license issued by the Agency, the Nuclear Regulatory Commission or an Agreement State, or as allowed in G.11b~~G.7b.~~ or G.11c~~G.7c~~.

b. A specific license is not needed for an individual who:

i. Receives, possesses, uses, or transfers~~An individual may receive, possess, use, or transfer~~ radioactive material in accordance with the regulations in Part G under the supervision of an authorized user as provided in G.27~~G.21~~, unless prohibited by license condition.

ii.~~c.~~ Prepares~~An individual may prepare~~ unsealed radioactive material for medical use in accordance with the regulations in Part G under the supervision of an authorized nuclear pharmacist or authorized user as provided in G.27~~G.21~~, unless prohibited by license condition.

c. [Reserved]

Sec. G.12~~G.8~~ - Application for License, Amendment, or Renewal.

a. An application ~~must~~shall be signed by the applicant's or licensee's management.

b. An application for a license for medical use of radioactive material as described in G.100~~G.44~~, G.200~~G.47~~, G.300~~G.52~~, G.400~~G.59~~, G.500~~G.69~~, G.600~~G.71~~ or G.1000~~G.89~~ ~~must~~shall be made by:

i. Filing an original ~~[and one copy]~~ of [insert Agency application form name], that includes the facility diagram, equipment, and training and experience qualifications of the Radiation Safety Officer, Associate Radiation Safety Officer(s), authorized user(s), authorized medical physicist(s), ophthalmic physicist(s) and authorized nuclear pharmacist(s); and

ii. Submitting procedures required by sections [G.41~~G.23~~, G.62~~[G.31~~,] G.610~~G.74~~, G.642~~G.80~~, G.643~~G.81~~ and G.645~~G.82~~, as applicable.

c. A request for a license amendment or renewal ~~must~~shall be made by:

i. Submitting an original ~~[and one copy] in letter format.~~ of either:

(1) [Insert Agency application form name]; or

(2) A letter containing all information required by [Insert Agency application form name]; and

ii. Submitting procedures required by sections [G.41~~G.23~~, ~~[~~G.62~~G.31~~,] G.610~~G.74~~ , G.642~~G.80~~, G.643~~G.81~~ and G.645~~G.82~~, as applicable.

d. In addition to the requirements in G.12b~~G.8b.~~ and G.12c~~G.8c.~~, an application for a license or amendment for medical use of radioactive material as described in G.1000~~G.89 of this Part~~ ~~must~~shall also include:

i. Any additional~~information regarding any radiation safety~~ aspects of the medical use of the material that are appliable to radiation safety that are~~is~~ not addressed in G.1 through G.92, and G.2024 through G.3204~~G.1 through G.43~~;~~, as well as any specific information on:~~

ii. Identification of and commitment to follow the applicable radiation safety program requirements in G.100 through G.690 that are appropriate for the specific G.1000 medical use;

iii. Any additional specific information on:

(1)~~i.~~ Radiation safety precautions and instructions;

(2)~~ii.~~ ~~Training and experience of proposed users;~~

~~iii.~~ Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

(3)iv. Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety; and.

e. (4) AnyThe applicant or licensee shall also provide any other information requested by the Agency in its review of the application; and.

[(5) Training and experience for proposed users.]

e.f. An applicant that satisfies the requirements specified in C.27b. may apply for a Type A specific license of broad scope.

Sec. G.9 – Mobile Medical Service Administrative Requirements.

a. The Agency shall license mobile medical services or clients of such services. The mobile medical service shall be licensed if the service receives, uses or possesses radioactive material. The client of the mobile medical service shall be licensed if the client receives or possesses radioactive material to be used by a mobile medical service.

b. Mobile medical service licensees shall obtain a letter signed by the management of each location where services are rendered that authorizes use of radioactive material at the client's address of use. This letter shall clearly delineate the authority and responsibility of both the client and the mobile medical service. If the client is licensed, the letter shall document procedures for notification, receipt, storage and documentation of transfer of radioactive material delivered to the client's address for use by the mobile medical service.

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

d. A mobile medical service shall inform the client's management who is on site at each client's address of use at the time that radioactive material is being administered.

e. A licensee providing mobile medical services shall retain the letter required in G.9b. in accordance with G.101.

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

i. The current operating and emergency procedures;

ii. A copy of the license;

iii. Copies of the letter required by G.9b.;

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

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

~~g. A mobile medical service licensee shall maintain all records required by Parts D and G of these regulations at a location within the Agency's jurisdiction that is:~~

~~i. A single address of use:~~

~~(1) Identified as the records retention location; and~~

~~(2) Staffed at all reasonable hours by individual(s) authorized to provide the Agency with access for purposes of inspection; or~~

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

~~(1) Identified in the license; and~~

~~(2) Whose current client's address schedule and location schedule is reported to the Agency.~~

Sec. G.13~~G.10~~ - License Amendments. A licensee shall apply for and ~~must~~shall receive a license amendment:

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

i. [Reserved]

ii. [Reserved]

b. Before it permits anyone to work as an authorized user, authorized nuclear pharmacist, ophthalmic physicist or authorized medical physicist under the license, except:~~ an individual who is:~~

i. For an authorized user, an individual who meets the requirements in G.59~~G.30~~ and G.190a~~G.46a.~~, G.290a~~G.51a.~~, G.390a~~G.56a.~~, G.392a~~G.57a.~~, G.394a~~G.58a.~~, G.490a~~G.67a.~~, G.590a~~G.70a.~~, and G.690a;~~or G.88a. or;~~

ii. For an authorized nuclear pharmacist, an individual who meets the requirements in G.55a~~G.27a.~~ and G.59~~G.30~~;

iii. For an authorized medical physicist, an individual who meets the requirements in G.51a~~G.26a.~~ and G.59~~G.30~~;

iv. An individual who is identified~~Identified~~ as an authorized user, an authorized nuclear pharmacist, ~~or~~ authorized medical physicist or an ophthalmic physicist:

(1) On ~~on~~ an Agency, a Nuclear Regulatory Commission or an Agreement State license ~~or Licensing State~~ 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;~~, respectively; or~~

~~v.~~ (2) On ~~Identified as an authorized user, an authorized nuclear pharmacist, or authorized medical physicist on~~ a permit issued by an Agency, a Nuclear Regulatory Commission or an Agreement State ~~or Licensing State~~ specific licensee of broad scope that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy;~~, respectively.~~

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

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

c. Before it changes Radiation Safety Officers, except as provided in G.24c~~G.18c.~~;

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

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

f.~~e.~~ Before it adds to or changes the areas of use identified in the application or on the license, including areas used in accordance with either G.100 or G.200 if the change includes addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide/PET radioactive drug production area. Other areas of use where radioactive material is used only in accordance with either G.100 or G.200 are exempt;~~except as specified in G.11b.iv.;~~

g.~~f.~~ Before it changes the address(es) of use identified in the application or on the license;

h.~~g.~~ Before it revises~~changes statements, representations, and~~ procedures required by G.610, G642, G.643, and G.645, as applicable, where such revision reduces radiation safety~~which are incorporated into the license~~; and

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

Sec. G.14~~G.11~~ - Notifications.

a. A licensee shall provide ~~to~~ the Agency ~~a copy of the board certification, the Nuclear Regulatory Commission, Agreement State or Licensing State license, or the permit issued by a licensee of broad scope for each individual~~ no later than 30 days after the date that the licensee permits an~~the~~ individual to work under the provisions of G.13b as an authorized user, an authorized nuclear pharmacist, ~~or~~ an authorized medical physicist, or an ophthalmic physicist:~~pursuant to G.10b.~~

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

(1) Training for the authorized medical physicist under G.51c;

(2) Any additional case experience required in G.390b.i(2)(g) for an authorized user under G.390; or

(3) Device specific training in G.690c for the authorized user under G.600; or

ii. [Reserved]

b. A licensee shall notify the Agency, in writing, ~~by letter~~ no later than 30 days after

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

ii. The licensee permits an individual qualified to be a Radiation Safety Officer, under G.50 and G.59, to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer in accordance with G.24c;

iii. The licensee's mailing address changes;

iv.~~iii.~~ The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in C.31b~~.~~ of these regulations; ~~or~~

v.~~iv.~~ The licensee has added to or changed the areas of use identified in the application or on the license where radioactive material is used in accordance with either G.100~~G.44~~ and G.200~~G.47.~~ if the change does not include addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide/PET radioactive drug production area, or

vi. The licensee obtains a sealed source for use in manual brachytherapy from a different manufacturer or with a different model number than authorized by its license for which it did not require a license amendment as provided in G.13(i). The notification shall include the manufacturer and model number of the sealed source, the isotope, and the quantity per sealed source.

c. The licensee shall send the documents required in G.14 to the appropriate address identified in

A.12. of these regulations.

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

a. The provisions of G.12d~~G.8d.~~ regarding the need to file an amendment to the license for medical uses of radioactive material as described in G.1000~~G.89~~;

b. The provisions of G.13b;~~G.10b.~~

c. The provisions of G.13f regarding additions to or changes in the areas of use at the addresses identified in the application or on the license;

d. The provisions of G.14a;

e. The provisions of G.14b.i for ~~regarding the need to file an amendment before permitting anyone to work as~~ an authorized user, an authorized nuclear pharmacist, ~~or~~ an authorized medical physicist, or an ophthalmic physicist; ~~under the license;~~

f.~~c.~~ The provisions of G.14b.v~~G.10e. regarding;~~ ~~additions to or changes in the areas of use at the addresses specified in the license;~~

g.~~d.~~ The provisions of G.49a~~G.11a. regarding notification to the Agency for new authorized users, new authorized nuclear pharmacists and new authorized medical physicists;~~ .

~~e. The provisions of G.24a. regarding suppliers for sealed sources.~~

Sec. G.18~~G.16~~ - License Issuance.

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

i. The applicant has filed [insert name of proper Agency license application or form ID] in accordance with the instructions in G.12~~G.8~~;

ii. The applicant has paid any applicable fee as provided in [insert Agency's rule reference to Agency's fee table];

iii. ~~The applicant meets the requirements of Part C of these regulations; and~~

~~iv.~~ The Agency finds the applicant equipped and committed to observe the safety standards established by the Agency in the requirements applicable to licensed radioactive materials found in Parts A through Z of these regulations ~~in these regulations~~ for the protection of the public health and safety.

iv. The applicant meets the requirements of Part C of these regulations.

b. The Agency shall issue a license for mobile services if the applicant:

i. Meets the requirements in G.18a~~G.16a.~~; and

ii. Assures that individuals or human research subjects to whom unsealed radioactive material~~drugs~~ or radiation from implants containing radioactive material will be administered, may be released following treatment in accordance with G.75~~G.40~~.

Sec. G.19~~G.17~~ - Specific Exemptions. The Agency may, upon application of any interested person or upon its own initiative, grant such exemptions from the regulations in Part G as it determines are authorized by law and will not endanger life or property ~~or the common defense and security~~ and are otherwise in the public interest.

General Administrative Requirements

Sec. G.24~~G.18~~ - Authority and Responsibilities for the Radiation Protection Program.

a. In addition to the radiation protection program requirements of ~~D.101~~D.1101 of these regulations ~~of these regulations~~, a licensee's management ~~must~~shall approve in writing:

i. Requests for license application, renewal, or amendment(s) before submittal to the Agency;

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

iii. Radiation protection program changes that do not require a license amendment and are permitted under G.26~~G.19~~.

b. A licensee's management shall appoint a Radiation Safety Officer, who agrees in writing to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. A licensee's management may appoint, in writing. one or more Associate Radiation Safety Officers to support the Radiation Safety Officer. The Radiation Safety Officer, with written agreement of the licensee's management, shall assign the specific duties and tasks to each Associate Radiation Safety Officer. These duties and tasks are restricted to the types of use for which the Associate Radiation Officer is listed on a license. The Radiation Safety Officer may delegate duties and tasks to the Associate Radiation Safety Officer but shall not delegate the authority or responsibilities for implementing the radiation protection program.

c. For up to ~~sixty~~ 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,~~radiation safety officer~~ to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation

Safety Officer, as provided in G.24gG.18e., ifprovided the licensee takes the actions required in G.24b, G.24e, G.24g and G.24h.G.18b.,d.,e. and h. and notifies the Agency in accordance with G.14b.

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

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

f.e. Licensees that are authorized for two or more different types of uses of radioactive material under G.300 through G.396, G.400 through G.491, and G.600 through G.690, or two or more types of units under G.600 through G.690, shall establish a Radiation Safety Committee to oversee all uses of radioactive material permitted by the license. The Committee shall include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. The Committee may include other members the licensee considers appropriate.

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

i. Identify radiation safety problems;

ii. Initiate, recommend, or provide corrective actions;

iii. Stop unsafe operations; and,

iv. Verify implementation of corrective actions.

f. Licensees that are authorized for two or more different types of radioactive material use under G.52, G.59, G.71, and G.89, or two or more types of units under G.71 shall establish a Radiation Safety Committee to oversee all uses of radioactive material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer, and may include other members as the licensee deems appropriate.

[g. A licensee's Radiation Safety Committee shall meet as necessary, but at a minimum shall meet at intervals not to exceed 12 [6] months. The licensee shall maintain minutes of each meeting in accordance with G.90.]

h. A licensee shall retain a record of actions taken under G.24a, G.24b and G.24epursuant to G.18a., G.18b. and G.18d. in accordance with G.2024G.90.

[i. A licensee's Radiation Safety Committee shall meet as necessary, but at a minimum shall meet at

intervals not to exceed 12 [6] months. The licensee shall maintain minutes of each meeting in accordance with G.2024d.]

Sec. G.26~~G.19~~ - Radiation Protection Program Changes.

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

i. The revision does not require an amendment under G.13~~G.10~~;

ii. The revision is in compliance with the regulations and the license;

iii. The revision has been reviewed and approved by the Radiation Safety Officer, licensee management and licensee's Radiation Safety Committee, ~~(~~if applicable~~)~~; and

iv. The affected individuals are instructed on the revised program before the changes are implemented.

b. A licensee shall retain a record of each change in accordance with G.2026~~G.91~~.

~~Sec. G.20 - Duties of Authorized User and Authorized Medical Physicist.~~

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

~~i. Prescribe the radiopharmaceutical dosage and/or dose to be administered through the issuance of a written directive or reference to the diagnostic clinical procedures manual; and~~

~~ii. Direct, as specified in G.21 and G.22, or in license conditions, the administration of radioactive material for medical use to patients or human research subjects;~~

~~iii. Prepare and administer, or supervise the preparation and administration of radioactive material for medical use, in accordance with G.7b., G.7c. and G.21;~~

~~[iv. 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:~~

~~i. Full calibration measurements as described in G.77, G.78, and G.79;~~

~~ii. Periodic spot checks as described in G.80, G.81, and G.82; and~~

~~iii. Radiation surveys as described in G.84.~~

Sec. G.27~~G.21~~ - 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, ~~or~~ as allowed by G.11b.i~~G.7b.~~ shall:

i. In addition to the requirements in J.12 of these regulations, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, in the requirements applicable to licensed radioactive materials found in Parts A through Z of these regulations ~~of Part G~~, and license conditions with respect to the use of radioactive material; and

ii. Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures established by the licensee, written directive procedures, ~~regulations of Part G~~requirements applicable to licensed radioactive materials found in Parts A through Z of these regulations, and license conditions with respect to the medical use of radioactive material.

b. A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by G.11b.ii~~G.7c.~~, shall:

i. In addition to the requirements in J.12 of these regulations instruct~~Instruct~~ the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and

ii. Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, ~~the~~ written radiation protection procedures established by the licensee, the requirements applicable to licensed radioactive materials found in Parts A through Z of these regulations ~~of Part G~~, 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.21a. and G.21b. shall require an authorized user to be immediately available (by telephone within ten minutes) to communicate with the supervised individual, and able to be physically present within one hour of notification;] and~~

c.~~d.~~ A licensee that permits supervised activities under G.21a. and G.21b. is responsible for the acts and omissions of the supervised individual.

[d. Unless physical presence as described in other sections of Part G is required, a licensee who permits supervised activities under G.27a and G.27b shall require an authorized user to be immediately available by telephone or other means to communicate with the supervised individual, within one hour of notification.]

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

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

i. Prescribe the radiopharmaceutical dosage and/or radiation dose to be administered through the issuance of a written directive or reference to the diagnostic clinical procedures manual; and

ii. Direct, as specified in G.27 and G.40, or in license conditions, the administration of radioactive material for medical use to patients or human research subjects;

iii. Prepare and administer, or supervise the preparation and administration of radioactive material for medical use, in accordance with G.11b, G.11c and G.27;

b. A licensee shall assure that only authorized medical physicists perform full calibration measurements as described in G.632, G.633, and G.635;

c. A licensee shall assure that only authorized medical physicists or their designee perform, as applicable:

i. Periodic spot checks as described in G.642, G.643, and G.645; and

ii. Radiation surveys as described in G.652.

Sec. G.40~~G.22~~ - Written Directives.

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

i. If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is~~will be~~ acceptable.~~, provided that the~~ The information contained in the oral directive shall be ~~is~~ documented as soon as possible in writing in the patient's record. A ~~and a~~ written directive shall be~~is~~ prepared within 48 hours of the oral directive.

b. The written directive ~~must~~shall contain the patient or human research subject's name and the following information:

i. For any administration of quantities greater than 1.11 megabecquerels (30 µCi) of sodium iodide I-131: The dosage;

ii. For an administration of a therapeutic dosage of unsealed ~~radioactive drug containing~~ radioactive material other than sodium iodide I-131:~~, the~~ The radioactive drug ~~containing radioactive material~~, dosage, and route of administration;

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

iv.~~iii.~~ For teletherapy:~~, the~~ The total dose, dose per fraction, number of fractions, and treatment site;

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

vi.~~v.~~ For permanent implant brachytherapy:

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

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

vii. For all other brachytherapy including low, medium, and pulsed dose rate afterloaders~~LDR, MDR, and PDR~~:

(1) Before~~Prior to~~ implantation: The treatment site, ~~the~~ radionuclide, and dose; and

(2) After implantation but before~~prior to~~ completion of the procedure: The~~the~~ radionuclide~~radioisotope,~~ treatment site, number of sources,~~ and~~ either the total source strength and exposure time ~~(~~or~~,~~ the total dose~~)~~, and date.

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

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

d. The licensee shall retain the written directive in accordance with G.2040~~G.92~~.

Sec. G.41~~G.23~~ - Procedures for Administrations Requiring a Written Directive.

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

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

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

b. At a minimum, the~~The~~ procedures required by G.41a~~G.23a.~~ shall~~must, at a minimum,~~ address the following items that are applicable to~~for~~ the licensee's use of radioactive material:

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

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

iii. Checking both manual and computer-generated dose calculations;~~ and~~

iv. Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by G.600~~G.71~~ or G.1000;~~.~~

v. Determining if a medical event, as defined in G.3045, has occurred; and

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

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

Sec. G.49~~G.24~~ - Suppliers for Sealed Sources or Devices for Medical Use. For medical use, a licensee may only use:

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

b. Sealed sources or devices noncommercially transferred from a Part G licensee or a Nuclear Regulatory Commission or Agreement State medical use licensee.

c. Teletherapy sources manufactured and distributed in accordance with a license issued under~~pursuant to~~ Part C of these regulations or ~~the~~ equivalent requirements of the Nuclear Regulatory Commission, or an Agreement State~~ or a Licensing State~~.

Sec. G.50~~G.25~~ - Training for Radiation Safety Officer. Except as provided in G.57~~G.29~~, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer (RSO) or an individual assigned duties and tasks as an Associate Radiation Safety Officer (ARSO) as provided in G.24~~as provided in G.18~~ to be an individual who:

a. Is certified by a ~~speciality~~specialty board whose certification process ~~includes all of the requirements in G.25b. and whose certification~~ has been recognized by the Agency, the Nuclear

Regulatory Commission or an Agreement State and who meets the requirements in G.50d. The names of board certifications that have been recognized by the Agency, the Nuclear Regulatory Commission or an Agreement State are posted on the Nuclear Regulatory Commission's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to~~, or;~~[*] :

i. (1) Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

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

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

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

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

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

(b) In clinical nuclear medicine facilities providing diagnostic or therapeutic services under the direction of physicians who meet the requirements for authorized users in G.57, G.290, or G.390; and

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

b. i. Has completed a structured educational program consisting of both:

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

(a) Radiation physics and instrumentation;

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[*] ~~*Licensing State not included because compatibility B. State may want to recognize the Licensing State certification for NARM.*~~

(b) Radiation protection;

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

(d) Radiation biology; and

(e) Radiation dosimetry; and

(2) One year of full-time radiation safety experience under the supervision of the individual identified as the RSO on an Agency, a Nuclear Regulatory Commission or an Agreement State license or permit issued by a Nuclear Regulatory Commission master material license that authorizes similar type(s) of use(s) of radioactive material. An ARSO may provide supervision for those areas for which the ARSO is authorized on an Agency, a Nuclear Regulatory Commission or an Agreement State license or permit issued by a Nuclear Regulatory Commission master material licensee. The full-time radiation safety experience shall involve~~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~~dose calibrators~~, survey meters, and instruments used to measure radionuclides;

(c) Securing and controlling radioactive material;

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

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

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

(g) Disposing of radioactive material; and

ii. This individual shall ~~Has~~ obtain~~obtained~~ a written attestation~~certification~~, signed by a preceptor RSO, or ARSO who has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual is seeking approval as an RSO or an ARSO. The written attestation shall state, that the individual has satisfactorily completed the requirements in G.50b.i~~G.25b.i.~~ and G.50d, and is able~~has achieved a level of radiation safety knowledge sufficient~~ to independently fulfill the radiation safety-related duties~~function~~ as an RSO or as an ARSO for a medical use license~~uses of radioactive material~~; or

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

Agreement State under G.51a, has experience with the radiation safety aspects of similar types of use of radioactive material for which the licensee seeks the approval of the individual as RSO or ARSO, and meets the requirements in G.50d; or

ii. Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on an Agency, a Nuclear Regulatory Commission or Agreement State license, a permit issued by a Nuclear Regulatory Commission master material licensee, a permit issued by an Agency, Nuclear Regulatory Commission, or Agreement State licensee of broad scope, or a permit issued by a Nuclear Regulatory Commission master material license broad scope permittee,~~the licensee's license and~~ has experience with the radiation safety aspects of similar types of use of radioactive material for which the licensee seeks the approval of the individual as the~~has Radiation Safety Officer~~ RSO or ARSO and meets the requirements in G.50d; or~~responsibilities.~~

iii. Has experience with the radiation safety aspects of the types of use of radioactive material for which the individual is seeking simultaneous approval both as the RSO and the authorized user on the same new medical use license or new medical use permit issued by a Nuclear Regulatory Commission master material licensee. The individual shall also meet the requirements in G.50d.

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

Sec. G.51~~G.26~~ - Training for Authorized Medical Physicist. Except as provided in G.57, the~~The~~ licensee shall require the authorized medical physicist to be an individual who:

a. Is certified by a specialty~~speciality~~ board whose certification process ~~includes all of the training and experience requirements in G.26b. and whose certification~~ has been recognized by the Nuclear Regulatory Commission or an Agreement State~~*/; or~~ and who meets the requirements in G.51c. The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State are posted on the Nuclear Regulatory Commission's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

~~b.~~ i. Hold ~~Holds~~ a master's or doctor's degree in physics, ~~biophysics, radiological physics,~~ medical physics, or other physical science, engineering~~health physics~~, or applied mathematics from an accredited college or university;~~an equivalent training program approved~~

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

~~*/ Licensing State not included because compatibility B. State may want to recognize the Licensing State certification for NARM.~~

(1) Under the supervision of a medical physicist who is certified in medical physics by a specialty board whose certification process has been recognized under G.51 by the Agency, ~~the Agency, another~~an Agreement State or the Nuclear Regulatory Commission; or

(2) In clinical radiation facilities providing high-energy, external beam therapy using photons and electrons with energies greater than or equal to one million electron volts and brachytherapy services under the direction of physicians who meet the requirements in G.57, G.490, or G.690; and

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

b. i. Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university, ~~-~~and has completed one year of full-time training in medical~~therapeutic radiological~~ physics and an additional year of full-time work~~practical~~ experience under the supervision of an individual who meets the requirements for an~~a~~ authorized medical physicist for the type(s) of use for which the individual is seeking authorization. This training and work experience shall be conducted in clinical radiation facilities that provide high-energy, external beam therapy using photons and electrons with energies greater than or equal to one million electron volts and brachytherapy services and shall include:~~at a medical institution that includes the tasks listed in G.36, G.64e.,G.77, G.78, G.79, G.80, G.81, G.82 and G.84, as applicable; and~~

(1) Performing sealed source leak tests and inventories;

(2) Performing decay corrections;

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

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

ii.~~–~~ Has obtained written attestation ~~certification, signed by a preceptor authorized medical physicist,~~ that the individual has satisfactorily completed the requirements in G.51b.i~~G.26b.i.~~ and G.51c and is able ~~has achieved a level of competency sufficient~~ to independently fulfill the radiation safety-related duties~~function~~ as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation shall be signed by a preceptor authorized medical physicist who meets the requirements in G.51, G.57, or equivalent Nuclear Regulatory Commission or Agreement State requirements for an authorized

medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.

c. Has training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

Sec. G.55~~G.27~~ - Training for an Authorized Nuclear Pharmacist. Except as provided in G.57, the~~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.27b. and whose certification~~ has been recognized by the Agency, ~~-~~the Nuclear Regulatory Commission or an Agreement State. ~~*/; or~~ The names of board certifications that have been recognized by the Agency, the Nuclear Regulatory Commission or an Agreement State are posted on the Nuclear Regulatory Commission's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

i. Have graduated from a pharmacy program accredited by the Accreditation Council for Pharmacy Education[1] (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

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

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

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

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

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

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

[1] *previously named the American Council on Pharmaceutical Education.*

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

(e) Radiation biology; and

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

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

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

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

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

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

ii. Has obtained written attestation~~certification~~, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in G.55b.i~~G.27b.i.~~ and is able~~has achieved a level of competency sufficient~~ to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist.~~operate a nuclear pharmacy.~~

~~[Sec. G.28 – Training and Technical Requirements for Nuclear Medicine Technologists and Radiation Therapists.~~

~~a. The licensee shall require a nuclear medicine technologist using radioactive materials under the supervision of an authorized user to be an individual who:~~

~~i. Is certified in:~~

~~(1) Nuclear Medicine by the Nuclear Medicine Technology Certification Board;~~

~~(2) Nuclear Medicine by the American Registry of Radiologic Technologists with competency in Nuclear Medicine; or,~~

~~ii. Be board eligible to take the CNMT or ARRT(N) examinations; or,~~

~~iii. Has successfully completed a training program in nuclear medicine which has resulted in a certificate, associate degree, or baccalaureate degree in a nuclear medicine technology program from an accredited institution; or,~~

~~iv. Has performed as a full-time nuclear medicine technologist for a minimum of two years during the past five-year period under the supervision of an authorized user who certifies the experience in writing; or,~~

~~v. Has completed 80 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material that includes:~~

~~(1) Classroom and laboratory training in the following areas:~~

~~(a) Radiation physics and instrumentation;~~

~~(b) Radiation protection;~~

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

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

~~(e) Radiation biology; and~~

~~(2) Work experience, under the supervision of an authorized user involving:~~

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

~~(b) Quality Control checking of instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;~~

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

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

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

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

~~(3) Has obtained written certification, signed by a preceptor authorized user that the individual has satisfactorily completed the requirements of this section and has achieved a level of radiation safety competency sufficient to independently function as a nuclear medicine technologist.~~

~~b. The licensee shall require a radiation therapist using radioactive materials under the supervision of an authorized user to be an individual who:~~

~~i. Is certified in Radiation Therapy by the American Registry of Radiologic~~

~~Technologists(ARRT(T)); or~~

~~ii. Be board eligible to take the ARRT(T) examination; or,~~

~~iii. Has successfully completed a training program in radiation therapy which has resulted in a certificate, associate degree, or baccalaureate degree in a radiologic technology program that complies with the requirements of the Joint Review Committee on Education in Radiologic Technology;[2/] or,~~

~~iv. Has performed as a full-time radiation therapist for a minimum of two years during the past five-year period under the supervision of an authorized user who certifies the experience in writing; or~~

~~v. Has completed 200 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of radioactive material that includes:~~

~~(1) Classroom and laboratory training in the following areas:~~

~~(a) Radiation physics and instrumentation;~~

~~(b) Radiation protection;~~

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

~~(d) Radiation biology; and~~

~~(2) Work experience, under the supervision of an authorized user involving:~~

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

~~(b) Assisting the authorized user in simulating the patient for treatment;~~

~~(c) Preparing the patient for treatment;~~

~~(d) Implementing treatment plans as prescribed by the authorized user;~~

~~(e) Providing written documentation of treatment setup and patient treatments;~~

~~[2/] *"Essentials and guidelines of an Accredited Educational Program for the Radiation Therapy Technologist", Joint Review Committee on Education in Radiologic Technology, 1988.*~~

~~(f) Quality control checks to determine that devices used to deliver the radiation doses are in compliance with institutional standards and performing checks for proper operation of survey meters;~~

~~(g) Preparing or assisting in the preparation of sources, and implantation and removal of sealed sources;~~

~~(h) Delivering doses to patients or human research subjects under the supervision of the authorized user;~~

~~(i) Maintaining running inventories of radioactive material on hand;~~

~~(j) Using administrative controls to prevent a misadministration involving the use of radioactive material; and,~~

~~(k) Properly implementing emergency procedures; and~~

~~(3) Has obtained written certification, signed by a preceptor authorized user that the individual has satisfactorily completed the requirements of this section and has achieved a level of radiation safety competency sufficient to independently function as a radiation therapist~~

~~c. Individuals working as nuclear medicine technologists or radiation therapists for a facility holding an Agency license prior to [insert effective date of these rules] need not comply with the training requirements of this section.~~

~~d. The licensee shall maintain records of the above training as specified in G.104.]~~

Sec. G.57~~G.29~~ - Training~~Provisions~~ for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Medical Physicist, Authorized User, ~~and~~ Nuclear Pharmacist and Authorized Nuclear Pharmacist.

a. i. An individual identified ~~as a Radiation Safety Officer, a medical physicist, or a nuclear pharmacist on a Nuclear Regulatory Commission,~~ on an Agency, a Nuclear Regulatory Commission, or an Agreement State license or ~~on~~ a permit issued by an Agency, a Nuclear Regulatory Commission or Agreement State broad scope licensee or an NRC master material license permit or by an NRC master material license permittee of broad scope as a Radiation Safety Officer, a teletherapy or medical physicist, an authorized medical physicist, a nuclear pharmacist or an authorized nuclear pharmacist on or~~that authorizes medical use or the practice of nuclear pharmacy,~~ before ~~[insert effective date of the rule~~January 14, 2019~~]~~ need not comply with the training requirements of G.50~~G.25~~, G.51~~G.26~~ and G.55~~G.27~~, respectively~~.[*/]~~, except the Radiation Safety Officers and authorized medical physicists identified in G.57a shall meet the training requirements

~~[*/] Licensing State not included because compatibility B. State may want to recognize the Licensing State certification for NARM.~~

in G.50d or G.51c, as appropriate, for any material or uses for which they were not authorized prior to this date.

ii. An individual certified by the American Board of Health Physics in Comprehensive Health Physics; American Board of Radiology; American Board of Nuclear Medicine; American Board of Science in Nuclear Medicine; Board of Pharmaceutical Specialties in Nuclear Pharmacy; American Board of Medical Physics in radiation oncology physics; Royal College of Physicians and Surgeons of Canada in nuclear medicine; American Osteopathic Board of Radiology, or American Osteopathic Board of Nuclear Medicine on or before October 24, 2005, need not comply with the training requirements of G.50 to be identified as a Radiation Safety Officer or as an Associate Radiation Safety Officer on an Agency, a Nuclear Regulatory Commission or an Agreement State license or a Nuclear Regulatory Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005.

iii. Any individual certified by the American Board of Radiology in therapeutic radiological physics, Roentgen ray and gamma ray physics, x-ray and radium physics, or radiological physics, or certified by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2005, need not comply with the training requirements for an authorized medical physicist described in G.51, for those materials and uses that these individuals performed on or before October 24, 2005.

iv. [Reserved]

b. i. Physicians, dentists, or podiatrists identified as authorized users for the medical~~, dental, or podiatric~~ use of radioactive material on a license issued by an Agency, a Nuclear Regulatory Commission or an Agreement State~~, license or~~ a permit issued by a Nuclear Regulatory Commission master material licensee, ~~on~~ a permit issued by an Agency, a Nuclear Regulatory Commission or an Agreement State broad scope licensee, or a permit issued by a Nuclear Regulatory Commission master material license broad scope permittee on or ~~that authorizes medical use or the practice of nuclear pharmacy, issued~~ before ~~[insert effective date of the rule~~January 14, 2019~~]~~ who perform only those medical uses for which they were authorized on~~-~~ or before that date need not comply with the training requirements of G.100 through G.690. ~~G.46, G.51, G.56, G.57, G.58, G.67, G.68, G.70 and G.88.~~

ii. Physicians, dentists, or podiatrists not identified as authorized users for the medical use of radioactive material on a license issued by the Agency, the Nuclear Regulatory Commission or an Agreement State, a permit issued by a Nuclear Regulatory Commission master material licensee, a permit issued by an Agency, a Nuclear Regulatory Commission or Agreement State broad scope licensee, or a permit issued in accordance with a Nuclear Regulatory Commission master material broad scope license on or before October 24, 2005, need not comply with the training requirements of G.100 through G.690 for those materials and uses that these individuals performed on or before October 24, 2005, as follows:

(1) For uses authorized under G.100 or G.200, or oral administration of sodium

iodide I–131 requiring a written directive for imaging and localization purposes, a physician who was certified on or before October 24, 2005, in nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology by the American Board of Radiology; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or American Osteopathic Board of Nuclear Medicine in nuclear medicine;

(2) For uses authorized under G.300, a physician who was certified on or before October 24, 2005, by the American Board of Nuclear Medicine; the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or the American Osteopathic Board of Radiology after 1984;

(3) For uses authorized under G.400 or G.600, a physician who was certified on or before October 24, 2005, in radiology, therapeutic radiology or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and

(4) For uses authorized under G.500, a physician who was certified on or before October 24, 2005, in radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

iii. [Reserved]

c. Individuals who need not comply with training requirements as described in G.57 may serve as preceptors for, and supervisors of, applicants seeking authorization on Agency licenses for the same uses for which these individuals are authorized.

Sec. G.59~~G.30~~ - Recentness of Training. The training and experience specified in ~~Part G~~ G.24 through G.59, and G.100 through G.690~~must~~ shall have been obtained within the ~~7~~ seven years preceding the date of application or the individual ~~must~~shall have had related continuing education and experience since the required training and experience was completed.

General Technical Requirements

~~[Sec. G.31 – Quality Control of Diagnostic Equipment. Each licensee shall establish written quality control procedures for all diagnostic equipment used for radionuclide studies. As a minimum, quality control procedures and frequencies shall be those recommended by equipment manufacturers or procedures which have been approved by the Agency. The licensee shall conduct quality control~~

~~procedures in accordance with written procedures.]~~

Sec. G.60~~G.32~~ - Possession, Use, Calibration and Testing of Instruments to Measure the Activity of Unsealed Radioactive Materials.

a. For direct measurements performed in accordance with G.63~~G.34~~, a licensee shall possess and use instrumentation to measure the activity of unsealed radioactive materials before it is administered~~prior to administration~~ to each patient or human research subject.

b. A licensee shall test and calibrate the instrumentation required in G.60a~~G.32a.~~ in accordance with nationally recognized standards or the manufacturer's instructions.

c. A licensee shall retain a record of each instrument test and calibration required in G.60 in accordance with G.2060.

[d.~~c.~~ ~~[~~The tests required in G.60b~~G.32b.~~ shall, at a minimum. include tests for constancy~~,~~ and linearity~~, accuracy and geometry dependence,~~ as appropriate to demonstrate proper operation of the instrument.

e.~~d.]~~ The calibrations required in G.60b shall, at a minimum. include accuracy and geometric dependence, as appropriate, to demonstrate proper operation of the instrument.]~~A licensee shall retain a record of each instrument test required by G.32 in accordance with G.95.~~

Sec. G.61~~G.33~~ - Calibration of Survey Instruments.

a. A licensee shall ensure that the survey instruments used to show compliance with Part G and Part D of these regulations have been calibrated before first use, annually, and following any repair that will affect the calibration. The

~~b. To satisfy the requirements of G.33a., the~~ licensee shall:

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

ii. Calibrate two separated readings on each scale or decade that will be used to show compliance; and

~~ii. Have each radiation survey instrument calibrated:~~

~~(1) At energies appropriate for use and at intervals not to exceed 12 months or after instrument servicing, except for battery changes;~~

~~(2) For linear scale instruments, at two points located approximately one-third and two-thirds of full-scale on each scale; for logarithmic scale instruments, at mid-range of each decade, and at two points of at least one decade; and for digital~~

~~instruments, at 3 points between 0.02 and 10 millisieverts (2 and 1000 mrem) per hour; and~~

~~(3) 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.~~

iii. Conspicuously note on the instrument the date of calibration.

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

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

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

~~e.] The licensee shall retain a record of each survey instrument calibration in accordance with G.96.~~

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

Sec. G.63~~G.34~~ - Determination of Dosages of Unsealed Radioactive Material for Medical Use.

a. A licensee shall determine and record the activity of each dosage before~~prior to~~ medical use. [For photon-emitting radioactive material, this determination shall be within 30 minutes before~~prior to~~ medical use. For all other radioactive material, this determination shall be within the period before medical use that is no greater than 10 percent of the physical half-life of the radioactive material.]

b. For a unit dosage, this determination ~~must~~shall be made ~~either~~ by:

i. Direct ~~direct~~ measurement of radioactivity; or

ii. A ~~by a~~ decay correction, based on the activity or activity concentration determined by:

(1) A~~measurement made by a~~ manufacturer or preparer licensed pursuant to C.28j of these regulations~~Part C of these regulations~~ or equivalent ~~provisions of the~~ Nuclear Regulatory Commission~~,~~ or Agreement State requirements~~or Licensing State.~~; or

(2) An Agency, Nuclear Regulatory Commission, or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by the U.S.

Food and Drug Administration; or

(3) A PET radioactive drug producer licensed under C.24h of these regulations or equivalent Nuclear Regulatory or Agreement State requirements.

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

i. Direct ~~direct~~ measurement of radioactivity;

ii. Combination ~~or by a combination~~ of measurements of radioactivity and mathematical calculations; or

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

(1) A ~~a~~ manufacturer or preparer licensed under~~pursuant to~~ C.28j of these regulations~~Part C of these regulations~~ or equivalent ~~provisions of the~~ Nuclear Regulatory Commission, or Agreement State requirements~~or Licensing State~~.

(2) A PET radioactive drug producer licensed under C.24h of these regulations or equivalent Nuclear Regulatory Commission or Agreement State requirements.

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

e. A licensee shall retain a record of the dosage determination required by G.63~~Part G~~ in accordance with G.2063~~G.97~~.

Sec. G.65~~G.35~~ - Authorization for Calibration, Transmission and Reference Sources. Any person authorized by G.11~~G.7~~ for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration and reference use:

a. i. Sealed sources, not exceeding 1.11 gigabecquerels (30 mCi) each, manufactured and distributed by persons specifically licensed pursuant to C.28k of these regulations~~Part C of these regulations~~ or equivalent ~~provisions of the~~ Nuclear Regulatory Commission~~,~~ or Agreement State requirements~~or Licensing State~~;

ii. Sealed Sources ~~and that do~~ not exceeding~~exceed~~ 1.11 gigabecquerels (30 mCi) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under C.28k of these regulations or equivalent Nuclear Regulatory Commission or Agreement State regulations, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions;Any radioactive material with a half-life of not longer then 120 days ~~or less~~ in individual amounts not to exceed 0.56 gigabecquerels~~555 megabecquerels~~ (15 mCi);

Any radioactive material with a half-life longer~~greater~~ than 120 days in individual amounts not

to exceed the smaller of:

i. 7.4 megabecquerels (200 µCi); or

ii. 1000 times the quantities in Appendix B of Part C Appendix A of Part S of these regulations; or and

v. d. Technetium-99m in amounts as needed.

b. Radioactive material in sealed sources authorized by G.65 shall not be:

i. Used for medical use as defined in G.2 except in accordance with the requirements in G.500; or

ii. Bundled, aggregated, or otherwise combined to create an activity greater than the maximum activity of any single sealed source authorized under G.65.

c. A licensee using calibration, transmission, and reference sources in accordance with the requirements in G.65a or G.65b need not list these sources on a specific medical use license.

Sec. G.67 G.36 - Requirements for Possession of Sealed Sources and Brachytherapy Sources.

a. A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer[or equivalent instructions approved by the Agency].

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

i. Test the source for leakage before its first use unless the licensee has a certificate from the supplier indicating the source was tested within six months before transfer to the licensee; and in accordance with Part D of these regulations.

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

c. To satisfy the leak test requirements of G.67, the licensee shall measure the sample so that the leak test can detect If the leak test reveals the presence of 185 becquerels (0.005 µCi) or more of radioactive material in the sample. removable contamination, the licensee shall:

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

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

i. Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements in of Parts C and D of these regulations;

ii. File a report with the Agency within ~~5~~ five days of receiving the leak tests results in accordance with G.3067~~G.121~~.

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

i. Sources containing only radioactive material with a half-life of less than 30 days;

ii. Sources containing only radioactive material as a gas;

iii. Sources containing 3.7 megabecquerels (100 µCi) or less of beta or gamma-emitting material or 0.37 megabecquerels (10 µCi) or less of alpha-emitting material;

iv. Seeds of iridium-192 encased in nylon ribbon; and

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

g.~~d.~~ A licensee in possession of a sealed source or brachytherapy source, except for gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such sources. The licensee shall retain each inventory record in accordance with G.2067b~~G.98~~.

Sec. G.69~~G.37~~ - ~~Labels~~Labeling and Shielding of Vials and Syringes.

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

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

~~[Sec. G.38 – Vial Shields. A licensee shall require each individual preparing or handling a vial that contains a radioactive drug to keep the vial in a vial radiation shield.]~~

Sec. G.70~~G.39~~ - Surveys for Ambient Radiation Dose Rate [and Contamination].

a. Except as provided in G.70b~~G.39b.~~, in addition to the surveys required by Part D of these regulations, a licensee shall survey with a radiation detection survey instrument at the end of each day of use. A licensee shall survey all areas where ~~radioactive drugs containing~~ unsealed radioactive material~~material~~ requiring a written directive ~~were~~was prepared for use or administered.

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

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

[~~b~~d. A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radioactive drugs or radioactive wastes are stored, unless conditions have not changed.]

[e.~~c.~~ A licensee shall conduct the surveys required by G.70a~~G.39a.~~ and G.70b~~b.~~ so as to be able to measure dose rates as low as 1 microsievert (0.1 mrem) per hour.]

[f.~~d.~~ A licensee shall establish dose rate action levels for the surveys required by G.70a~~G.39a.~~ and G.70b~~G.39b.~~ and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if a dose rate exceeds an action level.]

[g.~~e.~~ A licensee shall survey for removable contamination each day of use all areas where generators and bulk radioactive drugs are prepared for use or administered and each week where radioactive materials are stored.

[h.~~f.~~ A licensee shall conduct the surveys required by G.70e~~G.39e.~~ so as to be able to detect contamination on each wipe sample of 33.3 becquerels (2000 dpm).]

[i.~~g.~~ A licensee shall establish removable contamination action levels for the surveys required by G.70e~~G.39e.~~ and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds action levels.]

~~h. A licensee does not need to perform the surveys required by G.39a. in area(s) where patients or human research subjects are confined when they can not be released pursuant to G.40.~~

~~i. A licensee shall retain a record of each survey in accordance with G.99.~~

Sec. G.75~~G.40~~ - Release of Individuals Containing ~~Radioactive Drugs~~Unsealed Radioactive Material or Implants Containing Radioactive Material.

a. A licensee may authorize the release ~~[~~from its control~~]~~ of any individual who has been administered unsealed radioactive materials~~radioactive drugs~~ or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisievert (0.5 rem).[3]

b. A~~For patients administered radioactive material for which a written directive is required, a~~ licensee shall provide the released individual, or the individual's parent or guardian, with ~~oral and written~~ instructions, including oral and written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 millisievert (0.1 rem). If the total effective dose equivalent to a breast-feeding infant or child could exceed 1 millisievert (0.1 rem) assuming there was~~were~~ no interruption of breast-feeding, the instructions shall also include:[*/]

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3 The current revision of NREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program Specific Guidance About Medical Licenses" describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem).

~~*/ This may have health and safety implications, see Rational for Part G 2002~~

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

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

[b. A licensee shall provide the released individual, or the individual's parent or guardian, with oral and written instructions on actions recommended to maintain doses to other individuals as low as is reasonably achievable. If a breast-feeding infant or child could receive a radiation dose as a result of the release of the patient, the instructions shall also include:

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

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

[c. Release of t be approved by an individual 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.]

cd. The licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with G.2075aG.100.

d.e. The licensee shall maintain a record of instructions provided to breast-feeding women in accordance with G.2075bG.100.

[e.f. Notwithstanding G.75aG.40a., the licensee may be held responsible for the proper disposal of any individual's radioactive waste discovered in a solid waste stream that can be traced to the licensee.]

g. The licensee shall immediately notify the Agency in accordance with G.122 if a patient departs prior to an authorized release.

h. The licensee shall notify the Agency in accordance with G.123:

i. When they are aware that a patient containing radioactive material and who has been released in accordance with G.40 dies; and,

ii. 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.

Sec. G.80G.41 - Provision of Mobile Medical Service Technical Requirements.

a. A licensee providing mobile medical services shall:

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

i. Obtain a letter signed by the management of each client for which services are rendered that permits the use of radioactive material at the client's address of use and clearly delineates the authority and responsibility of both the client and the mobile

medical service. [If the client is licensed, the letter shall document procedures for notification, receipt, storage, and documentation of transfer of radioactive material delivered to the client's address for use by the mobile medical service.];

ii. Check instruments used to measure the activity of unsealed radioactive material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function, required by G.80a, shall include a constancy check;

iii. Check survey instruments for proper operation with a dedicated check source before use at each client's address;

iv. Before leaving a client's address, survey all areas of use to ensure compliance with Part D of these regulations;

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

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

b. A mobile medical service shall not have radioactive material delivered directly from the manufacturer or the distributor to the client, unless the client has a license allowing possession of the radioactive material. Radioactive material delivered to the client shall be received and handled in conformance with the client's license.~~Bring into each client's address all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;~~

c. A licensee providing mobile medical services shall retain the letter required in G.80a.i and the record of each survey required in G.80a.iv in accordance with G.2080a and G.2080b, respectively.~~Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at a client's address;~~

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

[e. A mobile medical service licensee shall, at a minimum, maintain or have access to the following documents on each mobile unit:

i. The current operating and emergency procedures;

ii. A copy of the license;

iii. Copies of the letter required by G.80a.i;

iv. Copies of and/or access to electronic records with proper signatures of:

(1) Current calibration records for each survey instrument and diagnostic equipment or dose delivery device in use; and

(2) Survey records covering uses associated with the mobile unit during, at a minimum, the preceding [insert number of calendar days determined by Agency].

[f. A mobile medical service licensee shall maintain all records required by Parts D and G of these regulations at a location within the Agency's jurisdiction identified on the license. For purposes of inspection, these records shall be available to the Agency at all reasonable hours of operation at:

i. A single address of use; or

ii When no address of use is identified on the license for records retention, the mobile unit identified in the license.]

~~d. Check instruments used to measure the activity of unsealed radioactive material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function shall include a constancy check;~~

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

~~f. Prior to leaving a client's address, perform area surveys and survey for removable contamination in all areas of use, to ensure compliance with Part D of these regulations;~~

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

~~h. Retain a record of each survey required by G.41f. in accordance with G.101.~~

[Sec. G.85~~G.42~~ - Storage and Control of Volatiles and Gases.

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

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

c. A licensee who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed in Part D of these regulations.

d. The system shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.

e. A licensee shall check the operation of collection systems monthly. Records of these checks shall be maintained for ~~3~~ three years.]

Sec. G.92~~G.43~~ - Decay-in-Storage.

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

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

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

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

b. A~~For radioactive material disposed in accordance with G.43a. of this section, the~~ licensee shall retain a record of each disposal permitted under G.92a in accordance with G.2092~~G.102~~.

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

Sec. G.100~~G.44~~ - Use of Unsealed Radioactive Material for Uptake, Dilution, or Excretion Studies for which a Written Directive is Not Required. Except for quantities that require a written directive under G.40b, a~~A~~ licensee may use any unsealed radioactive material, prepared for medical use for ~~in quantities that do not require a written directive, for a diagnostic use involving measurements of~~ uptake, dilution, or excretion studies that is:

a. Obtained from:

i. A~~a~~ manufacturer or preparer licensed pursuant to C.28j~~Part C~~ of these regulations or equivalent ~~regulations of another~~ Agreement State~~, a Licensing State,~~ or ~~the~~ Nuclear Regulatory Commission requirements; or

ii. A PET radioactive drug producer licensed under C.24h of these regulations, or equivalent Agreement State or Nuclear Regulatory Commission requirements; or

b. Excluding production of PET radionuclides, prepared~~Prepared~~ by:

i. An~~an~~ authorized nuclear pharmacist;

ii. A~~, a~~ physician who is an authorized user and who meets the requirements specified in

G.290~~G.46~~, or G.390~~G.51~~ and G.290c.i(2)(g);~~,~~ or

iii. An ~~an~~ individual under the supervision, ~~of either~~ as specified in G.27~~G.21~~,~~; or~~ of the authorized nuclear pharmacist in G.100b.i or the physician who is an authorized user in G.100b.ii; or

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

d. Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA. ~~for use in research.~~

~~[Sec. G.45 – 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.33.]~~

Sec. G.190~~G.46~~ - Training for Uptake, Dilution, and Excretion Studies. Except as provided in G.57~~G.29~~, the licensee shall require an authorized user of an unsealed radioactive material for the uses authorized under G.100~~G.44~~ to be a physician who:

a. Is certified by a medical specialty board whose certification process ~~includes all of the requirements in G.46c. and whose certification~~ has been recognized by the Agency, the Nuclear Regulatory Commission, or an Agreement State.~~; or~~ The names of board certifications which have been recognized by the Agency, the Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolbox web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

~~b. Is an authorized user under G.51 or G.56, or equivalent Agreement State or Nuclear Regulatory Commission requirements; or~~

~~c.~~ i. Complete~~Has completed~~ 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:~~as described in G.190c.i(1) through G.190c.i(2)(f); and

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

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~~[*/] *Licensing State not included because compatibility B. State may want to recognize the Licensing State certification for NARM.*~~

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

c. i. Has completed 60 hours of training and experience, including a minimum of eight hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience shall include:

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

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

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

(e) Radiation biology; and

(2) Work experience, under the supervision of an authorized user who meets the requirements in G.57~~G.46~~, G.190~~G.51~~, G.290, ~~or~~ G.390~~G.56~~ or equivalent Agreement State~~,~~ or Nuclear Regulatory Commission requirements, involving:

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

(b) Performing quality control procedures on~~Calibrating~~ 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~~misadministration~~ involving the use of unsealed radioactive material;

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

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

ii. Has obtained written attestation~~certification, signed by a preceptor authorized user, who meets the requirements in G.46, G.51 or G.56 or equivalent Agreement State, or Nuclear Regulatory Commission requirements,~~ that the individual has satisfactorily completed the

requirements in G.190c.iG.46c.i. and has achieved a level of competency sufficient is able to independently fulfill the radiation safety-related dutiesfunction as an authorized user for the medical uses authorized under G.100G.44.. The attestation shall be obtained from either:

(1) A preceptor authorized user who meets the requirements in G.57, G.190, G.290, G.390, or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

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

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

Sec. G.200G.47 - Use of Unsealed Radioactive Material for Imaging and Localization Studies for which a Written Directive is Not Required. Except for quantities that require a written directive under G.40(b), aA licensee may shall use, for imaging and localization studies, any radioactive material prepared for medical use, in quantities that do not require a written directive as described in G.22 that is:

a. Obtained from:

i. A a manufacturer or preparer licensed pursuant tounder C.28jPart C of these regulations or equivalent regulations of another Agreement State, a Licensing State, or the Nuclear Regulatory Commission requirements; or

ii. A PET radioactive drug producer licensed under C.28h of these regulations, or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

b. Excluding production of PET radionuclides, preparedPrepared by:

i. An an authorized nuclear pharmacist;

ii. A, a physician who is an authorized user and who meets the requirements specified in G.290G.51, or G.390 and G.290c.i(2)(g); or

iii. An~~an~~ individual under the supervision, ~~of either~~ as specified in G.27~~G.21~~, of the authorized nuclear pharmacist in G.290b.i or the physician who is an authorized user in G.290b.ii; or

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

d. Prepared by the licensee, for use in research, in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

[e. Provided the conditions of G.85~~G.42~~ are met, a licensee shall use radioactive aerosols or gases only if specific application is made to and approved by the Agency.]

Sec. G.204~~G.48~~ - Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations~~Radionuclide Contaminants~~.

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

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

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

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

b. A licensee that uses molybdenum-99/technitium-99 generators for preparing a technitium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in each eluate from a generator to demonstrate compliance with G.204.a.~~To demonstrate compliance with G.48a., the licensee preparing radioactive drugs from radionuclide generators shall:~~

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

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

c. A licensee that uses a strontium-82/rubidium-82 generator for preparing a rubidium-82 radiopharmaceutical shall, before the first patient use of the day, measure the concentration of radionuclides strontium-82 and strontium-85 to demonstrate compliance with G.204a.

d. If a~~A~~ licensee ~~who must~~is required to measure the molybdenum-99~~radionuclide contaminant~~ concentration or strontium-82 and strontium-85 concentrations, the licensee shall retain a record

of each measurement in accordance with G.2204~~G.103~~.

e.~~d.~~ A licensee shall report any measurement that exceeds the limits in G.204a at the time of generator elution, in accordance with G.3204~~immediately to the Agency each occurrence of radionuclide contaminasnt concentration exceeding the limits specified in G.48a~~.

~~[Sec. G.49 – Reserved.]~~

~~[Sec. G.50 – Possession of Survey Instruments. A licensee authorized to use radioactive material for imaging and localization studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrems) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 10 microsieverts (1 mrem) per hour to 10 millisieverts (1000 mrems) per hour. The instruments shall be operable and calibrated in accordance with G.33.]~~

Sec. G.290~~G.51~~ - Training for Imaging and Localization Studies. Except as provided in G.57~~G.29~~, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under G.200~~G.47~~ to be a physician who:

a. Is certified by a medical specialty board whose certification process ~~includes all of the requirements in G.51c. and whose certification~~ has been recognized by the Agency, an Agreement State or the Nuclear Regulatory Commission.~~;*/ or~~ The names of board certifications which have been recognized by the Agency, the Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

i. Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for imaging and localization studies as described in G.290c.i(1) through G.290c.i(2)(g); and

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

b. Is an authorized user under G.390~~G.56~~, or equivalent Agreement State, or Nuclear Regulatory Commission requirements; or

c. i. Has completed 700 hours of training and experience including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. ~~that includes,~~The training and experience shall include, at a minimum:

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

~~*/ Licensing State not included because compatibility B. State may want to recognize the Licensing State certification for NARM.~~

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

(d) Chemistry of radioactive material for medical use;

(e) Radiation biology; and

(2) Work experience, under the supervision of an authorized user, who meets the requirements in G.57~~G.51 or G.56~~, G.290, or G.390 and G.290c.i(2)(g) or equivalent Agreement State~~,~~ or Nuclear Regulatory Commission requirements.~~,~~ ~~involving:~~ An authorized nuclear pharmacist who meets the requirements in G.55 or G.57 may provide the supervised work experience for G.290c.i.(2)(g). Work experience shall involve:

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

(b) Performing quality control procedures on~~Calibrating~~ 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~~misadministration~~ involving the use of unsealed radioactive material;

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

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

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

ii. Has obtained written attestation~~certification, signed by a preceptor authorized user, who meets the requirements in G.51 or G.56, or equivalent Agreement State, or Nuclear Regulatory Commission requirements,~~ that the individual has satisfactorily completed the requirements in G.290c.i~~G.51c.i.~~ and ~~has achieved a level of competency sufficient to~~is able to ~~independently~~ fulfill the radiation safety-related duties~~function~~ as an authorized user for the medical uses authorized under G.100 and G.200~~G.47~~. The attestation shall be

obtained from either:

(1) A preceptor authorized user who meets the requirements in G.57, G.290, or G.390 and G.290c.i(2)(g), or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

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

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

Sec. G.300~~G.52~~ - Use of Unsealed Radioactive Material for which a Written Directive is Required. A licensee may use any unsealed radioactive material identified in G.390b.i(2)(g) prepared for ~~diagnostic or therapeutic~~ medical use for which a written directive is required that ~~has been~~ is:

a. Obtained from:

i. A ~~a~~ manufacturer or preparer licensed in accordance with C.28j~~Part C~~ of these regulations or equivalent Nuclear Regulatory Commission or Agreement State regulations; or

ii. A PET radioactive drug producer licensed under C.24h of these regulations or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

b. Excluding production of PET radionuclides prepared~~Prepared~~ by:

i. An ~~an~~ authorized nuclear pharmacist;

ii. A~~, a~~ physician who is an authorized user and who meets the requirements specified in G.290~~G.51 or~~, G.390~~G.56;~~, or

iii. An ~~an~~ individual under the supervision, ~~of either~~ as specified in G.27~~G.29~~, of the authorized nuclear pharmacist in G.300b.i or the physician who is an authorized user in G.300b.ii; or

c. Obtained from and prepared by an Agency, Nuclear Regulatory Commission, or Agreement State~~, or Licensing State~~ licensee for use in research in accordance with ~~a Radioactive Drug~~

Research Committee-approved protocol ori an Investigational New Drug (IND) protocol accepted by the FDA for use in research; or

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

Sec. G.310G.53 - Safety Instruction. In addition to the requirements of J.12 of these regulations:

a. A licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects that have received therapy with a radioactive drug, and cannot be released underin accordance with G.75G.40. To satisfy this agreement, the instruction shallThe training must be provided initially and at least annually. The instruction must be appropriate to the personnel's assigned with the duties of the personnel and include the following:

i. Patient or human research subject control;

ii. Visitor control includingto include the following:

(1) Routine visitation to hospitalized individuals in accordance with D.1301a.iPart D of these regulations;

(2) Visitation authorized in accordance with D.1301c of these regulations;

iii. Contamination control;

iv. (3) Waste control; and

v. (4) Notification of the RSO, or his or her their designee, and the an authorized user for the type of radioactive materials used in the treatment if the patient or the human research subject dies or has a medical emergency.

b. A licensee shall retain a record of individuals receiving instruction in accordance with G.2310G.105.

Sec. G.315G.54 - Safety Precautions.

a. For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance withwho cannot be released under G.75G.40, a licensee shall:

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

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

(2) A room, with a private sanitary facility, with another individual who also has received similar radiopharmaceutical therapy and who cannot be released underin accordance with G.75G.40; and,

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

iii. Note ~~and note~~ on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room; and

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

b. A licensee shall notify the~~The~~ Radiation Safety Officer, or their~~his or her~~ designee, and an~~the~~ authorized user approved for the use of the type of radioactive materials used in the treatment as soon as possible~~shall be notified immediately~~ if the ~~hospitalized~~ patient or human research subject has a ~~dies or~~ has a medical emergency or dies. ~~The licensee shall also notify the Agency in accordance with G.123 if it is possible that any individual could receive exposures in excess of Part D.301 of these regulations as a result of the deceased's body.~~

~~[Sec. G.55 – Possession of Survey Instruments. 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 radiation measurement survey instrument capable of measuring dose rates over the range of 10 microsieverts (1 mrem) per hour to 10 millisieverts (1000 mrems) per hour. The instruments shall be operable and calibrated in accordance with G.33.~~]

Sec. G.390~~G.56~~ - Training for Use of Unsealed Radioactive Material for which a Written Directive is Required. Except as provided in G.57~~G.29~~, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under G.300~~G.52~~ to be a physician who:

a. Is certified by a medical specialty board whose certification process ~~includes all of the requirements of G.56b. and whose certification~~ has been recognized by the Agency, an Agreement State or the Nuclear Regulatory Commission;~~[*/] or~~ and who meets the requirements in G.390b.i(2)(g). The names of board certifications that have been recognized by the Agency, the Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses License Toolkit web page. To be recognized, a specialty board shall require all candidates for certification to:

i. Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs shall include 700 hours of training and experience as described in G.390b.i(1) through G.390b.i(2)(e). Eligible training programs shall be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the

~~[*/] *Licensing State not included because compatibility B. State may want to recognize the Licensing State certification for NARM.*~~

Royal College of Physicians and Surgeons of Canada, or the Council on Postdoctoral Training of the American Osteopathic Association; and

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

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

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

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

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

(e) Radiation biology; and

(2) Work experience, under the supervision of an authorized user who meets the requirements in G.57~~G.56~~, G.390, or equivalent Agreement State~~,~~ or Nuclear Regulatory Commission requirements. A supervising authorized user, who meets the requirements in G.390b~~of G.56b.~~ ~~must~~ shall have experience in administering dosages in the same dosage category or categories listed in G.390b.ii(2)(g)~~G.56b.ii.~~ as the individual requesting authorized user status. The work experience ~~must~~shall involve:

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

(b) Performing quality control procedures on~~Calibrating~~ 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~~misadministration~~ involving the use of unsealed radioactive material;

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

proper decontamination procedures;

(f) [Reserved]~~Administering dosages to patients or human research subjects; and~~

(g) ~~Eluting generator systems, measuring and testing the eluate for radiochemical purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs containing radioactive material; and~~

~~ii.~~ Administering dosages of radioactive drugs to patients or human research subjects from the three categories in G.390b.i(2)(g). Radioactive drugs containing radionuclides not included in G.390b.i.(2)(g) are regulated under G.1000. This work experience shall involve~~involving~~ a minimum of ~~3~~ three cases in each of the following categories for which the individual is requesting authorized user status:~~. This experience may be obtained concurrently with the supervised work experience required by G.56b.i.(2):~~

(i)~~(1)~~ Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131. for which a written directive is required;

(ii)~~(2)~~ Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131;[4/]

(iii)~~(3)~~ Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics,~~emitter~~ or ~~a photon-emitting radionuclide with a~~ photon energy less than 150 keV, for which a written directive is required; and~~/or~~

~~(4) Parenteral administration of any other radionuclide; and~~

iii. Has obtained written attestation~~certification, signed by a preceptor authorized user, who meets the requirements in G.56 or equivalent Agreement State, or Nuclear Regulatory Commission requirements,~~ that the individual has satisfactorily completed the requirements in G.392b.i~~G.56b.i. and G.56b.ii.~~ and ~~has achieved a level of competency sufficient~~ is able to independently fulfill~~function~~ the radiation safety-related duties as an authorized user for the medical uses authorized under G.300~~G.56~~ for which the authorized user is requesting authorized user status. The written attestation shall be obtained from either:~~. The preceptor authorized user who meets the requirements of G.56b. must have experience in administering dosages in the same dosage category or categories listed in G.56b.ii. as the individual requesting authorized user status.~~

[4/] Experience with at least ~~3~~ three cases in category G.390b.i.(2)(g)(ii) also satisfies the requirement in category G.390b.i(2)(g)(i)~~(1)~~.

(1) A preceptor authorized user who meets the requirements in G.57, G.390 or equivalent Nuclear Regulatory Commission or Agreement State requirements and has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status; or

(2) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in G.57, G.390 or equivalent Nuclear Regulatory Commission or Agreement State requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training shall be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and shall include training and experience specified in G.390b.i.

~~G.57~~ - Training for the Oral Administration of Sodium Iodide I-131 in Quantities Less than or Equal to 1.22 Gigabecquerels (33 millicuries) for which a Written Directive is Required.~~*/~~ Except as provided in G.57~~G.29~~, 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)~~, for which a written directive is required,~~ to be a physician who:

a. Is certified by a medical specialty board whose certification process includes all of the requirements in G.392c.i and G.392c.ii~~G.57c.~~ and whose certification process has been recognized by the Agency, an Agreement State or the Nuclear Regulatory Commission. The names of board certifications whose certification has been recognized by the Agency, Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page.);~~**/~~ or

b. Is an authorized user under G.390~~G.56a., G.56b.~~, for uses listed in G.390b.i(2)(g)(i) or G.390b.i(2)(g)(ii)~~G.56b.ii.(1) or (2)~~, G.394~~G.58~~ or equivalent Agreement State or Nuclear Regulatory Commission requirements; or

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

(1) Radiation physics and instrumentation;

(2) Radiation protection;

~~*/ This rule has possible health and safety implications, please see Rationale for Part G 2002 for additional information.~~
~~**/ Licensing States not included because of compatibility B. States may want to recognize the Licensing States Certification for NARM.~~

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

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

(5) Radiation biology; and

ii. Has work experience under the supervision of an authorized user who meets the requirements in G.57~~G.56a.~~, G.390~~G.56b.~~, G.392~~G.57~~, ~~or~~ G.394~~G.58~~, or equivalent Agreement State, or Nuclear Regulatory Commission requirements. A supervising authorized user who meets the requirements of G.390b~~G.56b~~. ~~must~~shall also have experience in administering dosages as specified in G.390b.i(2)(g)(i)~~G.56b.ii.(1)~~ or G.390b.i(2)(g)(ii)~~G.56b.ii.(2);~~. The~~the~~ work experience ~~must~~shall involve:

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

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

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

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

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

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

iii. Has obtained written attestation~~certification~~ that the individual has satisfactorily completed the requirements in G.392c.i~~G.57c.i.~~ and G.392c.ii~~G.57c.ii.~~, and ~~has achieved a level of competency sufficient~~is able to independently fulfill the radiation safety-related duties~~function~~ as an authorized user for oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of ~~medical uses of unsealed radioactive material using~~ sodium iodide I-131 for medical uses authorized under G.300. The attestation~~written certification~~ ~~must~~ shall be obtained from~~signed by~~:

(1) A ~~a~~ preceptor authorized user who meets the requirements of G.57~~G.56a.~~, G.390~~G.56b~~, G.392~~G.57~~, ~~or~~ G.394~~G.58~~, or equivalent Agreement State or Nuclear Regulatory Commission requirements and has~~. The preceptor authorized user who meets the requirements of G.56b. must have~~ experience in administering dosages as specified in G.390b.i(2)(g)(i)~~G.56b.ii.(1) and/~~ or G.390b.i(2)(g)(ii)~~(2);~~ or~~.~~

(2) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in G.57, G.390, G.392, G.394, or equivalent Nuclear Regulatory Commission or Agreement State requirements, has experience in administering dosages as specified in G.390b.i(2)(g)(i) or G.390b.i(2)(g)(ii),a and concurs with the attestation provided by the residency program director. The residency training shall be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and shall include training and experience specified in G.392c.i or G.392c.ii.

Sec. G.394~~G.58~~ - Training for the Oral Administration of Sodium Iodide I-131 in Quantities Greater than 1.22 Gigabecquerels (33 millicuries) for which a Written Directive is Required.~~*/~~ Except as provided in G.57~~G.29~~, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries), to be a physician who:

a. Is certified by a medical specialty board whose certification process includes all of the requirements in G.394c.i and G.394c.ii~~G.57c.~~ and whose certification has been recognized by the Agency, an Agreement State or the Nuclear Regulatory Commission. The names of board certifications that have been recognized by the Agency, the Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensees Toolkit web page; or

b. Is an authorized user under G.390~~G.56a., G.56b.~~ for uses listed in G.390b.i(2)(g)(ii)~~G.56b.ii.(2i)~~, or equivalent Agreement State, ~~Licensing State~~ or Nuclear Regulatory Commission requirements; or

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

(1) Radiation physics and instrumentation;

(2) Radiation protection;

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

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

(5) Radiation biology; and

ii. Has work experience, under the supervision of an authorized user who meets the requirements in G.57~~G.56a.~~, G.390~~G.56b.~~, G.394~~G.58~~, or equivalent Agreement State~~,~~ or

~~*/ This rule has possible health and safety implications, please see Rationale for Part G 2002 for more information.~~

Nuclear Regulatory Commission requirements. A supervising authorized user, who meets the requirements ~~of~~ in G.390b~~G.56b.~~, ~~must~~shall also have experience in administering dosages as specified in G.390b.i(2)(g)(ii)~~G.56b.ii.(2)~~. ~~-~~The work experience ~~must~~shall involve:

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

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

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

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

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

(6) Administering dosages to patients or human research subjects that includes at least three~~3~~ cases involving the oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

iii. Has obtained written attestation~~certification~~ that the individual has satisfactorily completed the requirements in G.390c.i~~G.58c.i.~~ and G.390c.ii~~G.58c.ii.~~ and ~~has achieved a level of competency sufficient~~is able to independently fulfill the radiation safety-related duties~~function~~ as an authorized user for oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses of ~~unsealed radioactive material using sodium iodide I-131 in activities~~ greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under G.300. The attestation~~written certification~~ ~~must~~shall be ~~signed by~~obtained from either:

(1) A ~~a~~ preceptor authorized user, who meets the requirements ~~of~~ in G.57~~G.56b.~~, G.390~~G.58~~, G.394, or equivalent Agreement State or Nuclear Regulatory Commission requirements and has~~. A preceptor authorized user who meets the requirements of G.56b., must have~~ experience in administering dosages as specified in G.390b.i(2)(g)(ii)~~G.56b.ii.(2).~~ ; or

(2) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in G.57, G.390, G.394, or equivalent Nuclear Regulatory Commission or Agreement State requirements, has experience in administering dosages as specified in G.390b.i.(2)(g)(ii), and concurs with the attestation provided by the residency program director. The residency training shall be approved by the Residency Review Committee of the

Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and shall include training and experience specified in G.390c.i and G.390c.ii.

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

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

i. Is an authorized user under G.390 for uses listed in G.390b.i(2)(g)(iii), or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

ii. Is an authorized user under G.490, G.690, or equivalent Nuclear Regulatory Commission or Agreement State requirements, and who meets the requirements in G.396b;

iii. Is certified by a medical specialty board whose certification process has been recognized by the Agency, the Nuclear Regulatory Commission, or an Agreement State under G.490 or G.690, and who meets the requirements in G.390b.

b. The physician:

i. Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations listed in G.390b.i(2)(g)(iii). The training shall include:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

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

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

(5) Radiation biology; and

ii. Has work experience, under the supervision of an authorized user who meets the requirements in G.57, G.390, G.396, or equivalent Agreement State requirements, in the parenteral administrations listed in G.390b.i(2)(g)(iii). A supervising authorized user who meets the requirements in G.390, G.396, or equivalent Nuclear Regulatory Commission or Agreement State requirements, shall have experience in administering dosages in the same category or categories as the individual requesting authorized user status. The work experience shall involve:

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

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

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

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

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

(6) Administering dosages to patients or human research subjects, that include at least three cases of the parenteral administrations as specified in G.390b.i(2)(g)(iii); and

iii. Has obtained written attestation that the individual has satisfactorily completed the requirements in G.396b.i and G.396b.ii, and is able to independently fulfill the radiation safety-related duties as an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive. The attestation shall be obtained from either:

(1) A preceptor authorized user who meets the requirements in G.57, G.390, G.396, or equivalent Nuclear Regulatory Commission or Agreement State requirements. A preceptor authorized user who meets the requirements in G.390, G.396, or equivalent Nuclear Regulatory Commission or Agreement State requirements, shall have experience in administering dosages in the same category or categories as the individual requesting authorized user status; or

(2) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in G.57, G.390, G.396, or equivalent Nuclear Regulatory Commission or Agreement State requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program shall be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and shall include training and experience specified in paragraphs G.396b.i and G.396b.ii.

Manual Brachytherapy

Sec. G.400~~G.59~~ - Use of Sealed Sources for Manual Brachytherapy. A licensee shall ~~use~~ only use

brachytherapy sources~~ for therapeutic medical uses~~:

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

b. In research to deliver therapeutic doses for medical use in accordance with an active~~effective~~ Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of G.49a~~G.24a.~~ are met.

Sec. G.404~~G.60~~ - Surveys After Source Implant and Removal.

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

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

c. A licensee shall retain a record of the surveys required by G.404a and G.404b in accordance with G.2404~~G.106~~.

Sec. G.406~~G. 61~~ - Brachytherapy Sources Accountability~~Inventory~~.

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

b. As soon as possible~~Promptly~~ 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~~G.107~~.

Sec. G.410~~G.62~~ - Safety Instruction. In addition to the requirements of J.12 of these regulations:

a. The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects ~~that are undergoing implant therapy~~who are receiving brachytherapy and cannot be released under~~in accordance with~~ G.75~~G.40~~. To satisfy this requirement, the instruction~~Instruction~~ ~~must~~ shall be commensurate with the duties of the personnel and shall include the~~ following~~:

i. Size and appearance of the brachytherapy sources;

ii. Safe handling and shielding instructions;

iii. Patient or human research subject control;

iv. Visitor control, including both:

(1) Routine visitation of hospitalized individuals in accordance with D1301a.i~~D.301a.i.~~ of these regulations; and

(2) Visitation authorized in accordance with D.1301c~~D.301c.~~ of these regulations; and

v. Notification of the Radiation Safety Officer, or his or her designee, and an authorized user if the patient or the human research subject ~~dies or~~ has a medical emergency or dies. ~~The licensee shall also notify the Agency in accordance with G.123 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.~~

b. A licensee shall retain a record of individuals receiving instruction in accordance with G.2310~~G.105~~.

Sec. G.415~~G.63~~ - Safety Precautions for Patients or Human Research Subjects Receiving Brachytherapy.

a. For each patient or human research subject that is receiving brachytherapy and cannot be released under~~in accordance with~~ G.75~~G.40~~, a licensee shall:

i. Not quarter~~place~~ the patient or human research subject in the same room as an individual who is not receiving brachytherapy;

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

iii. Note ~~and note~~ on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room.

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

i. Dislodged from the patient; or

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

c. A licensee shall notify the~~The~~ Radiation Safety Officer, or their~~his or her~~ designee, and an~~the~~ authorized user for the materials involved shall be notified as soon as possible immediately if the ~~hospitalized~~ patient or human research subject ~~dies or~~ has a medical emergency or dies.

Sec. G432~~G.64~~ - Calibration Measurements of Brachytherapy Sealed Sources.

a. Before~~Prior to~~ the first medical use of a brachytherapy ~~sealed~~ source on or after [insert effective date of the rule], a licensee shall have:~~perform the following:~~

i. Determined~~Determine~~ the source output or activity using a dosimetry system that meets the requirements of G.630a~~G.76a.~~;

ii. Determined~~Determine~~ source positioning accuracy within applicators; and

iii. Used~~Use~~ published protocols currently accepted by nationally recognized bodies to meet the requirements of G.432a.i~~G.64a.i.~~ and G.432a.ii~~G.64a.ii~~.

b. Instead of a licensee making its own measurements as required in G.432a, the~~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.432a~~G.64a~~.

c. A licensee shall mathematically correct the outputs or activities determined in G.432~~G.64a. of this section~~ for physical decay at intervals consistent with one~~1.0~~ percent physical decay.

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

[e.~~d.~~ An authorized medical physicist shall perform or review the calculation measurements made pursuant to G.432a~~G.64a.~~, G.432b~~G.64b.~~, or G.432c~~G.64c~~.]

[f.~~e.~~ 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~~shall be based on the activity determined in accordance with paragraphs G.432a~~G.64a.~~, G.432b~~G.64b.~~, and G.432c~~G.64c~~.]

~~f. A licensee shall retain a record of each calibration in accordance with G.108.~~

[g. A licensee shall retain a record of decay calculations required by G.432f~~G.64e.~~ in accordance with G.2432~~G.109.~~]

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

a. Licensees who use strontium-90 for ophthalmic treatments shall ensure that certain activities as specified in G.433b are performed by either:

i. An authorized medical physicist; or

ii. An individual who:

(1) is identified as an ophthalmic physicist on a specific medical use license issued by the Agency, the Nuclear Regulatory Commission or an Agreement State; permit issued by an Agency, a Nuclear Regulatory Commission or Agreement State broad scope medical use licensee; medical use permit issued by a Nuclear

Regulatory Commission master material licensee; or permit issued by a Nuclear Regulatory Commission master material licensee broad scope medical use permittee; and

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

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

(4) Has documented training in:

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

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

(iii) Performing the calibration measurements of brachytherapy sources as detailed in G.432.

b. The individuals who are identified in G.433a shall:

i. Calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay shall be based on the activity determined under G.432; and

ii. Assist the licensee in developing, implementing, and maintaining written procedures, to provide high confidence that the administration is in accordance with the written directive. These procedures shall include the frequencies that the individual meeting the requirements in G.433a will observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the administrations were in accordance with the written directives.

c. Licensees shall retain a record of the activity of each strontium-90 source in accordance with G.2433.

Sec. G.457~~G.65~~ - 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~~shall include, as applicable, verification of:

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

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

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

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

~~[Sec. G.66 - Possession of Survey Instruments. A licensee authorized to use manual brachytherapy sources shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrems) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 10 microsieverts (1 mrem) per hour to 10 millisieverts (1000 mrems) per hour. The instruments shall be operable and calibrated in accordance with G.33.]~~

Sec. G.490~~G.67~~ - Training for Use of Manual Brachytherapy Sources. Except as provided in G.57~~G.29~~, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under G.400~~G.59~~ to be a physician who:

a. Is certified by a medical specialty board whose certification process ~~includes all of the requirements in G.67b. and whose certification~~ has been recognized by the Agency, an Agreement State or the Nuclear Regulatory Commission.~~;[*] or~~ The names of board certifications that have been recognized by the Agency, the Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

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

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

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

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

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

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~~[*] *Licensing State not included because compatibility B. State may want to recognize the Licensing State certification for NARM.*~~

(d) Radiation biology; and

(2) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in G.57~~G.67~~, G.490, or equivalent Agreement State, or Nuclear Regulatory Commission requirements at a medical facility authorized to use radioactive materials under G.400~~institution~~, involving:

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

(b) Checking survey meters for proper operation;

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

(d) Maintaining running inventories of material on hand;

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

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

ii. Has completed three~~Three~~ years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in G.57, G.490~~G.67~~. or equivalent Agreement State or Nuclear Regulatory Commission requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada, or the Council ~~Committee~~ on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by G.490b.i(2)~~G.67b.i.(2)~~; and

iii. Has obtained written attestation~~certification, signed by a preceptor authorized user, who meets the requirements in G.67 or equivalent Agreement State or Nuclear Regulatory Commission requirements,~~ that the individual has satisfactorily completed the requirements in G.490b.i~~G.67b.i.~~ and G.490b.ii~~G.67b.ii.~~ and ~~has achieved a level of competency sufficient~~ is able to independently fulfill the radiation safety-related duties~~function~~ as an authorized user of manual brachytherapy sources for the medical uses authorized under G.400~~G.59~~. The attestation shall be obtain from either:

(1) A preceptor authorized user who meets the requirements in G.57, G.490, or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

(2) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in G.57, G.490, or equivalent Nuclear Regulatory Commission or Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program shall be approved by the Residency

Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and shall include training and experience specified in G.490b.i and G.490b.ii.

Sec. G.491~~G.68~~ - Training for ophthalmic use of strontium-90. Except as provided in G.57~~G.29~~, the licensee shall require an authorized user of a strontium-90 source for ophthalmic radiotherapy~~uses authorized under G.59~~ to be a physician who:

a. Is an authorized user under G.490~~G.67~~ or equivalent Agreement State or Nuclear Regulatory Commission requirements;~~*/~~ or,

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

(1) Radiation physics and instrumentation;

(2) Radiation protection;

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

(4) Radiation biology; and,

ii. Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice ~~who meets the requirements of G.67 or G.68, and~~ that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training shall involve: ~~that includes:~~

(1) Examination of each individual to be treated;

(2) Calculation of the dose to be administered;

(3) Administration of the dose; and,

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

iii. Has obtained written attestation~~certification~~, signed by a preceptor authorized user, who meets the requirements in G.57~~G.67~~, G.490, G.491, ~~or G.68~~ or equivalent Agreement State or Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in ~~paragraphs i. and ii. of this section~~G.491b.i and G.491b.ii and ~~has achieved a level of competency sufficient~~is able to independently fulfill the radiation safety-related duties~~function~~ as an authorized user of strontium-90 for ophthalmic use.

~~*/ Licensing State not included because compatibility B. State may want to recognize the Licensing State certification for NARM.~~

Sealed Sources For Diagnosis

Sec. G.500~~G.69~~ - Use of Sealed Sources and Medical Devices for Diagnosis.

a. A licensee shall ~~use~~ only use sealed sources that are not in medical devices for diagnostic medical uses if the sealed sources are~~:~~

~~a. Approved~~ approved in the Sealed Source and Device Registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but shall be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.~~; and,~~

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

c. Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of G.49a are met.

Sec. G.590~~G.70~~ - Training for Use of Sealed Sources and Medical Devices for Diagnosis. Except as provided in G.57~~G.29~~, the licensee shall require the authorized user of a diagnostic sealed source or~~for use in~~ a device authorized under G.500~~G.69~~ to be a physician, dentist, or podiatrist who:

a. Is certified by a ~~speciality~~specialty board whose certification process includes all of the requirements in G.590c and G.590d~~G.70b.~~ and whose certification has been recognized by the Agency, an Agreement State or the Nuclear Regulatory Commission;~~*/ or~~ The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page.); or

b. Is an authorized user for uses listed in G.200 or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

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~~*/ *Licensing State not included because of compatibility B. State may want to recognize the Licensing State certification for NARM.*~~

c. Has had eight~~8~~ hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training shall include: ~~that includes:~~

i. Radiation physics and instrumentation;

ii. Radiation protection;

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

iv. Radiation biology; and

d. ~~v.~~ Has completed training~~Training~~ in the use of the device for the uses requested.

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

Sec. G.600~~G.71~~ - Use of Sealed Sources in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit.

a. A licensee shall only use sealed sources: ~~in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses:~~

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

ii.~~b.~~ In research involving photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units in accordance with an active~~effective~~ Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of G.49a~~G.24a.~~ are met.

b. A licensee shall use photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units:

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

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

Sec. G.604~~G.72~~ - 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 ~~make a~~ survey ~~of~~ the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe, shielded position.

b. A licensee shall retain a record of the surveys in accordance with G.2404~~G.106~~.

Sec. G.605~~G.73~~ - Installation, Maintenance, Adjustment, and Repair.

a. Only a person specifically licensed by the Agency, the Nuclear Regulatory Commission or an Agreement State shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

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

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

d. A licensee shall retain a record of the installation, maintenance, adjustment and repair of~~done on~~ remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with G.2605~~G.110~~.

Sec. G.610~~G.74~~ - Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.

a. A licensee shall:

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

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

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

iv. Develop, implement, and maintain written procedures for responding to an abnormal

situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. This procedure ~~must~~shall include:

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

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

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

b. A copy of the procedures required by G.610a.iv~~G.74a.iv.~~ ~~must~~shall be physically located at the unit console.

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

i. The location of the procedures required by G.610a.iv~~G.74a.iv.~~; and

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

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

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

(1)~~i.~~ The procedures identified in G.610a.iv~~G.74a.iv.~~; and

(2)~~ii.~~ The operating procedures for the unit.

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

f. A licensee shall retain a record of individuals receiving instruction required by G.610d~~G.74d.~~, in accordance with G.2310~~G.105~~.

g. A licensee shall retain a copy of the procedures required by G.610a.iv and G.610d.ii in

accordance with G.2610.

Sec. G.615~~G.75~~ - Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.

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

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

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

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

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

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

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

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

f. In addition to the requirements specified in G.615a~~G.75a.~~ through G.615e~~G.75e.~~, a licensee shall:

i. For [low dose-rate,] medium dose-rate, and pulsed dose-rate remote afterloader units, require:

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

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

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

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

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

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

iv. Notify the Radiation Safety Officer, or their~~his or her~~ designee, and an authorized user as soon as possible, if the patient or human research subject has a medical emergency ~~and, immediately,~~or if ~~the patient~~ dies.

g. A licensee shall have applicable emergency response equipment available near each treatment room, to respond to a source ~~that inadvertently~~:

i. Remaining~~Remains~~ in the unshielded position; or

ii. Lodged~~Lodges~~ within the patient following completion of the treatment.

Sec. G.630~~G.76~~ - Dosimetry Equipment.

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

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

ii. The system ~~must~~shall have been calibrated within the previous four~~4~~ years; 18 to 30 months after that calibration, the system ~~must~~shall have been intercompared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison ~~must~~shall have indicated that the calibration factor of the licensee's system had not changed by more than two~~2~~ percent. The licensee ~~may~~ shall not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the

same radionuclide as the source used at the licensee's facility.

b. The licensee shall have available for use a dosimetry system for spot-check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with G.630a~~G.76a~~. This comparison ~~must~~shall have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in G.630a~~G.76a~~.

c. The licensee shall retain a record of each calibration, intercomparison, and comparison in accordance with G.2630~~G.111~~.

Sec. G.632~~G.77~~ - Full Calibration Measurements on Teletherapy Units.

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

i. Before the first medical use of the unit; and

ii. Before medical use under the following conditions:

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

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

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

iii. At intervals not exceeding one~~1~~ year.

b. To satisfy the requirement of G.632a~~G.77a.~~, full calibration measurements ~~must~~shall include determination of:

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

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

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

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

v. On-off error; and

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

c. A licensee shall use the dosimetry system described in G.630a~~G.76a.~~ to measure the output for one set of exposure conditions. The remaining radiation measurements required in G632b.i~~G77b.i.~~ may be made using a dosimetry system that indicates relative dose rates.

d. A licensee shall make full calibration measurements required by G.632a~~G.77a.~~ in accordance with published protocols accepted by nationally recognized bodies.

e. A licensee shall mathematically correct the outputs determined in G.632b.i~~G.77b.i.~~ for physical decay for intervals not exceeding one~~1~~ month for cobalt-60, six~~6~~ months for cesium-137, or at intervals consistent with one~~1~~ percent decay for all other nuclides.

f. Full calibration measurements required by G.632a~~G.77a.~~ and physical decay corrections required by G.632e~~G.77e.~~ ~~must~~shall be performed by the authorized medical physicist.

g. A licensee shall retain a record of each calibration in accordance with G.2632~~G.112~~.

Sec. G.633~~G.78~~ - Full Calibration Measurements on Remote Afterloader Units.

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

i. Before the first medical use of the unit;

ii. Before medical use under the following conditions:

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

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

iii. At intervals not exceeding one~~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

iv. At intervals not exceeding one~~1~~ year for low dose-rate remote afterloader units.

b. To satisfy the requirement of G.633a~~G.78a.~~, full calibration measurements ~~must~~shall include, as applicable, determination of:

i. The output within ~~+/-~~ five~~5~~ percent;

ii. Source positioning accuracy to within ~~+/-~~ one~~1~~ millimeter;

iii. Source retraction with backup battery upon power failure;

iv. Length of the source transfer tubes;

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

vi Length of the applicators; and

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

c. ~~In addition to the requirements for full calibrations for low dose-rate remote afterloader units in G.78b., a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding one quarter.~~

~~d.~~ A licensee shall use the dosimetry system described in G.630a~~G.76a.~~ to measure the output.

d.~~e.~~ A licensee shall make full calibration measurements required by G.630a~~G.78a. of this section~~ in accordance with published protocols accepted by nationally recognized bodies.

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

f. For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with G.633a~~G.78a.~~ through G.633e~~G.78e~~.

g. A licensee shall mathematically correct the outputs determined in G.633b.i~~G.78b.i.~~ for physical decay at intervals consistent with one~~1~~ percent physical decay.

h. Full calibration measurements required by G.633a~~G.78a.~~ and physical decay corrections required by G.633g ~~G.78g.~~ ~~must~~shall be performed by the authorized medical physicist.

i. A licensee shall retain a record of each calibration in accordance with G.2632~~G.112~~.

Sec. G.635~~G.79~~ - Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units.

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

i. Before the first medical use of the unit;

ii. Before medical use under the following conditions:

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

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

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

iii. At intervals not exceeding one~~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.635a~~G.79a.~~, full calibration measurements shall~~must~~ include determination of [the following items, if applicable]:

i. The output within ~~+/-~~ three~~3~~ percent;

ii. Relative helmet factors;

iii. Isocenter coincidence;

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

v. On-off error;

vi. Trunnion centricity;

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

viii. Helmet microswitchs;

ix. Emergency timing circuits; and

x. Stereotactic frames and localizing devices (trunnions).

c. A licensee shall use the dosimetry system described in G.630a~~G.76a.~~ to measure the output for one set of exposure conditions. The remaining radiation measurements required in G.635b.i~~G.79b.i.~~ may be made using a dosimetry system that indicates relative dose rates.

d. A licensee shall make full calibration measurements required by G.635a~~G.79a.~~ in accordance with published protocols accepted by nationally recognized bodies.

e. A licensee shall mathematically correct the outputs determined in G.635b.i~~G.79b.i.~~ at intervals not exceeding one~~1~~ month for cobalt-60 and at intervals consistent with one~~1~~ percent physical decay for all other radionuclides.

f. Full calibration measurements required by G.635a~~G.79a.~~ and physical decay corrections required by G.635e~~G.79e.~~ ~~must~~shall be performed by the authorized medical physicist.

g. A licensee shall retain a record of each calibration in accordance with G.2632~~G.112~~.

Sec. G.642~~G.80~~ - Periodic Spot-Checks for Teletherapy Units.

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

i. Timer accuracy, and timer linearity over the range of use;

ii. On-off error;

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

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

v. The output for one typical set of operating conditions measured with the dosimetry system described in G.630b~~G.76b.~~; and

vi. The difference between the measurement made in G.642a.v~~G.80a.v.~~ and the anticipated output, expressed as a percentage of the anticipated output ~~(i.e.,~~or the value obtained at last full calibration corrected mathematically for physical decay~~)~~.

b. A licensee shall perform measurements required by G.642a~~G.80a.~~ in accordance with written procedures established by the authorized medical physicist. 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 ~~promptly~~ notify the licensee as soon as possible in writing of the results of each spot-check.

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

i. Electrical interlocks at each teletherapy room entrance;

ii. Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation[5] ~~(restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism)~~;

[5] *Some examples of stops installed to limit use of primary beam of radiation are: restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism.*

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

iv. Viewing and intercom systems;

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

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

e. If the results of the checks required in G.642d~~G.80d.~~ indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

f. A licensee shall retain a record of each spot-check required by G.642a~~G.80a.~~ and G.642d~~G.80d.~~, and a copy of the procedures required by G.642b, in accordance with G.2642~~G.113~~.

Sec. G.643~~G.81~~ - Periodic Spot-Checks for Remote Afterloader Units.

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

i. Before the first use~~At the beginning of each day of use~~ of a high dose-rate, medium dose-rate or pulsed dose-rate remote afterloader unit on a given day;

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

iii. After each source installation.

b. A~~The~~ licensee shall perform the measurements required by G.643a in accordance with written procedures established by~~have~~ the authorized medical physicist.~~ establish written procedures for performing the spot-checks required in G.81a.~~ The authorized medical physicist need not actually perform the spot-check measurements.

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

d. To satisfy the requirements of G.643a~~G.81a.~~, spot-checks ~~must~~shall, at a minimum, assure proper operation of:

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

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

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

iv. Emergency response equipment;

v. Radiation monitors used to indicate the source position;

vi. Timer accuracy;

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

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

e. If the results of the checks required in G.643d~~G.81d.~~ indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

f. A licensee shall retain a record of each check required by G.643d,~~G.81d.~~ and a copy of the procedures required by G.643b in accordance with G.2643~~G.114~~.

Sec. G.645~~G.82~~ - Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units.

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

i. Monthly;

ii. Before the first use of the unit on a given~~At the beginning of each~~ day~~ of use~~; and

iii. After each source installation.

b. The licensee shall: ~~have the authorized medical physicist:~~

i. Perform the measurements required by G.645a in accordance with~~Establish~~ written procedures established by the authorized medical physicist.~~for performing the spot-checks required in G.82a.~~ The authorized medical physicist need not actually perform the spot-check measurements.~~; and~~

ii. Have the authorized medical physicist review~~Review~~ the results of each spot-check required by G.645a.i~~G.82a.i.~~ within 15 days~~ of the check~~.~~ The authorized medical physicist need not actually perform the spot-check measurements.~~ The authorized medical physicist shall notify the licensee as soon as possible, in writing, of the results of each~~the~~ spot check.

c. To satisfy the requirements of G.645a.i~~G.82a.i.~~, spot-checks shall~~must~~, at a minimum:

i. Assure proper operation, if applicable, of:

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

(2) Helmet microswitchs;

(3) Emergency timing circuits; and

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

ii. Determine :

(1) The output for one typical set of operating conditions measured with the dosimetry system described in G.630b~~G.76b.~~;

(2) The difference between the measurement made in G.645c.ii(1)~~G.82c.ii.(1)~~ and the anticipated output, expressed as a percentage of the anticipated output ~~(i.e.,~~or the value obtained at last full calibration corrected mathematically for physical decay~~)~~;

(3) Source output against computer calculation;

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

(5) On-off error; and

(6) Trunnion centricity.

d. To satisfy the requirements of G.645a.ii~~G.82a.ii.~~ and G.645a.iii~~G.82a.iii.~~, spot-checks ~~must~~shall assure proper operation of:

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

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

iii. Viewing and intercom systems;

iv. Timer termination;

v. Radiation monitors used to indicate room exposures; and

vi. Emergency off buttons.

e. A licensee shall arrange for ~~prompt~~the repair of any system identified in G.645c~~G.82c.~~ that is not operating properly as soon as possible.

f. If the results of the checks required in G.645d~~G.82d.~~ indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

g. A licensee shall retain a record of each check required by G.645c~~G.82c.~~ and G.645d~~G.82d.~~ and a copy of the procedures requires by G.645b in accordance with G.2645~~G.115~~.

Sec. G.647~~G.83~~ - Additional Technical Requirements for Mobile Remote Afterloader Units.

a. A licensee providing mobile remote afterloader service shall:

i. Check survey instruments ~~for consistent response~~ before medical use at each address of use or on each day of use, whichever is more frequent; and

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

b. In addition to the periodic spot-checks required by G.643~~G.81~~, 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~~shall be made to verify the operation of :

i. Electrical interlocks on treatment area access points;

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

iii. Viewing and intercom systems;

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

v. Radiation monitors used to indicate room exposures;

vi. Source positioning (accuracy); and

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

c. In addition to the requirements for checks in G.647b~~G.83b.~~, a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

d. If the results of the checks required in G.647b~~G.83b.~~ indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

e. A licensee shall retain a record of each check required by G.647b~~G.83b.~~ in accordance with G.2647~~G.116~~.

Sec. G.652~~G.84~~ - Radiation Surveys.

a. In addition to the survey requirements in D.1501~~D.501~~ of these regulations, a person licensed ~~pursuant to Part G~~under G.600 through G.690 shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position do~~does~~ not exceed the levels stated in the Sealed Source and Device Registry.

b. The licensee shall make the survey required by G.652a~~G.84a.~~ at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

c. A licensee shall retain a record of the radiation surveys required by G.652a~~G.84a.~~ in accordance with G.2652~~G.117~~.

Sec. G.655~~G.85~~ - ~~Five-Year~~ Full-Inspection Servicing for Teletherapy and Gamma Stereotactic Radiosurgery Units.

a. A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement ~~or at intervals not to exceed 5 years, whichever comes first,~~ to assure proper functioning of the source exposure mechanism and other safety components. The interval between each full-inspection servicing shall not exceed five years for each teletherapy unit and shall not exceed seven years for each gamma stereotactic radiosurgery unit.

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

c. A licensee shall keep a record of the inspection and servicing in accordance with G.2655~~G.118~~.

Sec. G.657~~G.86~~ - 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~~shall include, as applicable, verification of:

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

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

c. The accuracy of isodose plots and graphic displays;

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

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

~~[Sec. G.87 – Possession of Survey Instruments. A licensee authorized to use radioactive material in remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrems) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 10 microsieverts (1 mrem) per hour to 10 millisieverts (1000 mrems) per hour. The instruments shall be operable and calibrated in accordance with G.33.]~~

Sec. G.690~~G.88~~ - Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units. Except as provided in G.57~~G.29~~, the licensee shall require an authorized user of a sealed source for a use authorized under G.600~~G.71~~ to be a physician who:

a. Is certified by a medical specialty board whose certification process ~~includes all of the requirements in G.88b. and whose certification~~ has been recognized by the Agency, an Agreement State or the Nuclear Regulatory Commission.~~;[*/] or~~ The names of board certifications that have been recognized by the Agency, the Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

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

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

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

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

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

(d) Radiation biology; and

~~[*/] . Licensing State not included because compatibility B. State may want to recognize the Licensing State certification for NARM.~~

ii. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in G.57, G.690,~~G.88~~ or equivalent Agreement State or Nuclear Regulatory Commission requirements at a medical facility that is authorized to use radioactive materials in § 35.600~~institution~~, involving:

(1) Reviewing full calibration measurements and periodic spot checks;

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

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

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

(5) Checking and using survey meters; and

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

iii. Has completed three~~Three~~ years of supervised clinical experience in radiation therapy~~oncology~~, under an authorized user who meets the requirements in G.57, G.690~~G.88~~ or equivalent Agreement State or Nuclear Regulatory requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council~~Committee~~ on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by G.690b.i(2)~~G.88b.ii.~~; and

iv. Has obtained written attestation~~certification, signed by a preceptor authorized user, who meets the requirements in G.88, equivalent Agreement State or Nuclear Regulatory requirements,~~ that the individual has satisfactorily completed the requirements in G.690b.i~~G.88b.i.~~, G.690b.ii and G.690c~~G.88b.ii.~~ and ~~has achieved a level of competency sufficient~~is able to independently fulfill the radiation safety-related duties~~function~~ as an authorized user of each type of ~~the~~ therapeutic medical unit for which the individual is requesting authorized user status. The attestation must be obtained from either:

(1) A preceptor authorized user who meets the requirements in G.57, G.690, or equivalent Nuclear Regulatory Commission or Agreement State requirements for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status; or

(2) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in G.57, G.690, or equivalent Nuclear Regulatory Commission or Agreement State requirements, for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status, and concurs with the attestation provided by the residency program

director. The residency training program shall be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and shall include training and experience specified in G.690b.i and G.690b.ii.

c. Has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

Other Medical Uses of Radioactive Material or Radiation from Radioactive Material

Sec. G.1000~~G.89~~ - Other Medical Uses of Radioactive Material or Radiation From Radioactive Material. A licensee may use radioactive material or a radiation source approved for medical use that is not specifically addressed in G.100 through G.690~~Part G~~ if:

a. The applicant or licensee has submitted the information required by G.12b~~G.8b.~~, G.12c~~G.8c.~~ and G.12d~~G.8d.~~; and

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

Records

Sec. G.2024~~G.90~~ - Records of Authority and Responsibilities for Radiation Protection Programs.

a. A licensee shall retain a record of actions taken by the licensee's management in accordance with G.24a~~G.18a.~~ for five~~5~~ years. The record ~~must~~shall include a summary of the actions taken and a signature of licensee management.

b. The licensee shall retain a current copy of both~~the~~ ~~authorities~~ the authority, and the duties and responsibilities of the Radiation Safety Officer as required by G.24e~~G.18d.~~, and a signed copy of each~~the~~ Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by G.24b~~G.18b~~ for the duration of the license. The record ~~must~~shall include the signature of the Radiation Safety Officer and licensee management.

c. For each Associate Radiation Safety Officer appointed under G.24b, the licensee shall retain, for five years after the Associate Radiation Safety Officer is removed from the license, a copy of the

written document appointing the Associate Radiation Safety Officer signed by the licensee's management.

[d. The minutes of each Radiation Safety Committee meeting held in accordance with G.24i~~G.18g.~~ shall include:

i. The date of the meeting;

ii. Members present;

iii. Members absent; and

iv. Summary of deliberations and discussions.]

Sec. G.2026~~G.91~~ - Records of Radiation Protection Program Safety Changes. A licensee shall retain a record of each radiation protection program change made in accordance with G.26a~~G.19a.~~ for five~~5~~ years. The record ~~must~~shall include a copy of the old and new procedures; the effective date of the change; and the signature of the licensee management that reviewed and approved the change.

Sec. G.2040~~G.92~~ - Records of Written Directives. A licensee shall retain a copy of each written directive as required by G.40~~G.22~~ for three~~3~~ years.

Sec. G.2041 - Records for Procedures for Administrations Requiring a Written Directive. A licensee shall retain a copy of the procedures required by G.41a for the duration of the license'

~~Sec. G.93 - Records of Misadministrations. A licensee shall retain a record of misadministrations reported in accordance with G.119 for 3 years. The record must contain the licensee's name; names of the individuals involved; the social security number or other identification number if one has been assigned, of the individual who is the subject of the misadministration; a brief description of the event; why it occurred; the effect, if any, on the individual; the actions, if any, taken, or planned, to prevent recurrence; and, whether the licensee notified the individual (or the individual's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.~~

~~Sec. G.94 - Record of a Dose to an Embryo/Fetus or a Nursing Child.~~[*/] ~~A licensee shall retain a record of a dose to an embryo/fetus or a nursing child reported in accordance with G.120 for 3 years. The record must contain the licensee's name; names of all the individuals involved; social security number or other identification number if one has been assigned to the pregnant individual or nursing child who is the subject of the event; a brief description of the event; why it occurred; the effect, if any, on the embryo/fetus or nursing child; the actions, if any, taken, or planned, to prevent recurrence; and whether the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.~~

Sec. G.2060~~G.95~~ - 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~~G.32~~ for three~~3~~ years. The records ~~must~~shall include the model and serial number of the

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~~[*/] *This rule may have health and safety implications, please see Rational for Part G 2002 for more information.*~~

instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

Sec. G.2061~~G.96~~ - Records of Survey Instrument Calibrations. A licensee shall maintain a record of survey instrument calibrations required by G.61~~G.33~~ for three~~3~~ years. The record ~~must~~shall include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

Sec. G.2063~~G.97~~ - Records of Dosages of Unsealed Radioactive Material for Medical Use.

a. A licensee shall maintain a record of dosage determinations required by G.63~~G.34~~ for three~~3~~ years.

b. The record ~~must~~shall contain~~-~~:

i. The radiopharmaceutical~~the radioactive drug~~;

ii. The~~the~~ patient's or human research subject's name, or identification number if one has been assigned;

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

iv. The~~the~~ date and time of the dosage determination; and

v. The~~the~~ name of the individual who determined the dosage.

Sec. G.2067~~G.98~~ - Records of Leak Tests and Inventory ~~Possession~~ of Sealed Sources and Brachytherapy Sources.

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

b. A licensee shall retain ~~a~~ records~~record~~ of the semi-annual physical inventory of sealed sources and brachytherapy sources required by G.67g~~G.36d.~~ for three~~3~~ years. The inventory record ~~must~~shall contain the model number of each source, and serial number if one has been assigned, the identity of each source by radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

Sec. G.2070~~G.99~~ - Records of Surveys for Ambient Radiation Exposure Rate. A licensee shall retain a record of each survey required by G.70~~G.39~~ for three~~3~~ years. The record ~~must~~shall include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

Sec. G.2075~~G.100~~ - Records of the Release of Individuals Containing Unsealed Radioactive Material

~~Radioactive Drugs~~ or Implants Containing Radioactive Material.

a. A licensee shall retain a record~~, signed by the authorized user,~~ of the basis for authorizing the release of an individual in accordance with G.75, if the total effective dose equivalent is calculated by:~~, for 3 years after the date of release.~~

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

ii. Using an occupancy factor less than 0.25 at 1 meter;

iii. Using the biological or effective half-life; or

iv. Considering the shielding by tissue.

b. A licensee shall retain a record~~, for 3 years after the date of release,~~ that the instructions required by G.75b~~G.40b.~~ were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 millisieverts (0.5 rem) [1 millisievert (0.1 rem)].

c.
~~[b.~~ The records required by G.2075a and G.2075b~~A licensee~~ shall be retained~~retain a record,~~ for three~~3~~ years after the date of release of the individual.~~, that the instructions required by G.40b. were provided to a breast-feeding woman.]~~

Sec. G.2080~~G.101~~ - Records of ~~Administrative and Technical Requirements that Apply to the Provision of~~ Mobile Services.

a. A licensee shall retain a copy of each letter~~the letter(s)~~ that permits the use of radioactive material at a client's address of use, as required by G.80a.i~~G.9b.,~~. Each letter shall clearly delineate the authority and responsibility of the licensee and the client and shall be retained for three~~3~~ years after the last provision of service.

b. A licensee shall retain the record of each survey required by G.80a.iv~~G.41f.~~ for three~~3~~ years. The record ~~must~~shall include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

Sec. G.2092~~G.102~~ - Records of Decay-in-Storage. A licensee shall maintain records of the disposal of licensed materials, as required by G.92~~G.43~~, for three~~3~~ years. The record ~~must~~shall include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.

Sec. G.2204~~G.103~~ - Records of Molybdenum-99, Strontium-82, and Strontium-85 Concentrations.~~Radionuclide Purity.~~ A licensee shall maintain a record of the molybdenum-99 concentration or strontium-82 and strontium-85 radionuclide ~~contaminant~~ concentration tests required by G.204b~~G.48~~ and G.204c for three~~3~~ years. The record ~~must~~shall include:

a. For~~, for~~ each measured elution of technetium-99m~~radionuclide used to prepare a radioactive~~

drug, the ratio of the measures expressed as kilobecquerel of molybdenum-99contaminant per megabecquerel of technetium-99mdesired radionuclide (or microcuries of molybdenum per /millicurie of technetium), or microgram of contaminant per megabecquerel of desired radionuclide (microgram/millicurie), the time and date of the measurement, and the name of the individual who made the measurement.; or

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

[Sec. G.104 - Records of Training. A licensee shall maintain records of training required by G.28 for 3 years after the last date an individual was authorized to act as a nuclear medicine technologist or radiation therapist at the licensee's facility.]

Sec. G.2310G.105 - Records of Safety Instruction and Training. A licensee shall maintain a record of safety instructions and training required by G.310G.53,and G.410G.62 and the operational and safety instructions required by G.610G.74 for three3 years. The record mustshall include a list of the topics covered, the date of the instruction or training, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

Sec. G.2404G.106 - Records of Radiation Surveys After Source Implant and Removalof Patients and Human Research Subjects. A licensee shall maintain a record of the surveys required by G.404G.60 and G.604G.72 for three3 years. Each record mustshall include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

Sec. G.2406G.107 - Records of Brachytherapy Source AccountibilityInventory.

a. A licensee shall maintain a record of brachytherapy source accountability required by G.406G.61 for three3 years.

b. For temporary implants, the record mustshall include:

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

   ii. The number and activity of sources returned to storagenot implanted, 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 mustshall include:

   i. The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;

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

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

Sec. G.2432~~G.108~~ - Records of Calibration Measurements of~~on~~ Brachytherapy Sources.

a. A licensee shall maintain a record of the calibrations of ~~on~~ brachytherapy sources required by G.432~~G.64~~ for three~~3~~ years after the last use of the source.

b. The record ~~must~~shall include:

i. The~~the~~ date of the calibration;

ii. The~~the~~ manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source;

iii. The~~the~~ source output or activity;

iv. The source positioning accuracy within the applicators; and

v. The name of the individual, the source manufacturer, or the calibration laboratory that performed the calibration~~the signature of the authorized medical physicist~~.

Sec. G.2433~~G.109~~ - Records of Decay of Strontium-90 Sources for Ophthalmic Treatments.

a. The licensee shall maintain a record of the activity of a strontium-90 source required by G.433~~G.64~~ for the life of the source.

b. The record ~~must~~shall include~~-~~:

i. The~~the~~ date and initial activity of the source as determined under G.432~~G.64~~;~~,~~ and

ii. For~~for~~ each decay calculation, the date, and the source activity as determined under G.433.~~and the signature of the authorized medical physicist.~~

Sec. G.2605~~G.110~~ - 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~~G.73~~ for three~~3~~ years. For each installation, maintenance, adjustment and repair, the record ~~must~~shall include the date, description of the service, and name(s) of the individual(s) who performed the work.

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

Sec. G.2630~~G.111~~ - 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~~G.76~~ for the duration of the license.

b. For each calibration, intercomparison, or comparison, the record ~~must~~shall include:

i. The date;

ii. The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by G.630a~~G.76a.~~ and G.630b~~G.76b.~~;

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

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

Sec. G.2632~~G.112~~ - Records of Teletherapy, Remote Afterloader, and Gamma Stereotactic Radiosurgery Full Calibrations.

a. A licensee shall maintain a record of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations required by G.632~~G.77~~, G.633~~G.78~~ and G.635~~G.79~~ for three~~3~~ years.

b. The record ~~must~~shall include:

i. The date of the calibration;

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

iii. The results and assessments of the full calibrations;

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

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

Sec. G.2642~~G.113~~ - 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~~G.80~~ for three~~3~~ years.

b. The record ~~must~~shall include:

i. The date of the spot-check;

ii. The manufacturer's name, model number, and serial number for the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;

iii. An assessment of timer linearity and constancy;

iv. The calculated on-off error;

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

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

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

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

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

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

Sec. G.2643~~G.114~~ - 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~~G.81~~ for three~~3~~ years.

b. The record ~~must~~shall include, as applicable:

i. The date of the spot-check;

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

iii. An assessment of timer accuracy;

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

v. The name of the individual who performed the periodic spot-check and the signature of

the authorized medical physicist who reviewed the record of the spot-check.

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

Sec. G.2645~~G.115~~ - 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~~G.82~~ for three~~3~~ years.

b. The record ~~must~~shall include:

i. The date of the spot-check;

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

iii. An assessment of timer linearity and accuracy;

iv. The calculated on-off error;

v. A determination of trunnion centricity;

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

vii. An assessment of source output against computer calculations;

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

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

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

Sec. G.2647~~G.116~~ - 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~~G.83~~ for three~~3~~ years.

b. The record ~~must~~shall include:

i. The date of the check;

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

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

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

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

Sec. G.2652~~G.117~~ - 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~~G.84~~ for the duration of use of the unit.

b. The record ~~must~~shall include:

i. The date of the measurements;

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

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

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

Sec. G.2655~~G.118~~ - Records of Full Inspection Servicing~~5-Year Inspection~~ for Teletherapy and Gamma Stereotactic Surgery Units.

a. A licensee shall maintain a record of the full inspection servicing~~5-year inspections~~ for teletherapy and gamma stereotactic radiosurgery units required by G.655~~G.85~~ for the duration of use of the unit.

b. The record ~~must~~shall contain:

i. The inspector's radioactive materials license number;

ii. The date of inspection;

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

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

v. The signature of the inspector.

Reports

Sec.G.3045~~ G.119~~ - Reports and Notifications of a Medical Event~~Misadministrations~~.

a. A licensee shall report any event as a medical event, except for an event that results from patient intervention, in which:~~Other than events that result from intervention by a patient or human research subject, a licensee shall report any event in which the administration of radioactive material or radiation from radioactive material results in:~~

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

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

(a)~~(1)~~ The total dose delivered differs from the prescribed dose by 20 percent or more;

(b)~~(2)~~ The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

(c)~~(3)~~ The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

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

(a)~~(1)~~ An administration of a wrong radioactive drug containing radioactive material or the wrong radionuclide for a brachytherapy procedure;

(b)~~(2)~~ An administration of a radioactive drug containing radioactive material by the wrong route of administration;

(c)~~(3)~~ An administration of a dose or dosage to the wrong individual or human research subject;

(d)~~(4)~~ An administration of a dose or dosage delivered by the wrong mode of treatment; or

(e)(5) A leaking sealed source.

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

(a) 0.5 Sievert (50 rem) to an organ or tissue and 50 percentor more of the dose expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; anddefined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

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

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

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

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

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

(a) The wrong radionuclide;

(b) The wrong individual or human research subject;

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

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

b. A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results, or will result in, unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

c. The licensee shall notify the Agency by telephone no later than the next calendar day after

discovery of the medical event~~misadministration~~.[6]

d. The licensee shall submit a written report to the Agency within 15 days after discovery of the medical event~~misadministration~~.

i. The written report ~~must~~shall include:

(1) The licensee's name;

(2) The name of the prescribing physician;

(3) A brief description of the event;

(4) Why the event occurred;

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

(6) What actions~~Actions~~, if any, ~~that~~ have been taken, or are planned, to prevent recurrence; and

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

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

e. The licensee shall provide notification of the medical event~~misadministration~~ to the referring physician and also notify the individual who is the subject of the medical event~~misadministration~~ no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that they~~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~~misadministration~~, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the medical event~~misadministration~~ may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

f. Aside from the notification requirement, nothing in ~~this section~~G.3045 affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event~~misadministration~~, or to that individual's responsible relatives or guardians.

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6 The Agency's telephone number is (XXX) XXX-XXXX

g. A licensee shall-:

i. Annotate a copy of the report provided to the Agency with the:

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

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

ii. Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.~~retain a record of a misadministration in accordance with G.93. A copy of the record required under G.93 shall be provided to the referring physician if other than the licensee, within 15 days after discovery of the misadministration.~~

Sec. G.3047~~G.120~~ - Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child.~~*/~~

a. A licensee shall report any dose to an embryo/fetus that is greater than 50 mSv (5 rem) [5 millisievert (500 mrem)] dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

b. A licensee shall report any dose to a nursing child, that was not specifically approved, in advance, by the authorized user, that is a result of an administration of radioactive material to a breast feeding individual that:

i. Is greater than 50 mSv (5 rem) [5 millisievert (500 mrem)] total effective dose equivalent; or

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

c. The licensee shall notify by telephone the Agency no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in G.3047a~~G.120a.~~ or G.3047b~~G.120b~~.

d. The licensee shall submit a written report to the Agency within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in G.3047a~~G.120a.~~ or G.3047b~~G.120b~~.

i. The written report ~~must~~shall include:

(1) The licensee's name;

~~*/ *This rule may have health and safety implications, please see 2002 Rational for Part G for more information.*~~

(2) The name of the prescribing physician

(3) A brief description of the event;

(4) Why the event occurred;

(5) The effect on the embryo/fetus or the nursing child;

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

(7) Certification that the licensee notified the pregnant individual or mother ~~(~~or the mother's or child's responsible relative or guardian~~)~~, and if not, why not.

ii. The report ~~must~~shall not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

e. The licensee shall notify the referring physician of the event and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under G.3047a~~G.120a.~~ or G.3047b~~G.120b~~., unless the referring physician personally informs the licensee either that they~~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~~G.3047e, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother, when appropriate. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

f. A licensee shall~~.~~:

i. Annotate a copy of the report provided to the Agency with the:

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

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

ii. Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.~~retain a record of a dose to an embryo/fetus or a nursing child in accordance with G.94. A copy of the record required under G.94 shall be provided to the referring physician, if other than the~~

~~licensee, within 15 days after discovery of the event.~~

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

Sec. G.3067~~G.121~~ - Reports of Leaking Sources. A licensee shall file a report with the Agency within five~~5~~ days if a leakage test required by G.67~~G.36~~ reveals the presence of 185 becquerel~~Becquerel~~ (0.005 µCi) or more of removable contamination. The written report ~~must~~shall include the model number and serial number if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken.

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

~~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.40a.~~

~~b. The licensee shall submit a written report to the Agency within 30 days after discovery of the unauthorized departure. The written report must include:~~

~~i. The licensee's name;~~

~~ii. The date and time of the unauthorized departure;~~

~~iii. The projected date and time when release would have occurred;~~

~~iv. The address of the patient's or human research subject's home or anticipated destination following departure;~~

~~v. The radionuclide, chemical and physical form and calculated activity at time of release;~~

~~vi. The apparent reason(s) for the departure prior to authorized release; and~~

~~vii. 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.~~

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

~~a. 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 Part D.301 of these regulations as a result of the deceased's body.~~

~~b. 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.120a. has died. The written report must include:~~

~~i. The licensee's name;~~

~~ii. The date of death;~~

~~iii. The radionuclide, chemical and physical form and calculated activity at time of death; and,~~

~~iv. The names (or titles) and address(es) of known individuals who might have received exposures exceeding 5 millisieverts (500 mrem).~~

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

a. The licensee shall notify by telephone the Agency and the distributor of the generator within seven calendar days after discovery that an eluate exceeded the permissible concentration listed in G.204a at the time of generator elution. The telephone report to the Agency shall include the manufacturer, model number, and serial number or lot number of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects, when the distributor was notified, and the action taken.

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