INSTRUCTION SHEET

COMAR 26.12.01.01

Title: Regulations for the Control of Ionizing Radiation (1994)

SUPPLEMENT No. 31

Instructions: Supplement 31 to the document "Regulations for the Control of Ionizing Radiation (1994)" includes the following pages (all pages are inclusive):

Remove Pages	Insert Pages (future)
Cover Sheet	Cover Sheet
v through vi	v through vi
C37 through C38	C37 through C38
C39 through C40	C39 through C40
C47 through C48	C47 through C48
D1 through D2	D1 through D2
D39 through D42	D39 through D42 (add 2 pages)
F11 through F12	F11 through F12
G1 through G8	G1 through G8 (add 6 pages)
G11 through G20	G11 through G20 (add 4 pages)
G23 through G24	G23 through G24
G27 through G47-2	G27 through G47-2 (add 10 pages)
G49 through G50	G49 through G50
G61 through G64	G61 through G64
G67 through G68	G67 through G68
T17 through T18	T17 through T18
V31 through V32	V31 through V32

Verify to make certain that you have the pages listed above.

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REGULATIONS FOR THE CONTROL OF IONIZING RADIATION (1994)

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(g) Calibration or Reference Sources Containing Americium-241 or Radium-226: Labeling of Devices in Section C.28(f).

Each person licensed under Section C.28(f) shall affix to each source, or storage container for the source, a label which shall contain sufficient information relative to safe use and storage of the source and shall include the following statement or a substantially similar statement which contains the information called for in the following statement:

> The receipt, possession, use, and transfer of this source, Model _____, Serial No._____, are subject to a general license and the regulations of the United States Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION – RADIOACTIVE MATERIAL
THIS SOURCE CONTAINS AMERICIUM-241 (or RADIUM-226)
DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE

_____
(Name of Manufacturer or Initial Transferor)

(h)Manufacture and Distribution of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing Under General License. An application for a specific license to manufacture or distribute radioactive material for use under the general license of C.22(i) will be approved if:

(1) the applicant satisfies the general requirements specified in C.25.

(2) the radioactive material is to be prepared for distribution in prepackaged units of:

(i) carbon-14 in units not exceeding 10 microcuries (370 kBq) each.

(ii) cobalt-57 in units not exceeding 10 microcuries (370 kBq) each.

(iii) hydrogen-3 (tritium) in units not exceeding 50 microcuries (1.85 MBq) each.

(iv) iodine-125 in units not exceeding 10 microcuries (370 kBq) each.

(v) Mock Iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each.

(vi) iodine-131 in units not exceeding 10 microcuries (370 kBq) each.

(vii) iron-59 in units not exceeding 20 microcuries (740 kBq) each.

(viii) selenium-75 in units not exceeding 10 microcuries (370 kBq) each.

(3) each prepackaged unit bears a durable, clearly visible label:

(i) identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 10 microcuries (370 kBq) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 50 microcuries (1.85 MBq) of hydrogen-3 (tritium); 20 microcuries (740 kBq) of iron-59; or Mock Iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each; and

(ii) displaying the radiation caution symbol described in D.901(a)(1) and the words, "CAUTION, RADIOACTIVE MATERIAL," and "Not for Internal or External Use in Humans or Animals."

(4) one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

(i) This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for <u>in vitro</u> clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

Name of manufacturer

(ii) This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of a Licensing State.

Name of manufacturer

(5) the label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in D.1001 of these regulations.

(i) Licensing the Manufacture and Distribution of Ice Detection Devices. An application for a specific license to manufacture and distribute ice detection devices to persons generally licensed under C.22(j) will be approved if:

(1) the applicant satisfies the general requirements of C.25; and

(2) the criteria of Sections 32.61 and 32.62 of 10 CFR Part 32 are met.

(j) Manufacture, Preparation, or Transfer for Commercial Distribution of Radioactive Drugs Containing Radioactive Material for Medical Use Under Part G.

(1) An application for a specific license to manufacture, prepare or transfer for commercial distribution radioactive drugs containing radioactive material for persons authorized pursuant to Part G of this regulation will be approved if:

(i) The applicant satisfies the general requirements specified in C.25;

(ii) The applicant submits evidence that the applicant is at least one of the following:

(a) Registered or licensed with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a);

(b) Registered or licensed with a state agency as a drug manufacturer;

(c) Licensed as a pharmacy by a State Board of Pharmacy;

(d) Operating as a nuclear pharmacy within a Federal medical institution; or

(e) A Positron Emission Tomography (PET) drug production facility registered with a state agency.

(iii) The applicant submits information on the radionuclide; the chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radioactive drugs by medical use licensees; and

(iv) The applicant commits to ~~satisfies~~ the following labeling requirements:

(a) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL"; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half life greater than 100 days, the time may be omitted.

(b) A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

(2) A licensee described in C.28(j)(1)(ii)(c) or (d):

(i) May prepare radioactive drugs for medical use, as defined in Sec. A.2, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in C.28(j)(2)(ii) and (iv), or an individual under the supervision of an authorized nuclear pharmacist as specified in Sec. G.27.

(ii) May allow a pharmacist to work as an authorized nuclear pharmacist if:

(a) This individual qualifies as an authorized nuclear pharmacist as defined in Sec. A.2;

(b) This individual meets the requirements specified in Secs. G.55(b) and G.59 and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

(c) This individual is designated as an authorized nuclear pharmacist in accordance with C.28(j)(2)(iv).

(iii) The actions authorized in C.28(j)(2)(i) and (ii) are permitted in spite of more restrictive language in license conditions.

(iv) May designate a pharmacist (as defined in Sec. A.2) as an authorized nuclear pharmacist if:

(a) The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material, and

(b) The individual practiced at a pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the Agency.

(v) Shall provide to the Agency:

(a) A copy of each individual's certification by a specialty board whose certification process has been recognized by the Agency, NRC, or an Agreement State as specified in ~~Section~~ G.55(a) ~~of this regulation with the written attestation signed by a preceptor as required by Section G.55(b)(2) of this regulation~~; or

(b) The Agreement State or NRC license; or

(c) The NRC master materials licensee permit; or

(d) The permit issued by a licensee or NRC master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist; or

(e) Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the Agency; and

(f) A copy of the State pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, under Sections C.28(j)(2)(ii)(a) and C.28(j)(2)(ii)(c), the individual to work as an authorized nuclear pharmacist.

(3) A licensee shall possess and use i~~n~~strumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

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

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

(4) A licensee shall satisfy the labeling requirements in C.28.(j)(4). ~~paragraph (iv).~~

(~~4~~5) Nothing in this section relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

(k) Manufacture and Distribution of Generators or Reagent Kits for Preparation of Radiopharmaceuticals Containing Radioactive Material.10/ An application for a specific license to manufacture and distribute generators or reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons licensed pursuant to this part for the uses listed in G.200 of these regulations will be approved if:

(1) the applicant satisfies the general requirements specified in C.25;

(2) the applicant submits evidence that:

(i) the generator or reagent kit is to be manufactured, labeled and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA, or

(ii) the manufacture and distribution of the generator or reagent kit are not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act;

(3) the applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material contained in the generator or reagent kit;

(4) the label affixed to the generator or reagent kit contains information on the radionuclide, quantity, and date of assay; and

(5) the label affixed to the generator or reagent kit, or the leaflet or brochure which accompanies the generator or reagent kit, contains:

(i) adequate information, from a radiation safety standpoint, on the procedures to be followed and the equipment and shielding to be used in eluting the generator or processing radioactive material with the reagent kit, and

(ii) a statement that this generator or reagent kit, as appropriate, is approved for use by persons licensed by the Agency pursuant to G.200 of these regulations or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State. The labels, leaflets, or brochures required by C.28(k) are in addition to the labeling required by the Food and Drug Administration (FDA) and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

10/ Although the Agency does not regulate the manufacture and distribution of reagent kits that do not contain radioactive material, it does regulate the use of such reagent kits for the preparation of radiopharmaceuticals containing radioactive material as part of its licensing and regulation of the users of radioactive material. Any manufacturer of reagent kits that do not contain radioactive material who desires to have his reagent kits approved by the Agency for use by persons licensed pursuant to G.200 of these regulations may submit the pertinent information specified in C.28(k).

(l) Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to Part G for use as a calibration, transmission, or reference source, or for diagnostic, brachytherapy or teletherapy sources for the uses listed in G.400, G.500, G.600, and G.1000 of these regulations, will be approved if:

(1) the applicant satisfies the general requirements in C.25 of this part;

(2) the applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

(i) the radioactive material contained, its chemical and physical form, and amount,

(ii) details of design and construction of the source or device,

(iii) procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents,

(iv) for devices containing radioactive material, the radiation profile of a prototype device,

(v) details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests,

(vi) procedures and standards for calibrating sources and devices,

(vii) legend and methods for labeling sources and devices as to their radioactive content, and

(viii) instructions for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device; provided, that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label;

(3) the label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the source or device is licensed by the Agency for distribution to persons licensed pursuant to G.400, G.500, G.600, and G.1000 of these regulations or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State, provided that such labeling for sources which do not require long term storage may be on a leaflet or brochure which accompanies the source;

(4) the source or device has been registered in the Sealed Source and Device Registry;

(5) in the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than 6 months, he shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source; and

(6) in determining the acceptable interval for test of leakage of radioactive material, the Agency will consider information that includes, but is not limited to:

(i) primary containment or source capsule,

(ii) protection of primary containment,

(iii) method of sealing containment,

(iv) containment construction materials,

(v) form of contained radioactive material,

(vi) maximum temperature withstood during prototype tests,

Sec. C.30 Issuance of Specific Licenses.

(a) Upon a determination that an application meets the requirements of the Act and the regulations of the Agency, the Agency will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

(b) The Agency may incorporate in any license at the time of issuance, or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of radioactive material subject to this part as it deems appropriate or necessary in order to:

(1) minimize danger to public health and safety or property;

(2) require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary; and

(3) prevent loss or theft of material subject to this part.

Sec. C.31 Specific Terms and Conditions of Licenses.

(a) Each license issued pursuant to this part shall be subject to all the provisions of the Act, now or hereafter in effect, and to all rules, regulations, and orders of the Agency.

(b) (1) No license issued or granted under this part and no right to possess or utilize radioactive material granted by any license issued pursuant to this part shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the Agency shall, after securing full information find that the transfer is in accordance with the provisions of the Act, now or hereafter in effect, and to all valid rules, regulations, and orders of the Agency, and shall give its consent in writing.

(2) An application for transfer of license must include:

(i) The identity, technical and financial qualifications of the proposed transferee; and

(ii) Financial assurance for decommissioning information required by Section C.29.

(c) Each person licensed by the Agency pursuant to this part shall confine use and possession of the material licensed to the locations and purposes authorized in the license.

(d) Each licensee shall notify the Agency in writing when the licensee decides to permanently discontinue all activities involving materials authorized under the license.

(e) Each specific licensee shall notify the Agency in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

(1) the licensee;

(2) an entity (as that term is defined in 11 U.S.C. 101(15)) controlling the licensee or listing the license or licensee as property of the estate; or

(3) an affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.

(f) The notification specified in C.31(e) shall indicate the bankruptcy court in which the petition for bankruptcy was filed, a copy of the bankruptcy petition, and the date of the filing of the petition.

(g) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with Section G.204. The licensee shall report the results of any test that exceeds the permissible concentration listed in G.204 (a) at the time of generator elution, in accordance with D.1209. The licensee shall record the results of each test and retain each record for 3 years after the record is made.

(h) Production of PET Radioactive Drugs.

(1) Authorization under Section C.26(g) to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

(2) Each licensee authorized under Section C.2667(g) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

(i) Satisfy the labeling requirements in Section C.28(j)(1)(iv) for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.

(ii) Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in Section C.28(j)(3).

(3) A licensee that is a pharmacy authorized under Section C.26(g) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:

(i) an authorized nuclear pharmacist that meets the requirements in Section C.28(j)(2), or

(ii) an individual under the supervision of an authorized nuclear pharmacist as specified in Section G.27.

(4) A pharmacy, authorized under Section C.26(g) to produce PET radioactive drugs for non-commercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirement of Section C.28(j)(2)(v).

PART D

STANDARDS FOR PROTECTION AGAINST RADIATION

GENERAL PROVISIONS

Sec. D.1 Purpose. The requirements of Part D are designed to control the receipt, possession, use, transfer, and disposal of sources of radiation by any licensee or registrant so the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in Part D. However, nothing in Part D shall be construed as limiting actions that may be necessary to protect health and safety.

Sec. D.2 Scope. Part D applies to persons licensed or registered by the Agency to receive, possess, use, transfer, or dispose of sources of radiation. The limits in Part D do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, to exposure from individuals administered radioactive material and released in accordance with G.25, or to voluntary participation in medical research programs.

Sec. D.3 Definitions. As used in Part D:

“Air-purifying respirator” means a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

"Annual limit on intake" (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 0.05 Sv (5 rem) or a committed dose equivalent of 0.5 Sv (50 rem) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Table I, Columns 1 and 2, of Appendix B.

“Assigned protection factor (APF)” means the expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly fitted and trained users. Operationally, the inhaled concentration can be estimated by dividing the ambient airborne concentration by the APF.

“Atmosphere-supplying respirator” means a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere, and includes supplied-air respirators (SARS) and self-contained breathing apparatus (SCBA) units.

"Class" means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D, Days, of less than 10 days, for Class W, Weeks, from 10 to 100 days, and for Class Y, Years, of greater than 100 days. For purposes of these regulations, "lung class" and "inhalation class" are equivalent terms.

"Declared pregnant woman" means a woman who has voluntarily informed the licensee or registrant, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

“Demand respirator” means an atmosphere-supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation.

"Derived air concentration" (DAC) means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI. For purposes of these regulations, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in Table I, Column 3, of Appendix B.

"Derived air concentration-hour" (DAC-hour) means the product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee may take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 0.05 Sv (5 rem).

“Disposable respirator” means a respirator for which maintenance is not intended and that is designed to be discarded after excessive breathing resistance, sorbent exhaustion, physical damage, or end-of-service-life renders it unsuitable for use. Examples of this type of respirator are a disposable half-mask respirator or a disposable escape-only self-contained breathing apparatus (SCBA).

"Dosimetry processor" means a person that processes and evaluates individual monitoring devices in order to determine the radiation dose delivered to the monitoring devices.

“Filtering facepiece (dust mask)” means a negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium, not equipped with elastomeric sealing surfaces and adjustable straps.

“Fit factor” means a quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

“Fit test” means the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.

“Helmet” means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

“Hood” means a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

“Loose-fitting facepiece” means a respiratory inlet covering that is designed to form a partial seal with the face.

“Negative pressure respirator (tight fitting)” means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

"Nonstochastic effect" means a health effect, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. For purposes of these regulations, "deterministic effect" is an equivalent term.

“Permanent implant brachytherapy” means the use of very small implants called seeds or pellets inserted directly into a tumor and left in place until all the radiation has been used.

"Planned special exposure" means an infrequent exposure to radiation in an exceptional situation when alternatives that might avoid the higher exposures are unavailable or impractical. A planned special exposure shall be separate from and in addition to the annual occupational dose limits.

“Positive pressure respirator” means a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

Sec. D.1207 Annual Reports from General Licensees.

a. A licensee granted a general license under Section C.22(e), (g), (i), or (j) shall report annually, the following information on a form provided by the Agency:

   i. The amount and kind of radioactive material received during the previous year;

   ii. The form of the radioactive material;

   iii. The amount possessed by the licensee at the time of the report; and

   iv. The pathways and amounts of radioactive material disposed of by that person during the previous year.

b. The information required by D.1207a.iv. shall be estimated using a technique that is acceptable to the Department.

c. The report required by D.1207a. shall cover the calendar year from January 1 to December 31 and shall be forwarded to the Department not later than March 1 of the following year.

Sec. D.1208 Report and Notification of a Misadministration.

a. Licensees and registrants shall establish appropriate procedures, through compliance with the written directive, to prevent the occurrence of a misadministration.

b. A licensee or registrant shall report any misadministration in which the administration of byproduct material, or radiation from byproduct material or a radiation machine, except for an event that results from patient intervention, results in:

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

      (1) The total dose delivered differs from the prescribed dose by 20 percent or more;

      (2) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

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

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

      (1) An administration of a wrong radioactive drug containing byproduct material;

      (2) An administration of a radioactive drug containing byproduct material by the wrong route of administration;

      (3) An administration of a byproduct material dose or dosage to the wrong individual or human research subject;

      (4) An administration of a byproduct material dose or dosage delivered by the wrong mode of treatment; or

      (5) A leaking sealed source.

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

iv. For permanent implant brachytherapy, the administration of byproduct material or radiation from byproduct 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 differing by 20 percent or more from the total source strength documented in the post-implantation portion of the written directive;

(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.

~~i~~v. A radiation therapy dose or dose from a radiation machine:

(1) Involving the wrong individual, wrong mode of treatment, or wrong treatment site, or of a type other than the one intended; or

(2) When the treatment consists of three or fewer fractions, a difference of the calculated total administered dose from the total prescribed dose by more than 10 percent of the total prescribed dose; or

(3) A calculated weekly administered dose that is 30 percent greater than the weekly prescribed dose; or

(4) A calculated total administered dose that differs from the total prescribed dose by more than 20 percent of the total prescribed dose.

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

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

i. The written report must include:

(1) The licensee's or registrant's name;

(2) The name of the prescribing physician;

(3) A brief description of the misadministration;

(4) Why the misadministration occurred;

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

(6) What actions, if any, have been taken or are planned to prevent recurrence; and

(7) A certification signed by the appropriate authorized user or registrant that the licensee or registrant 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 or registrant shall provide notification of the misadministration to the referring physician and also notify the individual who is the subject of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee or registrant either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee or registrant 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 or registrant shall notify the individual as soon as possible thereafter. The licensee or registrant may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the misadministration may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee or registrant shall inform the individual, or appropriate responsible relative or guardian, that a written description of the misadministration can be obtained from the licensee or registrant upon request. The licensee or registrant shall provide such a written description if requested.

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

g. A licensee or registrant shall:

i. Append to a copy of the report provided to the Agency the:

(1) Name of the individual who is the subject of the misadministration; and

(2) Social security number or other identification number, if one has been assigned, of the individual who is the subject of the misadministration; and

ii. Provide the appended report in Sec. D.1208g.i. to the referring physician, if other than the licensee or registrant, no later than 15 days after the discovery of the misadministration.

h. Each licensee or registrant shall retain a record of each misadministration for five years. The record must contain the names of all individuals involved (including the prescribing physician, allied health personnel, the individual who received the misadministration, and that individual's referring physician, if applicable), the individual's social security number or identification number if one has been assigned, a brief description of the misadministration, why it occurred, the effect on the individual, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence.

Sec. D.1209 ~~Reserved~~ Report and Notification for an Eluate Exceeding Permissible Molybdenum-99 Strontium-82, and Strontium~~.~~

(a) The licensee shall notify by telephone Maryland's Radioactive Materials Program, the NRC Operations Center and the distributor of the generator within 7 calendar days after discovery that an eluate exceeded the ~~permissible~~permissible concentration listed in 10 CFR § 35.204(a) at the time of generator elution. The telephone report to the NRC must 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 10 CFR § 30.6(a) ~~of this chapter~~, the licensee shall submit a written report to the appropriate NRC Regional Office listed in 10 CFR § 30.6 ~~of this chapter~~ within 30 calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report must 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 ~~paragraph (a) of this section.~~D.1209(a)

Sec. D.1210 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 5 rem (50 mSv) 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 is a result of an administration of radioactive material to a breast-feeding individual that:

i. Is greater than 5 rem (50 mSv) 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 D.1210a. or b.

d. The licensee shall submit a written report to the Agency within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in D.1210(a) or (b).

i. The written report must include:

(1) The licensee's name;

(2) The name of the prescribing physician;

(3) A brief description of the misadministration;

(4) Why the misadministration occurred;

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(5) The effect, if any, 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 not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

e. The licensee shall provide notification of the misadministration to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of a misadministration that would require reporting under D.1210a. or b., unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the misadministration, because of any delay in notification. To meet the requirements of D.1210e., the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the misadministration can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

f. A licensee shall:

i. Append to a copy of the report provided to the Agency the:

(1) Name of the pregnant individual or the nursing child who is the subject of the misadministration; and

(2) Social security number or other identification number, if one has been assigned, of the pregnant individual or the nursing child who is the subject of the misadministration; and

ii. Provide the appended report in D.1210f.i. to the referring physician, if other than the licensee, no later than 15 days after the discovery of the misadministration.

Sec. D.1211 Additional Reporting Requirements for Radioactive Materials.

a. Immediate report. Each licensee shall notify the Agency as soon as possible but no later than 4 hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or release of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.).

b. Twenty-four hour report. Each licensee shall notify the Agency within 24 hours after the discovery of any of the following events involving licensed material:

i. An unplanned contamination event that:

(1) Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;

(2) Involves a quantity of material greater than five times the lowest annual limit on intake specified in Appendix B of Part D; and

~~(v)~~viii Except for patients who cannot be moved out of the room, only the staff and ancillary personnel required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:

(a) All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by no less than 0.5 millimeter lead equivalent.

(b) All persons shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent.

(c) Patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of not less than 0.25 millimeter lead equivalent or shall be so positioned that the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.

~~(vi)~~ix Gonad shielding of not less than 0.5 millimeter lead equivalent shall be used for patients, who have not passed the reproductive age, during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

~~(vii)~~(x) Thyroid shielding consisting of a ≥0.5 mm lead equivalent thyroid collar or shield shall be provided to and used for all patients upon request or whenever the useful beam is expected to or may strike the thyroid gland, so long as such shielding does not interfere with diagnostic x-ray procedures.

~~(viii)~~xi Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed practitioner of the healing arts. This provision also prohibits deliberate exposure for the purpose of training, demonstration, or other non-healing-arts purposes.

~~(ix)~~xii When a patient or film must be provided with auxiliary support during a radiation exposure:

(a) Mechanical holding devices shall be used when the technique permits. The written safety procedures, required by Section F.3(a)(1)(iv), shall list individual projections where holding devices cannot be utilized;

(b) Written safety procedures, as required by Section F.3(a)(l)(iv), shall indicate the requirements for selecting a holder and the procedure the holder shall follow;

(c) The human holder shall be protected as required by Section F.3(a)(1)(v);

(d) No individual shall be used routinely to hold film or patients; and

(e) In those cases where the patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material.

(f) The beam defining light, if present, shall be turned on during all exposures for which a human holder is used. The operator shall not initiate the exposure except on permission from the holder.

(g) No individual who is occupationally exposed to radiation shall be required to hold patients during radiographic exposures.

~~(ix)~~xiii Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized. Such procedures and equipment shall include, but are not limited to the following requirements:

(a) The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objective of the examinations;

(b) The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality;

(c) Portable or mobile x-ray equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a stationary x-ray installation; or

(d) X-ray systems subject to Section F.6 shall not be utilized in procedures where the source to patient distance is less than 30 centimeters.

(e) Filmless diagnostic x-ray systems shall use technique factors not to exceed the maximum of the technique range recommended by manufacturers' specifications to generate images.

~~(x)~~xiv All individuals who are associated with the operation of an x-ray system are subject to the requirements of Part D of these regulations. In addition:

(a) When protective clothing or devices are worn on portions of the body and a personnel monitoring device(s) is required, at least one such monitoring device shall be utilized as follows:

(1) When an apron is worn, the monitoring device shall be worn at the collar outside of the apron.

Part G

USE OF RADIONUCLIDES IN THE HEALING ARTS

General Regulatory Information

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

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

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

"Associate Radiation Safety Officer" means an individual who:

(1) Meets the requirements in G.50 ~~a~~b~~d~~ and G.59; and

(2) Is currently identified as an Associate Radiation Safety Officer for the types of use of byproduct 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 NRC or an Agreement State; or

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

"Authorized medical physicist" means an individual who:

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

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

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

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

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

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

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

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

(2) Is identified as an authorized user on:

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

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

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

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

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

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

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

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

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

“Hub” means the main office of a mobile nuclear medicine service where patient doses are received from a manufacturer or distributor, where patient doses are assayed prior to being delivered to the point of use, and where records are maintained for Agency inspection.

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

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

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

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

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

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

“Ophthalmic physicist” means an individual who:

(1) Meets the requirements in G.433 (a) and G.59; and

(2) Is identified as an ophthalmic physicist on a:

(i) Specific medical use license issued by the NRC or an Agreement State;

(ii) Permit issued by the NRC or an 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 materials 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 teletherapy unit for a specified set of exposure conditions.

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

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

(1) In a written directive; or

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

"Recordable event" means the administration of:

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

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

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

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

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

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

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

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

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

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

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

Secs. G.3 – G.5 Reserved.

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

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

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

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

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

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

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

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

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

Secs. G.7 – G.10 Reserved.

Sec. G.11 -License Required.

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

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

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

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

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

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

(3) The provisions of §G.14(a);

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

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

Sec. G.12 License Applications and Amendments.

(a) Applications.

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

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

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

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

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

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

(i) An authorized user in each category of use certified by the organizations specified in G.51(a), G.57(a), G.190(a), G.290(a), G.390(a), G.392(a), G.394(a), G.396(a), G.490(a), G.491(a) and G.590(a);

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

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

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

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

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

(~~4~~5) Before it orders radioactive material in excess of the amount, or radionuclide or form different than authorized on the license; and

(~~5~~6) Before it adds to or changes the areas of use or addresses of use identified in the application or on the license.

(7) Before it revises procedures required by ~~§§ 35~~G.610, ~~35~~G.642, ~~35~~G.643, and ~~35~~G.645, as applicable, where such revision reduces radiation safety; and

(8) Before it receives a sealed source from a different manufacturer or of a different model number than authorized by its license unless the sealed source is used for manual brachytherapy, is listed in the Sealed Source and Device Registry, and is in a quantity and for an isotope authorized by the license.

Sec. G.13 Reserved.

Sec. G.14 Notifications.

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

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

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

(2) The licensee's mailing address changes.

(~~4~~3) The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in § C.31(b) ~~of this chapter~~;

(~~5~~4) The licensee has added to or changed the areas of use identified in the application or on the license where byproduct material is used in accordance with either § G.100 or § G.200 if the change does not include addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide/PET radioactive drug production area; or

(~~6~~5) 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 must include the manufacturer and model number of the sealed source, the isotope, and the quantity per sealed source.

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

Secs. G.15 – G.23 Reserved.

General Administrative Requirements

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

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

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

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

(b) A licensee's management shall appoint a Radiation Safety Officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. 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, must 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 Safety Officer is listed on a license. The Radiation Safety Officer may delegate duties and tasks to the Associate Radiation Safety Officer but shall not delegate the authority or responsibilities for implementing the radiation protection program.

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

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

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

(f) Reserved.

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

(1) Identify radiation safety problems;

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

(3) Stop unsafe operations; and,

(4) Verify implementation of corrective actions.

(h) ALARA Program.

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

(2) To satisfy the requirement of G.24(h)(1):
(i) The management, Radiation Safety Officer, and all authorized users shall participate in the establishment, implementation, and operation of the program as required by these regulations or the Radiation Safety Committee; or

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

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

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

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

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

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

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

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

Sec. G.25 Radiation Safety Officer.

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

(b) The Radiation Safety Officer shall:

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

(2) Implement written policy and procedures for:

(i) Authorizing the purchase of radioactive material;

(ii) Receiving and opening packages of radioactive material;

(iii) Storing radioactive material;

(iv) Keeping an inventory record of radioactive material;

(v) Using radioactive material safely;

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

(vii) Performing periodic radiation surveys;

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

(ix) Disposing of radioactive material;

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

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

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

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

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

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

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

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

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

(i) The date of the meeting;

(ii) Members present;

(iii) Members absent;

(iv) Summary of deliberations and discussions;

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

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

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

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

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

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

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

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

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

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

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

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

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

Sec. G.27 Supervision.

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

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

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

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

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

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

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

Secs. G.28 – G.39 Reserved.

Sec. G.40 Written Directives.

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

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

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

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

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

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

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

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

(6) For permanent implant brachytherapy:

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

(ii) 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

(7~~6~~) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:

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

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

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

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

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

G.41 Procedures for Administrations Requiring a Written Directive.

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

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

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

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

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

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

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

(4) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by G.600 or G.1000.

(5) Determining if a medical misadministration, as defined in D.1208, has occurred; and

(6) 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 in G.41 in accordance with G.2041.

Secs. G.42 – G.48 Reserved.

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

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

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

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

Sec. G.50 Training For Radiation Safety Officer.

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

(a) Is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in G.50(d) ~~and G.50(e)~~. T ~~(~~the names of board certifications which have been recognized by the NRC or an Agreement State will be posted on the NRC's Medical Uses Licensee Toolkit ~~W~~web page~~)~~:

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

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

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

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

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

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

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

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

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

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

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

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

(iv) Radiation biology; and

(v) Radiation dosimetry; and

(2) One year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on an NRC or Agreement State license or permit issued by an NRC master material licensee that authorizes similar type(s) of use(s) of radioactive material. An Associate Radiation Safety Officer may provide supervision for those areas for which the Associate Radiation Safety Officer is authorized on a NRC~~Commission~~ or an Agreement State license or permit issued by an NRC~~a Commission~~ master material licensee. The full-time radiation safety experience must involve the following ~~involving the following~~:

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

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

(iii) Securing and controlling radioactive material;

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

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

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

(vii) Disposing of radioactive material; ~~or~~and:

(3) This individual must obtain a written attestation, signed by a preceptor Radiation Safety Officer or Associate Radiation Safety Officer who has experience with the radiation safety aspects of similar types of use of ~~byproduct~~ radioactive material for which the individual is seeking approval as a Radiation Safety Officer or an Associate Radiation Safety Officer. The written attestation must state that the individual has satisfactorily completed the requirements in G.50(b)(1) and G.50(d)~~paragraphs (b)(1) and (d) of this section~~, and is able to independently fulfill the radiation safety-related duties as a Radiation Safety Officer or as an Associate Radiation Safety Officer for a medical use license; or

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

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

(3) Has experience with the radiation safety aspects of the types of use of ~~byproduct~~ radioactive material for which the individual is seeking simultaneous approval both as the Radiation Safety Officer and the authorized user on the same new medical use license or new medical use permit issued by an NRC ~~Commission~~ master material license. The individual must also meet the requirements G.50 (d).

(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 a Radiation Safety Officer, an Associate Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

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~~(d)Has obtained written attestation, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in paragraph (e) and in G.50(a)(1)(i) and (a)(1)(ii) or G.50(a)(2)(i) and (a)(2)(ii) or G.50(b)(1) or G.50(c)(1) or (c)(2) and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; and~~

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

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

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

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

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

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

(i) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized under G.51~~this section~~ by the NRC or an Agreement State; or

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

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

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

(i) Performing sealed source leak tests and inventories;

(ii) Performing decay corrections;

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

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

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in ~~G.51(c) and G.51(a)(1) and (2), or~~ G.51(b)(1) and G.51(c), and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in G.51, G.57, or equivalent Agreement State or NRC requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

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

Secs. G.52 – G.54 Reserved.

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

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

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

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

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

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

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

(b) Has completed:

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

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

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

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

(e) Radiation biology; and

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

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

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

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

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

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

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

Sec. G.56 Reserved.

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

(a) (1) An individual identified as a Radiation Safety Officer, a teletherapy physicist or authorized medical physicist, or an authorized nuclear pharmacist on an NRC or Agreement State license or a permit issued by an NRC or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope before the effective date of these regulations need not comply with the training requirements of G.50, G.51, or G.55, respectively except the Radiation Safety Officers and authorized medical physicists identified in G.57(a)~~this paragraph~~ must meet the training requirements in G.50(d) or G.51(c), as appropriate, for any material or uses for which they were not authorized prior to this date.

(2) Any 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 NRC ~~Commission~~ or an Agreement State license or an NRC~~Commission~~ master material license permit for those materials and uses that these individuals performed on or before October 24, 2005.

(3) 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 ~~§ 35G.~~51, for those materials and uses that these individuals performed on or before October 24, 2005.

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

(b) (1) Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the NRC or Agreement State, a permit issued by an NRC master material licensee, a permit issued by an NRC or Agreement State broad scope licensee, or a permit issued by an NRC master material license broad scope permittee who perform only those medical uses for which they were authorized before the effective date of these regulations need not comply with the training requirements of G.100 through G.690.~~.~~

(2) Physicians, dentists, or podiatrists not identified as authorized users for the medical use of radioactive material on a license issued by the NRC or Agreement State, a permit issued by an NRC master material licensee, a permit issued by an NRC or Agreement State broad scope licensee, or a permit issued by an NRC master material license broad scope permittee who perform only those medical uses for which they were authorized 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:

(i) For uses authorized under G~~§§ 35~~.100 or G~~35~~.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;

(ii) For uses authorized under G~~§ 35~~.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;

(iii) For uses authorized under G~~§§ 35~~.400 orG~~ 35~~.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

(iv) For uses authorized under G~~§ 35~~.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.

(3) Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses performed at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of G.100 through G.690~~ubparts D through H of this part~~ when performing the same medical uses. A physician, dentist, or podiatrist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses at the locations and time period identified in this paragraph, qualifies as an authorized user for those materials and uses performed before these dates, for the purposes of this chapter.

(c) Individuals who need not comply with training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on a specific license for the same uses for which these individuals are authorized.

Sec. G.58 Reserved.

Sec. G.59 Recentness of Training.

The training and experience specified in Secs. G.24-G.59 and G.100 through G.690 must have been obtained within the 7 years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

General Technical Requirements

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

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

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

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

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

(3) Maintain records of tests required in G.60.A(b)(1) and (2) for 3

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

(a) All medical use licensees excluding certain mobile or temporary sites as described in Section G.63 authorized to administer radiopharmaceuticals shall possess a dose calibrator and use it to measure the amount of activity administered to each patient or human research subject.

(b) A licensee shall:

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

(2) Test each dose calibrator for accuracy upon installation and at intervals not to exceed 12 months thereafter by assaying at least 2 sealed sources containing different radionuclides, the activity of which the manufacturer has determined within 5 percent of the stated activity, with minimum activity of 10 microcuries (370 kBq) for radium-226 and 50 microcuries (1.85 MBq) for any other photon-emitting radionuclide, and at least one of which has a principal photon energy between 100 keV and 500 keV;

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

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

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

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

Sec. G.64 Reserved.

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

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

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

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

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

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

(f) Byproduct material in sealed sources authorized by this provision shall not be:

(1) Used for medical use as defined in ~~§ 35.2~~ COMAR 26.12.01.01.A.2 except in accordance with the requirements in ~~§ 35.500~~ G.500; or

(2) Combined (i.e., bundled or aggregated) to create an activity greater than the maximum activity of any single sealed source authorized under ~~this section~~.G.65.

(g) A licensee using calibration, transmission, and reference sources in accordance with the requirements in G.65(a) or (b)~~paragraphs (a) or (b) of this section~~ need not list these sources on a specific medical use license.

Sec. G.66 Reserved.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Sec. G.68 Reserved.

Sec. G.69 Labeling of Vials and Syringes.

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

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

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

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

Unsealed Radioactive Material—Written Directive Not Required

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

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

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

(b) Prepared by a PET radioactive drug producer licensed under Section C.26(g) or equivalent Agreement State or NRC requirements; or

(c) Prepared by an authorized nuclear pharmacist; a physician who is an authorized user and who meets the requirements specified in G.290, or G.390 and G.290(c)(1)(ii)(g); or an individual under the supervision of either as specified in G.27. The authorization given in G.100(c) to obtain unsealed byproduct material excludes the production of PET radionuclides; or

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

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

Secs. G.101 – G.189 Reserved.

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

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

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

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

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

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

(c) Has completed the following:

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

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

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

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

(e) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in G.57, G.190, G.290, G.390, or equivalent NRC or Agreement State requirements, involving:

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

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

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

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

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

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

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

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in G.190 (c)(1) and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under G.100. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in G.57, G.190, G.290, or G.390, or equivalent NRC or Agreement State requirements; or

(ii) 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, or G.390, or equivalent NRC or Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must 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 must include training and experience specified in G.190 (c)(1).

Secs. G.191 – G.199 Reserved.

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

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

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

(b) Prepared by a PET radioactive drug producer licensed under Section C.26(g) or equivalent Agreement State or NRC requirements; or

(c) Prepared by an authorized nuclear pharmacist; a physician who is an authorized user and who meets the requirements specified in G.290, or G.390 and G.290(c)(1)(ii)(g); or an individual under the supervision of either as specified in G.27. The authorization given in G.200(c) to obtain unsealed byproduct material excludes the production of PET radionuclides; or

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

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

Secs. G.201 – G.203 Reserved.

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

(a) A licensee may not administer to humans a radiopharmaceutical that contains:

(1) More than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m); or

(2) More than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 microcurie of strontium-82 per millicurie of rubidium-82 chloride); or more than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 microcurie of strontium-85 per millicurie of rubidium-82).

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

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

(d~~e~~) The licensee shall report any measurement that exceeds the limits in G.204(a)~~paragraph (a) of this section~~ at the time of generator elution, in accordance with D.1209.

Secs. G.205 – G.289 Reserved.

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

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

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

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

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

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

(c) Has completed the following:

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

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

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

(d) Chemistry of radioactive material for medical use;

(e) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user, who meets the requirements in G.57, G.290, or G.290(c)(1)(ii)(g) and G.390, or equivalent Agreement State or NRC requirements~~,~~. ~~involving~~ An authorized nuclear pharmacist who meets the requirements in G.55 or G.57 may provide the supervised work experience for G.290~~paragraph~~ (c)(1)(ii)(g). ~~of this section.~~ Work experience must involve:

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

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

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

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

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

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

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

~~Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in G.57, G.290, or G.390 and G.290(c)(1)(ii)(g), or equivalent Agreement State or NRC requirements, that the individual has satisfactorily completed the requirements in G.290(a)(1) or G.290(c)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under G.100 and G.200.~~

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in G.290(c)(1)~~paragraph (c)(1) of this section~~ and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under ~~§§ 35~~G.100 and ~~35~~G.200. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in G.~~§§ 35~~.57, G.~~35~~.290, or G.~~35~~.390 and G.~~35~~.290(c)(1)(ii)(~~-g~~G), or equivalent Agreement State or NRC requirements; or

ii) 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 ~~§§. 35~~G.57, ~~35~~G.290, or ~~35~~G.390 and ~~35~~G.290(c)(1)(ii)(~~G~~g), or equivalent Agreement State or NRC requirements, and concurs with the attestation provided by the residency program director. The residency training program must 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 must include training and experience specified in G.290(c)(1).~~paragraph (c)(1) of this section.~~

Secs. G.291 – G.299 Reserved.

Unsealed Radioactive Material—Written Directive Required

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

~~A licensee may use any unsealed radioactive material prepared for medical use and for which a written directive is required that is~~ A licensee may use any unsealed byproduct material identified in G.390(b)(1)(ii)(g) prepared for medical use and for which a written directive is required that is:

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

(b) Prepared by a PET radioactive drug producer licensed under Section C.26(g) or equivalent Agreement State or NRC requirements; or

(c) Prepared by an authorized nuclear pharmacist; a physician who is an authorized user and who meets the requirements specified in G.290, G.390; or an individual under the supervision of either as specified in G.27. The authorization given in G.300(c) to obtain unsealed byproduct material excludes the production of PET radionuclides; or

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

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

Secs. G.301 – G.309 Reserved. Sec.

G.310 Safety Instruction.

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

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

(1) Patient or human research subject control;

(2) Visitor control, including:

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

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

(3) Contamination control;

(4) Waste control; and

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

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

Secs. G.311 – G.314 Reserved.

Sec. G.315 Safety Precautions.

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

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

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

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

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

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

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

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

Secs. G.316 – G.389 Reserved.

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

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

(a) Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in G.390(b)(1)(ii)(g) and G.390(b)(2). The names of board certifications that have been recognized by the NRC~~Commission~~ or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit w~~W~~eb page.~~(Specialty boards whose certification processes have been recognized by the NRC or an Agreement State will be posted on the NRC's Web page.)~~ To be recognized, a specialty board shall require all candidates for certification to:

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

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

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

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

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

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

(e) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in G.57, G.390, or equivalent Agreement State or NRC requirements. A supervising authorized user, who meets the requirements in G.390(b), must also have experience in administering dosages in the same dosage category or categories (i.e., G.390(b)(1)(ii)(g)) as the individual requesting authorized user status. The work experience must involve:

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

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

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

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

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

(f) [Reserved]

(g) ~~Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status)~~ Administering dosages of radioactive drugs to patients or human research subjects from the three categories in G.390(b)(1)(ii)(g) ~~this paragraph~~. Radioactive drugs containing radionuclides in categories not included in this paragraph are regulated under G.1000. This work experience must involve a minimum of three cases in each of the following categories for which the individual is requesting authorized user status:

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

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

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

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

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

(2) ~~Has obtained written attestation that the individual has satisfactorily completed the requirements in G.390(a)(1) and G.390(b)(1)(ii)(g) or G.390(b)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under G.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in G.57, G.390 or equivalent Agreement State or NRC requirements. The preceptor authorized user, who meets the requirements in G.390(b), must have experience in administering dosages in the same dosage category or categories (i.e., G.390(b)(1)(ii)(g)) as the individual requesting authorized user status.~~ Has obtained written attestation that the individual has satisfactorily completed the requirements in G.390(b)(1)~~paragraph (b)(1) of this section~~ and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under ~~§ 35.~~G.300 for which the individual is requesting authorized user status. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in G.57, G.390, or equivalent NRC 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

(ii) 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 NRC 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 must 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 must include training and experience specified in G.390 (b)(1).

Sec. G.391 Reserved.

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

Except as provided in G.57, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries), to be a physician who:

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

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

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

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

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

(v) Radiation biology; and

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(2) Has work experience, under the supervision of an authorized user who meets the requirements in G.57, G.390, G.392, G.394, or equivalent Agreement State or NRC requirements. A supervising authorized user who meets the requirements in G.390(b) must also have experience in administering dosages as specified in G.390(b)(1)(ii)(g)(*1*) or (*2*). The work experience must involve:

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

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

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

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

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

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

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in G.392(c)(1) and G.392(c)(2), and ~~has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under G.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in G.57, G.390, G.392, G.394, or equivalent Agreement State or NRC requirements. A preceptor authorized user, who meets the requirement in G.390(b), must also have experience in administering dosages as specified in G.390(b)(1)(ii)(g)(1) or (2).~~ is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under ~~§ 35.~~G.300. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in ~~§§~~ G.35.G.57, G.~~35.~~390, G.~~35.~~392, G.~~35.~~394, or NRC or equivalent Agreement State requirements and has experience in administering dosages as specified in G~~§ 35~~.390(b)(1)(ii)(~~G~~g)(1) or ~~§ 35~~.390(b)(1)(ii)(~~G~~g)(2); or

(ii) 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~~§§ 35~~.57, G.~~35.~~390, G.~~35.~~392, G.~~35.~~394, or NRC or equivalent Agreement State requirements, has experience in administering dosages as specified in ~~§~~.390(b)(1)(ii)(~~G~~)(1) or ~~§ 5~~G.390(b)(1)(ii)(~~G~~g)(2), and concurs with the attestation provided by the residency program director. The residency training program must 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 must include training and experience specified in G.392(c)(1) and G.392(c)(2).~~paragraphs (c)(1) and (2) of this section~~.

Sec. G.393 Reserved.

Sec. G.394 Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Greater than 1.22 Gigabecquerels (33 millicuries).

Except as provided in G.57, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries), to be a physician who:

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in G.394(c)(1) and G.394(c)(2), and whose certification has been recognized by the NRC or an Agreement State.~~, and who meets the requirements in paragraph G.394(c)(3) (t~~The names of board certifications which have been recognized by the NRC or an Agreement State will be posted on the NRC's Medical Uses Licensee Toolkit~~W~~web page); or

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

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

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

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

(v) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in G.57, G.390, G.394, or equivalent Agreement State or NRC requirements. A supervising authorized user, who meets the requirements in G.390(b), must also have experience in administering dosages as specified in G.390(b)(1)(ii)(g)(2). The work experience must involve:

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

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

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

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

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

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

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in G.394(c)(1) and G.394(c)(2), and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under G.300. The attestation must be obtained from either:~~has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under G.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in G.57, G.390, G.394, or equivalent Agreement State or NRC requirements. A preceptor authorized user, who meets the requirements in G.390(b), must also have experience in administering dosages as specified in G.390(b)(1)(ii)(g)(2).~~

(i) A preceptor authorized user who meets the requirements in G.57, G.390, G.394 ~~§§ 35.57, 35.390, 35.394~~, or equivalent Agreement State or NRC requirements, and has experience in administering dosages as specified in G.390(b)(1)(ii)(g)(*2*)~~§ 35.390(b)(1)(ii)(G)(2)~~; or

(ii) 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 ~~§§ 35.57, 35.390, 35.394~~, or equivalent Agreement State or NRC requirements, has experience in administering dosages as specified in ~~§ 35~~G.390(b)(1)(ii)(~~G~~g)(*2*), and concurs with the attestation provided by the residency program director. The residency training program must 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 must include training and experience specified in G.394(c)(1) and G.394(c)(2)~~paragraphs (c)(1) and (2) of this section~~.

Sec. G.395 Reserved.

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

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

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

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

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

(d) The physician—

(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations listed in ~~§ 35~~.G.390(b)(1)(ii)(g~~G~~)(3). The training must include—

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

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

(v) Radiation biology; and

~~(d)~~ (2) Has work experience, under the supervision of an authorized user who meets the requirements in G.57, G.390, G.396, or equivalent NRC or Agreement State requirements, in the parenteral administrations listed in G.390(b)(1)(ii)(~~G~~g)(3). A supervising authorized user who meets the requirements in G390, G.396, or equivalent NRC or Agreement State requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status. The work experience must involve: ~~(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. The training must include:~~

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

~~(ii) Radiation protection;~~

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

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

~~(v) Radiation biology; and~~

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~~(2) 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 or NRC requirements, in the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in G.390 must have experience in administering dosages as specified in G.390(b)(1)(ii)(g)(3) and/or G.390(b)(1)(ii)(g)(4). The work experience must involve:~~

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

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

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

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

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

(vi) Administering dosages to patients or human research subjects, that include at least ~~3~~ three cases of ~~involving~~ the parenteral administrations~~, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV and/or at least 3 cases involving the parenteral administration of any other radionuclide, for which a written directive is required~~ as specified in ~~§ 35~~G.390(b)(1)(ii)(~~G~~g)(3); and

~~Has obtained written attestation that the individual has satisfactorily completed the requirements in G.396(b) or (c), and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in G.57, G.390, G.396, or equivalent Agreement State or NRC requirements. A preceptor authorized user, who meets the requirements in G.390, must have experience in administering dosages as specified in G.390(b)(1)(ii)(g)(3) and/or G.390(b)(1)(ii)(g)(4).)~~

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (b)(1) and (2) of this section, and is able to independently fulfill the radiation safety-related duties as an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in §§ 35.57, 35.390, 35.396, or equivalent Agreement State requirements. A preceptor authorized user who meets the requirements in § 35.390, 35.396, or equivalent Agreement State requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status; or

(ii) 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 §§ 35.57, 35.390, 35.396, or equivalent 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 must 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 must include training and experience specified in paragraphs (b)(1) and (2) of this section.

Secs. G.397 – G.399 Reserved.

Manual Brachytherapy

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

(a) As approved in the Sealed Source and Device Registry 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 must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

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

Secs. G.401 – G.403 Reserved.

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

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

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

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

Sec. G.405 Reserved.

Sec. G.406 Brachytherapy Sources Accountability**.**

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

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

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

Secs. G.407 – G.409 Reserved.

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

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

(1) Size and appearance of the brachytherapy sources;

(2) Safe handling and shielding instructions;

(3) Patient or human research subject control;

(4) Visitor control, including both:

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

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

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

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

Secs. G.411 – G.414 Reserved.

Sec. G.415 Safety Precautions.

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

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

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

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

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

(1) Dislodged from the patient; and

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

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

Secs. G.416 – G.431 Reserved.

Sec. G.432 Calibration Measurements of Brachytherapy Sources.

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

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

(2) Determined source positioning accuracy within applicators; and

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

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

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

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

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

(a) ~~Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under G.432.~~ Licensees who use strontium-90 for ophthalmic treatments must ensure that certain activities as specified in G.433(b)~~paragraph (b) of this section~~ are performed by either:

(1) An authorized medical physicist; or

(2) An individual who:

(i) is identified as an ophthalmic physicist on a specific medical use license issued by the NRC~~Commission~~ or an Agreement State; permit issued by the NRC~~a Commissio~~n or Agreement State broad scope medical use licensee; medical use permit issued by an NRC ~~Commission~~ master material licensee; or permit issued by an NRC ~~Commission~~ master material licensee broad scope medical use permittee; and

(ii) 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

(iii) has successfully completed 1 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

(iv) Has documented training in:

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

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

(c) Performing the calibration measurements of brachytherapy sources as detailed in G.432~~§ 35.432~~.

(b) The individuals who are identified in paragraph (a) of this section must:

(1) Calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under § G.432~~35.432~~; and

(2) 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 must include the frequencies that the individual meeting the requirements in paragraph (a) of this section 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~~b~~) A licensee shall retain a record of the activity of each strontium-90 source in accordance with G.2433.

Secs. G.434 – G.456 Reserved.

Sec. G.457 Therapy-related Computer Systems.

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

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

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

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

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

Secs. G.458 – G.489 Reserved.

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

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

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

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

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

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

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

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

(d) Radiation biology; and

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

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

(b) Checking survey meters for proper operation;

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

(d) Maintaining running inventories of material on hand;

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

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

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

(3) Has obtained written ~~attestation~~ attestation that the individual has satisfactorily completed the requirements in G. 490(b)(1) and (b)(2) and~~, signed by a preceptor authorized user who meets the requirements in G.57, G.490(b) (1) and (2) or equivalent Agreement State or NRC requirements, that the individual has satisfactorily completed the requirements in G.490(a)(1), or G.490(b)(1) and G.490(b)(2), and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under G.400~~ is able to independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy sources for the medical uses authorized under G~~§35.~~400. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in §§ G.~~35~~.57, G.~~35.~~490, or equivalent Agreement State requirements; or

(ii) 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 Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must 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 must include training and experience specified in G.490 (b)(1) and G.490(b)(2)~~.~~

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

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

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

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

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

(iv) Radiation biology; and

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

(i) Examination of each individual to be treated;

(ii) Calculation of the dose to be administered;

(iii) Administration of the dose; and

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

(3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in G.57, G.490, G.491, or equivalent Agreement State or NRC requirements, that the individual has satisfactorily completed the requirements in G.491(b) and ~~has achieved a level of competency sufficient to function independently~~ is able to independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.

Secs. G.492 – G.499 Reserved.

Sealed Sources for Diagnosis

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

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

(a) A licensee must use only sealed sources that are not in medical devices for diagnostic medical uses if the sealed sources are approved in the Sealed Source and Device Registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

(b) A licensee must 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 must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

(c) Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of G.49(a)~~§ 35.49(a)~~ are met.

Secs. G.501 – G.589 Reserved.

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

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

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

(b) Is an authorized user for uses listed in G.200 ~~§ 35.200~~ or NRC or equivalent Agreement State requirements; or

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

(1) Radiation physics and instrumentation;

(2) Radiation protection;

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

(4) Radiation biology; and

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

Sections G.591 – G.599 Reserved.

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

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

(a) A licensee s~~hall~~must only use sealed sources: ~~in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses~~:

(1) As approved in the Sealed Source and Device Registry in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units to deliver therapeutic doses for medical uses; or

(2~~b~~) In research involving photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units ~~in accordance~~ in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration (FDA) provided the requirements of G.49(a) are met.

(b) A licensee must use photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units:

(1) 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 must be used in accordance with radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

(2) In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of G.49(a)~~§ 35.49(a)~~ are met

Sections G.601 – G.603 Reserved.

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

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

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

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

(a) Only a person specifically licensed by the NRC or an Agreement State shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

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

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

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

Secs. G.606 – G.609 Reserved.

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

(a) A licensee shall:

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

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

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

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

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

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

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

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

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

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

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

(d) ~~A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in~~(1) 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 must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training.

(2) A licensee shall provide operational and safety instructions initially and at least annually to all individuals who operate the unit at the facility, as appropriate to the individual's assigned duties. The instructions shall include instruction in:

(~~1~~i) The procedures identified in G.610(a)(4); 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.610(d) in accordance with G.2310.

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

Secs. G.611 – G.614 Reserved.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Sec. G.652 Radiation Surveys.

(a) In addition to the survey requirement in Sec. D.501, a person licensed under this part shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry.

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

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

Secs. G.653 – G.654 Reserved.

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

(a) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement ~~or at intervals not to exceed 5 years, whichever comes first,~~ to assure proper functioning of the source exposure mechanism~~.~~ and other safety components. The interval between each full inspection servicing shall not exceed 5 years for each teletherapy unit and shall not exceed 7 years for each gamma stereotactic radiosurgery unit.

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

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

G.656 Reserved.

Sec. G.657 Therapy-Related Computer Systems.

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

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

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

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

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

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

Secs. G.658 – G.689 Reserved.

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

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

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

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

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

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

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

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

(d) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in G.57, G.690, or NRC or equivalent Agreement State requirements, at a ~~medical institution~~ medical facility that is authorized to use ~~byproduct~~ radioactive materials in G.600, involving:

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

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

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

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

(e) Checking and using survey meters; and

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

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

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in ~~G.690(a)(1) or~~ G.690(b)(1) and G.690(b)(2), and G.690(c), and ~~has achieved a level of competency sufficient to function~~ is able to independently fulfill the radiation safety-related duties as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The ~~written~~ attestation must be obtained from either:

(i) ~~signed by~~ A~~a~~ preceptor authorized user who meets the requirements in G.57, G.690, or NRC or equivalent Agreement State requirements for the type(s) of therapeutic medical unit for which the individual is requesting ~~for an~~ authorized user status~~for each type of therapeutic medical unit for which the individual is requesting authorized user status~~;~~; and~~or

(ii) 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 Agreement State or NRC 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 must 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 must include training and experience specified in G.690(b)(1) and G.690(b)(2).

(c) Has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

Secs. G.691 – G.999 Reserved.

Other Medical Uses of Radioactive Material or Radiation From Radioactive Material

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

A licensee may use radioactive material or a radiation source approved for medical use which is not specifically addressed in G.100 through G.690 if:

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

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

Secs. G.1001 – G.2023 Reserved.

Records

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

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

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

~~(b)~~(c) For each Associate Radiation Safety Officer appointed under ~~§ 35~~G.24(b), the licensee shall retain, for 5 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.

Secs. G.2025 – G.2039 Reserved.

Sec. G.2040 Records of Written Directives.

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

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

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

(b) A licensee shall retain the record of each survey required by G.80(a)(6) for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

Secs. G.2081 – G.2203 Reserved.

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

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

Secs. G.2205 – G.2309 Reserved.

Sec. G.2310 Records of Safety Instruction.

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

Secs. G.2311 – G.2403 Reserved.

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

A licensee shall maintain a record of the surveys required by G.404 and G.604 for 3 years. Each record must include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

Sec. G.2405 Reserved.

Sec. G.2406 Records of Brachytherapy Source Accountability.

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

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

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

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

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

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

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

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

Secs. G.2407 – G.2431 Reserved.

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

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

(b) The record must include:

(1) The date of the calibration;

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

(3) The source output or activity;

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

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

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

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

(b) The record must include:

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

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

Secs. G.2434 – G.2604 Reserved.

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

(c) Procedures for submitting advance notification.

(1) The notification must be made in writing to:

(i) The office of each appropriate governor or governor's designee;

(ii) The office of each appropriate Tribal official or Tribal official's designee; and

(iii) The Director, ~~Division of Security Policy,~~ Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission.

(2) A notification delivered by mail must be postmarked at least 7 days before the beginning of the 7-day period during which departure of the shipment is estimated to occur.

(3) A notification delivered by any other means than mail must reach the office of the governor or of the governor's designee or the Tribal official or Tribal official's designee at least 4 days before the beginning of the 7-day period during which departure of the shipment is estimated to occur.

(i) A list of the names and mailing addresses of the governors' designees receiving advance notification of transportation of nuclear waste was published in the Federal Register on June 30, 1995 (60 FR 34306).

(ii) Contact information for each State, including telephone and mailing addresses of governors and governor's designees, and participating Tribes, including telephone and mailing addresses of Tribal officials and Tribal official's designees, is available on the NRC Web site at: https://scp.nrc.gov/special/designee.pdf.

(iii) A list of the names and mailing addresses of the governors' designees and Tribal officials' designees of participating Tribes is available on request from the Director, Division of Material Safety, State, Tribal, and Rulemaking Programs, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

(4) The licensee shall retain a copy of the notification as a record for 3 years.

(d) Information to be furnished in advance notification of shipment. Each advance notification of shipment of irradiated reactor fuel or nuclear waste must contain the following information:

(1) The name, address, and telephone number of the shipper, carrier, and receiver of the irradiated reactor fuel or nuclear waste shipment;

(2) A description of the irradiated reactor fuel or nuclear waste contained in the shipment, as specified in the regulations of DOT in 49 CFR 172.202 and 172.203(d);

(3) The point of origin of the shipment and the 7-day period during which departure of the shipment is estimated to occur;

(4) The 7-day period during which arrival of the shipment at State boundaries or Tribal reservation boundaries is estimated to occur;

(5) The destination of the shipment, and the 7-day period during which arrival of the shipment is estimated to occur; and

(6) A point of contact, with a telephone number, for current shipment information.

(c) Revision notice. A licensee who finds that schedule information previously furnished to a governor or governor's designee or to a Tribal official or Tribal official's designee, in accordance with this section, will not be met, shall telephone a responsible individual in the office of the governor of the State or of the governor's designee or the Tribal official or the Tribal official's designee and inform that individual of the extent of the delay beyond the schedule originally reported. The licensee shall maintain a record of the name of the individual contacted for 3 years.

(d) Cancellation notice.

(1) Each licensee who cancels an irradiated reactor fuel or nuclear waste shipment for which advance notification has been sent shall send a cancellation notice to the governor of each State or to the governor's designee previously notified, each Tribal official or to the Tribal official's designee previously notified, and the Director, ~~Division of Security Policy,~~ Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission.

(2) The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being canceled. The licensee shall retain a copy of the notice as a record for 3 years.

Secs. T.98 – T.100 Reserved.

QUALITY ASSURANCE

Sec. T.101 Quality Assurance Requirements.

(a) Purpose. Secs. T.101 through T.137 describe quality assurance requirements applying to design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components of packaging that are important to safety. As used in this these sections, "quality assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements. Each licensee is responsible for satisfying the quality assurance requirements that apply to its use of a packaging for the shipment of licensed material subject to these sections.

(b) Establishment of program. Each licensee shall establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of Secs. T.101 through T.137 and satisfying any specific provisions that are applicable to the licensee's activities including procurement of packaging. The licensee shall execute the applicable criteria in a graded approach to an extent that is commensurate with the quality assurance requirement's importance to safety.

(2) Ensure that periodic reports to the communications center are made at preset intervals.

ii. Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 2 quantity of radioactive material shall:

(1) Use carriers that have established package tracking systems. An established package tracking system is a documented, proven, and reliable system routinely used to transport objects of value. In order for a package tracking system to maintain constant control and/or surveillance, the package tracking system must allow the shipper or transporter to identify when and where the package was last and when it should arrive at the next point of control.

(2) Use carriers that maintain constant control and/or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance; and

(3) Use carriers that have established tracking systems that require an authorized signature prior to releasing the package for delivery or return.

c. Investigations. Each licensee who makes arrangements for the shipment of category 1 quantities of radioactive material shall immediately conduct an investigation upon the discovery that a category 1 shipment is lost or missing. Each licensee who makes arrangements for the shipment of category 2 quantities of radioactive material shall immediately conduct an investigation, in coordination with the receiving licensee, of any shipment that has not arrived by the designated no-later-than arrival time.

Sec. V.80 [Reserved].

Sec. V.81 Reporting of Events.

a. The shipping licensee shall notify the appropriate LLEA and the Agency within 1 hour of its determination that a shipment of category 1 quantities of radioactive material is lost or missing. The appropriate LLEA would be the law enforcement agency in the area of the shipment's last confirmed location. During the investigation required by V.79(c), the shipping licensee will provide agreed upon updates to the Agency on the status of the investigation.

b. The shipping licensee shall notify the Agency within 4 hours of its determination that a shipment of category 2 quantities of radioactive material is lost or missing. If, after 24 hours of its determination that the shipment is lost or missing, the radioactive material has not been located and secured, the licensee shall immediately notify the Agency.

c. The shipping licensee shall notify the designated LLEA along the shipment route as soon as possible upon discovery of any actual or attempted theft or diversion of a shipment or suspicious activities related to the theft or diversion of a shipment of a category 1 quantity of radioactive material. As soon as possible after notifying the LLEA, the licensee shall notify the Agency upon discovery of any actual or attempted theft or diversion of a shipment, or any suspicious activity related to the shipment of category 1 radioactive material.

d. The shipping licensee shall notify the Agency as soon as possible upon discovery of any actual or attempted theft or diversion of a shipment, or any suspicious activity related to the shipment, of a category 2 quantity of radioactive material.

e. The shipping licensee shall notify the Agency and the LLEA as soon as possible upon recovery of any lost or missing category 1 quantities of radioactive material.

f. The shipping licensee shall notify the Agency as soon as possible upon recovery of any lost or missing category 2 quantities of radioactive material.

g. The initial telephonic notification required by V.81(a) through (d) must be followed within a period of 30 days by a written report submitted to the Agency at the address specified in Section A.12 of this regulation. A written report is not required for notifications on suspicious activities required by V.81(c). ~~and (d). In addition, the licensee shall provide one copy of the written report addressed to the Director, Division of Security Policy, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001~~. The report must set forth the following information:

i. A description of the licensed material involved, including kind, quantity, and chemical and physical form;

ii. A description of the circumstances under which the loss or theft occurred;

iii. A statement of the disposition, or probable disposition, of the licensed material involved;

iv. Actions that have been taken, or will be taken, to recover the material; and

v. Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed material.

h. Subsequent to filing the written report, the licensee shall also report any additional substantive information on the loss or theft within 30 days after the licensee learns of such information.

Sec. V.82 – V.100 [Reserved].