INSTRUCTION SHEET

COMAR 26.12.01.01

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

SUPPLEMENT No. 22

Instructions: Supplement 22 to the document "Regulations for the Control of Ionizing Radiation (1994)" includes the following pages (all pages are inclusive):

Remove Pages	Insert Pages
Cover Sheet	Cover Sheet
iii through iv	iii through iv
B5 – B6	B5 – B6
C21 – C21-1	C21 – C21-1
C25 – C25-1	C25 – C25-1
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C47 – C48	C47 – C48
D3 – D6	D3 – D6
D13 – D14	D13 – D13-2 – D14
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G1 – G2	G1 – G2
G13 – G22	G13 – G22
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G35 – G40	G35 – G40
G45 – G46	G45 – G46
G61 – G64	G61 – G64
J1 – J2	J1 – J2

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

INQUIRIES TO: Michael Kurman
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Code of Maryland Regulations 26.12.01.01

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REGULATIONS FOR THE CONTROL OF IONIZING RADIATION (1994)

RADIOLOGICAL HEALTH PROGRAM
AIR AND RADIATION MANAGEMENT ADMINISTRATION
MARYLAND DEPARTMENT OF THE ENVIRONMENT
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Radiation Protection Programs

Occupational Dose Limits

Radiation Dose Limits for Individual Members of the Public

Testing for Leakage or Contamination of Sealed Sources

Surveys and Monitoring

Control of Exposure From External Sources in Restricted Areas

Respiratory Protection and Controls to Restrict Internal Exposure in Restricted Areas

Storage and Control of Licensed or Registered Sources of Radiation

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(a) Complete application forms for registration furnished by the Agency that contain all the information required by the forms and accompanying instructions;

(b) Designate on the application form the individual to be responsible for radiation protection.

(c) Include full payment of all fees in the application for registration, as specified in COMAR 26.12.03 for the type(s) of radiation machine(s).

(e) Prohibit any person from furnishing radiation machine servicing or services as described in B.6(d) to a radiation machine facility until such person provides evidence to the registrant that they are currently registered with the Agency as a service provider in accordance with B.6.

Sec. B.6 Application for Registration of Servicing and Services.

(a) Each person who is engaged in the business of installing or offering to install radiation machines or is engaged in the business of furnishing or offering to furnish radiation machine servicing or services in this State shall apply for registration of such services with the Agency prior to furnishing or offering to furnish any such services.

(b) Application for registration shall be completed on forms furnished by the Agency and shall contain all information required by the Agency as indicated on the forms and accompanying instructions.

(c) Each person applying for registration under this part shall specify:

(1) A knowledge and understanding of the requirements of these regulations;

(2) A list of services to be provided under the registration;

(3) The training and experience needed to perform the services;

(4) The type of measurement instrument(s) to be used, frequency of calibration, and source of calibration; and

(5) The type of personnel dosimeters supplied, frequency of reading, and replacement or exchange schedule.

(d) For the purposes of B.6, services may include but shall not be limited to:

(1) Installation and/or servicing of radiation machines and associated radiation machine components,

(2) Calibration of radiation machines or radiation measurement instruments or devices,

(3) Radiation protection or health physics consultations or surveys, and

(4) Personnel dosimetry services.

(e) No individual shall perform services which are not specifically stated for that individual on the notice of registration issued by the Agency.

Agency Issues

Sec B.7 Issuance and Posting of Notice of Registration.

(a) Upon a determination that an applicant meets the requirements of the regulations, the agency shall issue a notice of registration. For a radiation machine facility, this will be issued in the form of a certificate of registration. Each certificate of registration shall be publicly posted by the radiation machine facility.

(b) The Agency may incorporate in the notice of registration at the time of issuance or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the registrant's receipt, possession, use, transfer, or servicing of radiation machines as it deems appropriate or necessary.

Sec. B.8 Expiration of Notice of Registration.

Except as provided by B.9(b), each notice of registration shall expire at the end of the specified day in the month and year stated therein.

Sec. B.9 Renewal of Notice of Registration.

(a) The Agency will grant an application for renewal of registration upon receipt of all documentation and fees required by the Agency.

(b) If a registrant has filed a complete application, not less than 14 days prior to the expiration of the existing notice of registration, including payment of all fees and submission of required inspections or certifications with all violations corrected, the existing notice of registration shall not expire until the application status has been determined by the Agency.

Sec. B.10 Report of Changes.

The registrant shall notify the Agency in writing before making any change which would render the information contained in the application for registration and/or the notice of registration no longer accurate. This includes, but is not limited to, requests for registration cancellation, changes of location and ownership, or changes to radiation machines or tubes. The registrant shall notify the Agency of installation, disposal or disablement of radiation machines within 30 days following such action by providing the Agency with a copy of a completed Form MDE RX 24 signed and dated by a State registered service provider.

Sec. B.10A Compliance with Regulations.

All owners, operators, or possessors of a radiation machine(s) shall comply with all applicable requirements of COMAR 26.12.01, .02, and .03. Any Agency Form RX-2 or RX-2a citing a regulation violation(s) which is presented to a radiation machine facility during or following an inspection by an Agency or State-licensed private inspector constitutes a notice to the facility that a violation(s) has been observed by the inspector. An as-found violation(s):

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regulations except that such persons shall comply with the provisions of D.1001, D.1201, D.1202, and D.1207.

(3) This general license does not authorize the manufacture, assembly, disassembly or repair of strontium-90 in ice detection devices.

(4) This general license is subject to the provisions of A.4 through A.9, C.31, C.40, C.50, and Part T of these regulations.

(k) Registration of Generally Licensed Devices.

(1) All persons, within 30 days of initial receipt of a general licensed device, as defined in C.22(a), (d), and (e) (excluding tritium signs), shall register that device with the Agency in accordance with C.22(k)(5). Registration shall be done by submitting new information, verifying previously submitted registration information, correcting, and/or adding to the information from a previous registration. All registration information shall be updated with the Agency on an annual basis.

(2) All persons who possess generally licensed devices as defined in C.22(a), (d) and (e) (excluding tritium signs) prior to the effective date of this regulation shall register such devices within ninety days of the effective date of this regulation in accordance with C.22(k)(5). All registration information submitted for these devices shall be updated with the Agency on an annual basis.

(3) For the purposes of registration of devices received or possessed under C.22(a), (d) and (e), each address that represents a location of use is a separate general licensee and requires a separate registration.

(4) Persons generally licensed by the U.S. Nuclear Regulatory Commission or another Agreement State with respect to devices meeting the criteria in C.22(a), (d) and (e) are required to register those devices with the Agency, if used in Maryland for a period of greater than 180 days in any calendar year.

(5) Registration of generally licensed devices shall include submission of the following information to the Agency:

(i) Name and mailing address of the general licensee.

(ii) Information about each device: the manufacturer (or initial transferor), model number, serial number, the radioisotope and activity (as indicated on the label).

(iii) Name, title, and telephone number of the responsible person designated as a representative of the general licensee.

(iv) Address or location at which the device(s) is (are) used and/or stored and for portable devices, the address of the primary place of storage.

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Deleted: be conducted as follows:

Deleted: All persons who possess generally licensed devices as defined in C.22(d)(1) that contain at least 370 MBq (10mCi) of cesium-137, 3.7 MBq (0.1 mCi) of strontium-90, 37 MBq (1 mCi) of cobalt-60, 3.7 MBq (0.1 mCi) of radium-226, or 37 MBq (1 mCi) of americium-241 or any other transuranic element (i.e., element with atomic number greater than uranium (92), based on the activity indicated on the label), shall register the devices by submitting the following information to the Agency:¶

Deleted: (a) Name and mailing address of the general licensee.¶

Deleted: (b) Information about each device: the manufacturer (or initial transferor), model number, serial number, the radioisotope and activity (as indicated on the label).

Deleted: (c) Name, title, and telephone number of the responsible person designated as a representative of the general licensee under C.22(k)(5)(i)(c).¶
¶
(d) Address or location at which the device(s) is (are) used and/or stored and for portable devices, the address of the primary place of storage.¶

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(l) General License for Certain Items and Self-Luminous Products Containing Radium-226.

(1) A general license is hereby issued to any person to acquire, receive, possess, use, or transfer, in accordance with Section C.22(l)(2)-(4), radium-226 contained in the following products manufactured prior to November 30, 2007.

(i) Antiquities originally intended for use by the general public. For the purposes of this paragraph, antiquities mean products originally intended for use by the general public and distributed in the late 19th and early 20th centuries, such as radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads.

(ii) Intact timepieces containing greater than 0.037 megabecquerel (1 microcurie), nonintact timepieces, and timepiece hands and dials no longer installed in timepieces.

(iii) Luminous items installed in air, marine, or land vehicles.

(iv) All other luminous products provided that no more than 100 items are used or stored at the same location at any one time.

(v) Small radium sources containing no more than 0.037 megabecquerel (1 microcurie) of radium-226. For the purposes of the paragraph, "small radium sources" means discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in educational demonstrations (such as cloud chambers and spinthariscopes), electron tubes, lightning rods, ionization sources, static eliminators, or as designated by the NRC.

(2) Persons who acquire, receive, possess, use, or transfer byproduct material under the general license issued in Section C.22(l)(1) are exempt from the provisions of Parts D and J, to the extent that the receipt, possession, use, or transfer of byproduct material is within the terms of the general license; provided, however, that this exemption shall not be deemed to apply to any such person specifically licensed under Part C.

Deleted: (e) Certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and checking of label information.¶
¶
(f) Certification by the responsible representative of the general licensee that they are aware of the requirements of the general license.¶

Deleted: (ii) All persons who possess generally licensed devices as defined in C.22(a) and (e) excluding tritium signs, and all persons who possess generally licensed devices in C.22(d) that contain types or quantities of radionuclides less than defined in C.22(k)(5)(i), shall submit registration information to the Agency in accordance with C.22(k)(5)(i)(a-d).¶

(7) the environmental report, if required by the Agency under C.25(b), is acceptable.

(8) the radioactive material being licensed is not an isotope of Cesium for the use or storage in a liquid or water environment.

(b) In the case of an application for a license or amendment to an existing license to receive and possess radioactive material for the conduct of any activity which the Agency determines will significantly affect the quality of the environment, the applicant shall prepare an environmental report. The report shall address the environmental, economic, technical and other benefits against environmental costs considering available alternatives, with any appropriate conditions to protect environmental values. Commencement of construction prior to such conclusion shall be grounds for denial of a license to receive and possess radioactive material in such plant or facility. As used in this paragraph the term "commencement of construction" means any clearing of land, excavation, or other substantial action that would adversely affect the environment of a site. The term does not mean site exploration, necessary roads for site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values.

(c) Each specific license application shall contain a provision for an emergency plan as specified in C.23.

Sec. C.26 Special Requirements for Issuance of Certain Specific Licenses for Radioactive Material.

(a)-(b) Reserved.

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(c) Specific License for Certain Measurement and Control Devices.

Effective October 1, 2013, a specific license shall be obtained from the Agency in accordance with Sections C.24 and C.25 for the possession and use of sealed source devices containing radioactive material which contain at least 370 MBq (10 mCi) of cesium-137, 3.7 MBq (0.1 mCi) of strontium-90, 37 MBq (1 mCi) of cobalt-60, 3.7 MBq (0.1 mCi) of radium-226, or 37 MBq (1 mCi) of americium-241 or any other transuranic element (i.e., element with atomic number greater than uranium (92), based on the activity indicated on the label).

(d) Specific License for Well Logging. An application for a specific license for the use of licensed material in industrial radiography will be approved if the applicant meets the following requirements:

(1) The applicant satisfies the general requirements specified in Sec. C.25 for radioactive material, as appropriate, and any special requirements contained in this part.

(2) The applicant shall develop a program for training logging supervisors and logging assistants and submit to the Agency a description of this program which specifies the:

(i) Initial training;

(ii) On-the-job training;

(iii) Annual safety reviews provided by the licensee;

(iv) Means the applicant will use to demonstrate the logging supervisor's knowledge and understanding of and ability to comply with the Agency's regulations and licensing requirements and the applicant's operating and emergency procedures; and

(v) Means the applicant will use to demonstrate the logging assistant's knowledge and understanding of and ability to comply with the applicant's operating and emergency procedures.

(3) The applicant shall submit to the Agency written operating and emergency procedures as described in Sec.W.202 or an outline or summary of the procedures that includes the important radiation safety aspects of the procedures.

(4) The applicant shall establish and submit to the Agency its program for annual inspections of the job performance of each logging supervisor to ensure that the Agency's regulations, license requirements, and the applicant's operating and emergency procedures are followed. Inspection records must be retained for 3 years after each annual internal inspection.

(5) The applicant shall submit a description of its overall organizational structure as it applies to the radiation safety responsibilities in well logging, including specified delegations of authority and responsibility.

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(6) If an applicant wants to perform leak testing of sealed sources, the applicant shall identify the manufacturers and the model numbers of the leak test kits to be used. If the applicant wants to analyze its own wipe samples, the applicant shall establish procedures to be followed and submit a description of these procedures to the Agency. The description must include the:

(i) Instruments to be used;

(ii) Methods of performing the analysis; and

(iii) Pertinent experience of the person who will analyze the wipe samples.

(7) A licensee may perform well logging with a sealed source only after the licensee has a written agreement with the employing well owner or operator. This written agreement must identify who will meet the following requirements:

(i) If a sealed source becomes lodged in the well, a reasonable effort will be made to recover it;

(ii) A person may not attempt to recover a sealed source in a manner which, in the licensee's opinion, could result in its rupture;

(iii) The radiation monitoring required in Sec.W.202(n) will be performed;

(iv) If the environment, any equipment, or personnel are contaminated with licensed material, they must be decontaminated before release from the site or release for unrestricted use; and

(v) If the sealed source is classified as irretrievable after reasonable efforts at recovery have been expended, the following requirements must be implemented within 30 days:

(a) Each irretrievable well logging source must be immobilized and sealed in place with a cement plug;

(b) A means to prevent inadvertent intrusion on the source, unless the source is not accessible to any subsequent drilling operations; and

(c) A permanent identification plaque, constructed of long lasting material such as stainless steel, brass, bronze, or monel, must be mounted at the surface of the well, unless the mounting of the plaque is not practical. The size of the plaque must be at least 17 cm [7 inches] square and 3 mm [$^{1}/_{8}$-inch] thick. The plaque must contain:

(i) The word "CAUTION";

(ii) The radiation symbol (the color requirement in Sec. D.901(a) need not be met);

(iii) The date the source was abandoned;

(iv) The name of the well owner or well operator, as appropriate;

(v) The well name and well identification number(s) or other designation;

(vi) An identification of the sealed source(s) by radionuclide and quantity;

(vii) The depth of the source and depth to the top of the plug; and

(viii) An appropriate warning, such as, "DO NOT RE-ENTER THIS WELL."

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Name of manufacturer or distributor

(2) The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____ [9], are subject to a general license or the equivalent, and the regulations of a Licensing State. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL

Name of manufacturer or distributor

(2) In the event the applicant desires that the device be required to be tested at intervals longer than 6 months, either for proper operation of the "on-off" mechanism and indicator, if any, or for leakage of radioactive material or for both, the applicant shall include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the "on-off" mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the Agency will consider information which 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;

(vii) maximum pressure withstood during prototype tests;

(viii) maximum quantity of contained radioactive material;

(ix) radiotoxicity of contained radioactive material; and

(x) operating experience with identical devices or similarly designed and constructed devices.

[9] The model, serial number, and name of the manufacturer or distributor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device.

(3) In the event the applicant desires that the general licensee under C.22(d), or under equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the "on-off" mechanism and indicator, or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and bases for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a calendar quarter dose in excess of 10 percent of the limits specified in the table in D.201(a) of these regulations.

(4) Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the isotope and quantity, the words, "Caution – Radioactive Material", the radiation symbol described in D.901 and the name of the manufacturer or initial distributor.

(5) Each device meeting the criteria of C.26(c) bears a permanent (e.g., embossed, etched, stamped, or engraved) label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, "Caution – Radioactive Material", and, if practicable, the radiation symbol described in D.901.

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(6) If a device containing byproduct material is to be transferred for use under the general license contained in C.22, each person that is licensed under C.28(d) shall provide the information specified in this paragraph to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

(i) A copy of the general license contained in C.22; if requirements in C.22(d)(3)(ii-iv) or C.26(c) do not apply to the particular device, those requirements may be omitted;

Deleted: C.22(k)(5)(i)

(ii) A copy of Sections C.20(a), C.22(d), C.38, D.1201 and D.1202;

(iii) A list of the services that can only be performed by a specific licensee;

(iv) Information on acceptable disposal options including estimated costs of disposal; and

(v) An indication that the U.S. Nuclear Regulatory Commission's policy is to issue high civil penalties for improper disposal.

(7) If byproduct material is to be transferred in a device for use under an equivalent general license of an Agreement State, each person that is licensed under C.28(d) shall provide the information specified in this paragraph to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

(2) No person shall receive, possess, use, transfer, own or acquire radioactive material of a type described in paragraph (a) or (b) of this section for more than 180 days following the dates prescribed in this section for submittal of a decommissioning funding plan or certification, if that decommissioning funding plan or certification has not been approved by the Agency.

(h) Financial assurance for decommissioning pursuant to termination under restricted conditions as described in Section D.1403 of Part D shall not be considered a potential financial mechanism until such time as the licensee has submitted its intent to decommission in accordance with C.32 and has submitted a License Termination Plan (LTP) in accordance with Section D.1403(d).

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) 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.

(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:

Deleted: , or general licensee possessing radioactive material as defined in C.22(k)(5)(i),

(1) the licensee;

(2) an entity (as that term is defined in 11 U.S.C. 101(14)) 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 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.26(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).

“Powered air-purifying respirator (PAPR)” means an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

“Pressure demand respirator” means a positive pressure atmosphere-supplying respirator that admits breathing air to the faceplate when the positive pressure is reduced inside the facepiece by inhalation.

“Qualitative fit test (QLFT)” means a pass/fail fit test to assess the adequacy of respirator fit that relies on the individual’s response to the test agent.

“Quantitative fit test (QNFT)” means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

"Quarter" means a period of time equal to one-fourth of the year observed by the licensee, approximately 13 consecutive weeks, providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

"Reference Man" means a hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base. A description of the Reference Man is contained in the International Commission on Radiological Protection report, ICRP Publication 23, "Report of the Task Group on Reference Man."

"Respiratory protective equipment" means an apparatus, such as a respirator, used to reduce an individual's intake of airborne radioactive materials.

"Sanitary sewerage" means a system of public sewers for carrying off waste water and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee.

“Self-contained breathing apparatus (SCBA)” means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

"Self-Shielded Irradiator" means a source of radiation that is used to irradiate materials where the source of radiation is both stored and operated within the same radiation shielding barrier and, in the designed configuration of the irradiator, does not allow exposure of any part of an individual to an exposure rate of 5 Gy (500 rads) per hour or greater.

"Stochastic effect" means a health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects. For purposes of these regulations, "probabilistic effect" is an equivalent term.

“Supplied-air respirator (SAR) or airline respirator” means an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

“Tight-fitting facepiece” means a respiratory inlet covering that forms a complete seal with the face.

“User seal check (fit check)” means an action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, or isoamyl acetate check.

Sec. D.4 Implementation.

a. Any existing license or registration condition that is more restrictive than Part D remains in force until there is an amendment or renewal of the license or registration.

b. If a license or registration condition exempts a licensee or registrant from a provision of Part D in effect on or before October 9, 1995, it also exempts the licensee or registrant from the corresponding provision of Part D.

c. If a license or registration condition cites provisions of Part D in effect prior to October 9, 1995, which do not correspond to any provisions of Part D, the license or registration condition remains in force until there is an amendment or renewal of the license or registration that modifies or removes this condition.

RADIATION PROTECTION PROGRAMS

Sec. D.101 Radiation Protection Programs.

a. In addition to complying with all other provisions of these regulations, a licensee or registrant shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to the members of the general public that are as low as is reasonably achievable (ALARA).

b. Each person licensed to receive, use, transfer, own, or acquire radioactive material under Part C of these regulations shall develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of these regulations.

c. The licensee shall, at intervals not to exceed 12 months, review the radiation protection program content and implementation.

d. To implement the ALARA requirements of D.101(a), and notwithstanding the requirements in D.301 of this part, a constraint on air emissions of radioactive material to the environment, excluding Radon-222 and its daughters, shall be established by licensees such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 10 mrem (0.1 mSv) per year from these emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee shall report the exceedence as provided in D.1203 and promptly take appropriate corrective action to ensure against recurrence.

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e. A registrant may incorporate the determination for effective dose equivalent for interventional/therapeutic fluoroscopy into its ALARA program as described in D.209. Fluoroscopic modalities may include but are not limited to interventional radiology, cardiac catheterization, vascular surgery, electrophysiology, and pain management.

OCCUPATIONAL DOSE LIMITS

Sec. D.201 Occupational Dose Limits for Adults.

a. The licensee or registrant shall control the occupational dose to individual adults, except for planned special exposures pursuant to D.206, to the following dose limits:

   i. An annual limit, which is the more limiting of:

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(1) The total effective dose equivalent being equal to 0.05 Sv (5 rem); or

(2) The sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 0.5 Sv (50 rem).

ii. The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities, which are:

(1) A lens dose equivalent of 0.15 Sv (15 rem), and

(2) A shallow-dose equivalent of 0.5 Sv (50 rem) to the skin of the whole body or to the skin of any extremity.

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b. Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, shall be subtracted from the limits for planned special exposures that the individual may receive during the current year and during the individual's lifetime. See D.206(f)(i) and (ii).

Comment [mdk1]: The reference to e. is incorrect.

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c. When the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent must be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the Agency. The assigned deep-dose equivalent must be for the part of the body receiving the highest exposure. The assigned shallow-dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure. The deep-dose equivalent, lens-dose equivalent, and shallow-dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

d. Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in Table I of Appendix B and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits. See D.1107.

e. Notwithstanding the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity. See footnote 3 of Appendix B.

f. The licensee or registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person. See D.205e.

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Sec. D.202 Compliance with Requirements for Summation of External and Internal Doses.

a. If the licensee or registrant is required to monitor pursuant to both D.502a. and b., the licensee or registrant shall demonstrate compliance with the dose limits by summing external and internal doses. If the licensee or registrant is required to monitor only pursuant to D.502a. or only pursuant to D.502b., then summation is not required to demonstrate compliance with the dose limits. The licensee or registrant may demonstrate compliance with the requirements for summation of external and internal doses pursuant to D.202b., c. and d. The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.

ii. The dose equivalent to the embryo/fetus resulting from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

d. If the dose equivalent to the embryo/fetus is found to have exceeded 0.5 rem (5 mSv), or is within 0.05 rem (0.5 mSv) of this dose, by the time the woman declares the pregnancy to the licensee or registrant, the licensee or registrant shall be deemed to be in compliance with paragraph (a) of this section if the additional dose equivalent to the embryo/fetus does not exceed 0.05 rem (0.5 mSv) during the remainder of the pregnancy.

Sec. D.209 Determination of Effective Dose Equivalent for Interventional/Therapeutic Fluoroscopy.

a. When a protective apron is worn while working as described in Section D.101(e) with C-arm Interventional/Therapeutic medical fluoroscopic equipment and monitoring is conducted as specified in D.502(a), the effective dose equivalent for external radiation shall be determined as follows:

i. When only one individual monitoring device is used and it is located at the neck (collar) outside the protective apron, the reported deep dose equivalent shall be the effective dose equivalent for external radiation; or

ii. When only one individual monitoring device is used and it is located at the neck (collar) outside the protective apron, and the reported dose exceeds 25 percent of the limit specified in D.201(a), the reported deep dose equivalent value multiplied by 0.3 shall be the effective dose equivalent for external radiation; or

iii. When individual monitoring devices are worn, both under the protective apron at the waist and outside the protective apron at the neck, the effective dose equivalent for external radiation shall be assigned the value of the sum of the deep dose equivalent reported for the individual monitoring device located at the waist under the protective apron multiplied by 1.5 and the deep dose equivalent reported for the individual monitoring device located at the neck outside the protective apron multiplied by 0.04.

b. Compliance with the following procedures provide a registrant with continuing automatic approval for such usage as described in D.209(a)(ii) and (iii) under the following conditions:

i. When an individual's external (collar) badge exceeds 25% (1.25 rem) of the 5 rem annual limit, a facility may automatically apply one of the alternative methodologies in D.209(a)(ii) and (iii) for calculating the effective dose equivalents.

ii. Once an individual's effective dose equivalent has reached 80% (4 rem) of the annual effective dose equivalent limit, the registrant shall notify the Agency, provide to the Agency the information listed in subsection (b)(ii)(1) – (3) below, and continue to apply the selected alternative methodology for calculating the effective dose equivalent:

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(1) A copy of the two most recent Radiation Safety Committee Meeting minutes that discuss issues identified in radiation safety involving occupational workers and the practice of achieving the "as low as reasonably achievable (ALARA)" principle and corrective actions taken for issues identified. The meeting notes must be detailed in regard to the film badge program, which can be satisfied by including the following information:

(a) Individuals required to wear film badges are wearing their badges correctly;

(b) Badges are being returned on time and handed out promptly to wearers at least 90% of the time;

(c) Badges are being worn at least 90% of the time before the start of a procedure by individuals required to wear film badges;

(d) Appropriate radiation protective tools including lead or lead equivalent protection are being utilized; and

(e) For any individual who reached or exceeded 80% of the effective annual dose limit, the badge information is being reviewed to detect any anomalies in the film badge pattern of use, such as if the individual had a zero or very low reading if a fluoroscope was utilized and a high number of fluoroscopic minutes were identified; and

(2) Assurance that the badge readings are being expedited in order for the registrant to effectively monitor the readings to ensure that the occupational worker does not exceed the annual dose limit; and

(3) A notification to the Agency of the next scheduled Radiation Safety Committee Meeting so that Agency representatives may attend.

(c) The Agency will inform the facility within two weeks of receipt of the required documentation in D.209(b)(ii) whether the information submitted by the registrant is deficient and therefore does not support continued approval of use of the weighting factor in D.209(a)(ii) and (iii).

i. In the event of such notification, the registrant shall immediately cease use of the selected weighting factor for the badged individual and discontinue its use until the deficiencies are corrected.

ii. If the registrant is not notified that the information submitted is deficient within the two week period specified in this subsection, the badged individual may

(1) continue to utilize the alternative methodology in D.209(a)(ii) and (iii) for calculating the effective dose equivalent for the remainder of the calendar year or

(2) until the 5 rem effective dose annual limit is met, whichever occurs earlier.

RADIATION DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC

Sec. D.301 Dose Limits for Individual Members of the Public.

a. Each licensee or registrant shall conduct operations so that:

   i. The total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed 0.1 rem (1 mSv) in a year, exclusive of the dose contributions from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released under G.75, from voluntary participation in medical research programs, and from the licensee's disposal of radioactive material into sanitary sewerage in accordance with D.1003, and

   ii. The dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released in accordance with Sec. G.75, does not exceed 0.002 rem (0.02 mSv) in any one hour.

b. The Agency may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee may release in effluents in order to restrict the collective dose.

c. If the licensee or registrant permits members of the public to have access to restricted areas, the limits for members of the public continue to apply to those individuals.

d. Notwithstanding paragraph (a)(i) of this section, a licensee may permit visitors to an individual who cannot be released, under Sec. G.75, to receive a radiation dose greater than 0.1 rem (1 mSv) if:

   i. The radiation dose received does not exceed 0.5 rem (5 mSv); and

   ii. The authorized user, as defined in Part G, has previously determined that the visit is appropriate.

e. The Agency may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee may release in effluents in order to restrict the collective dose.

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Sec. D.302 Compliance with Dose Limits for Individual Members of the Public.

a. The licensee or registrant shall make or cause to be made surveys of radiation levels in unrestricted areas and radioactive materials in effluents released to unrestricted areas to demonstrate compliance with the dose limits for individual members of the public in D.301.

b. At intervals not to exceed twelve months, a licensee or registrant shall show compliance with the annual dose limit in D.301a.i. for each calendar year by:

   i. Demonstrating compliance with D.101a.; and

   ii. (1) Demonstrating by measurement, or calculation, or appropriate simulation model that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed or registered source of radiation does not exceed the annual dose limit of D.301; or

   (2) Demonstrating that:

   (a) The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table II of Appendix B; and

   (b) If an individual were continually present in an unrestricted area, at the point of highest potential exposure from the licensed or registered source of radiation, the dose to that individual would not exceed 0.02 mSv (0.002 rem) in an hour and 0.5 mSv (0.05 rem) in any year.

TESTING FOR LEAKAGE OR CONTAMINATION OF SEALED SOURCES

Sec. D.401 Testing for Leakage or Contamination of Sealed Sources.

a. Each sealed source, other than hydrogen-3, with a half-life greater than 30 days and in any form other than gas, shall be tested for leakage or contamination prior to initial use and, unless otherwise authorized by the Agency, at intervals not to exceed 6 months. If, at any other time, there is reason to suspect that a sealed source might have been damaged or might be leaking, it shall be tested for leakage before further use. In the absence of a certificate from a transferor indicating that a test for leakage has been made within 6 months prior to the transfer, the sealed source shall not be put into use until tested and the results received.

   i. Tests for leakage for all sealed sources, except those manufactured to contain radium, shall be capable of detecting the presence of 185 Bq (0.005 μCi) of radioactive material on a test sample. Test samples shall be taken from the sealed source or from the surfaces of the container in which the sealed source is stored or mounted on which one might expect contamination to accumulate.

(3) Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.

ii. An event in which equipment is disabled or fails to function as designed when:

(1) The equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;

(2) The equipment is required to be available and operable when it is disabled or fails to function; and

(3) No redundant equipment is available and operable to perform the required safety function.

iii. An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.

iv. An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:

(1) The quantity of material involved is greater than five times the lowest annual limit on intake specified in Appendix B of Part D; and

(2) The damage affects the integrity of the licensed material or its container.

c. Preparation and submission of reports. Reports made by licensees in response to the requirements of this section must be made as follows:

i. Licensees shall make reports required by paragraphs a. and b. of this section by telephone to the Agency. To the extent that the information is available at the time of notification, the information provided in these reports must include:

(1) The caller's name and call back number;

(2) A description of the event, including date and time;

(3) The exact location of the event;

(4) The isotopes, quantities, and chemical and physical form of the licensed material involved; and

(5) Any personnel radiation exposure data available.

ii. Written report. Each licensee who makes a report required by paragraph a. or b. of this section shall submit a written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. These reports must be sent to the Agency. The reports must include the following:

(1) A description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;

(2) The exact location of the event;

(3) The isotopes, quantities, and chemical and physical form of the licensed material involved;

(4) Date and time of event;

(5) Corrective actions taken or planned and the results of any evaluations or assessments; and

(6) The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

d. 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:

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i. The licensee;

ii. An entity (as that term is defined in 11 U.S.C. 101(14)) controlling the licensee or listing the license or licensee as property of the estate; or

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

e. The notification specified in D.1211d. 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.

Sec. D.1220 Notification of Failure To Comply or Existence of a Defect and Its Evaluation.

a. Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall adopt appropriate procedures to--

1. Evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards as soon as practicable, and, except as provided in paragraph (a)(2) of this section, in all cases within 60 days of discovery, in order to identify a reportable defect or failure to comply that could create a substantial safety hazard, were it to remain uncorrected;

2. Ensure that if an evaluation of an identified deviation or failure to comply potentially associated with a substantial safety hazard cannot be completed within 60 days from discovery of the deviation or failure to comply, an interim report is prepared and submitted to the Department through a director or responsible officer or designated person as discussed in Sec. D.1220(c)(5). The interim report should describe the deviation or failure to comply that is being evaluated and should also state when the evaluation will be completed. This interim report must be submitted in writing within 60 days of discovery of the deviation or failure to comply; and

3. Ensure that a director or responsible officer subject to the regulations of this part is informed as soon as practicable, and, in all cases, within the 5 working days after completion of the evaluation described in Sec. D.1220(a)(1) or Sec. D.1220(a)(2) if the construction or operation of a facility or activity, or a basic component supplied for such facility or activity--

i. Fails to comply with COMAR 26.12.01.01 Regulations for the Control of Ionizing Radiation (1994), or any applicable rule, order, or license of the Department relating to a substantial safety hazard, or

ii. Contains a defect.

b. If the deviation or failure to comply is discovered by a supplier of basic components, or services associated with basic components, and the supplier determines that it does not have the capability to perform the evaluation to determine if a defect exists, then the supplier must inform the purchasers

Part G

USE OF RADIONUCLIDES IN THE HEALING ARTS

General Regulatory Information

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

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

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

"Authorized medical physicist" means an individual who:

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

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

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

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

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

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

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

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

(2) Is identified as an authorized user on:

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

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

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

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

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

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

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

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

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

“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.

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

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

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

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

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

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

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

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

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

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

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

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

Secs. G.42 – G.48 Reserved.

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

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

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

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

Sec. G.50 Training For Radiation Safety Officer.

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

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

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

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

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

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

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

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

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

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

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

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

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

(iv) Radiation biology; and

(v) Radiation dosimetry; and

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

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

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

(iii) Securing and controlling radioactive material;

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

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

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

(vii) Disposing of radioactive material; or

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

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

(d) Has obtained written attestation, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in 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 Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

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

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

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

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

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(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 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;

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

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

(b) Has completed:

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

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

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

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

(e) Radiation biology; and

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

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

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

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

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

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

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

Sec. G.56 Reserved.

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

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

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

(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).

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(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;

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(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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) A description of the calibration procedure; and

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

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

Sec. G.62 Reserved.

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

(a) A licensee shall determine with a dose calibrator and record the activity of each dosage prior to medical use in accordance with G.60.B except where allowed in G.63(b)(2) and G.63(c)(2).

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

(1) Direct measurement of radioactivity; or

(2) For radiopharmaceuticals delivered directly to a hub, after measurement with a dose calibrator at the hub, a decay correction, based on the activity or activity concentration determined by:

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

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

(iii) A PET radioactive drug producer licensed under Section C.26(g) or equivalent Agreement State or NRC regulations.

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

(1) Direct measurement of radioactivity; or

(2) For radiopharmaceuticals delivered directly to a hub, after measurement with a dose calibrator at the hub, a combination of volumetric measurements and mathematical calculations, based on the direct measurement made by:

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

(ii) A PET radioactive drug producer licensed under C.26(g) or equivalent Agreement State or NRC requirements.

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

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

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

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

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

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

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

Secs. G.71 – G.74 Reserved.

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

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

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

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

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

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

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

Secs. G.76 – G.79 Reserved.

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

Sec. G.80 Provision of Mobile Medical Service.

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

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

(2) Transport to each address of use only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits;

(3) Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at the client's location of use;

(4) Bring into each location of use all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;

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

(i) Test each dose calibrator for accuracy upon receipt, at intervals not to exceed 12 months thereafter, and after repair 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;

(ii) Test each dose calibrator for linearity upon receipt, at least quarterly thereafter, and after repair 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

(iii) Test each dose calibrator for geometry dependence upon receipt and after repair 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.

(6) 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.

(7) Carry two calibrated survey meters in each vehicle that is being used to transport radioactive material. Survey instruments shall be checked for proper operation with a dedicated check source before use at each client's address; and

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(8) Before leaving a client location of use, survey all areas of radiopharmaceutical use with a radiation detection survey instrument to ensure that all radiopharmaceuticals and all associated radioactive waste have been removed. Contamination smears of the client's address confirming unrestricted release of the area must be less than 220 disintegrations per minute for 100 square centimeters.

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(b) Provide to the Agency a signed certification from all proposed authorized users that they are willing and able to perform the responsibilities of authorized user as described in G.11(b) and G.27.

(c) Radioactive material may be delivered to a mobile medical service client if that client has a license allowing possession of the radioactive material. Radioactive material delivered to the licensed client must be received and handled in conformance with the client's license.

(d) A mobile medical service shall have radioactive material delivered from the manufacturer or the distributor to an unlicensed client's address only if the radioactive material is directly received by mobile medical service licensed personnel in accordance with procedures approved under the mobile medical service license.

(e) A licensee providing mobile medical services shall retain the letter required in G.80(a)(1) and the record of each survey required in G.80(a)(6) in accordance with G.2080(a) and (b), respectively.

(f) A licensee conducting mobile medical services shall provide accurate advance written notification to the Agency, describing client's addresses and times of work using a method and frequency approved by the Agency.

Secs. G.81 – G.99 Reserved.

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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 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

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(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.

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 of a generator to demonstrate compliance with G.204(a).

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

Secs. G.205 – G.289 Reserved.

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

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

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

(1) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for imaging and localization studies 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:

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

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

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

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

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

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

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

(2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in G.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.

Secs. G.291 – G.299 Reserved.

Unsealed Radioactive Material—Written Directive Required

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

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

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

(b) Prepared by 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);

(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:

(*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*).

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(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.

Sec. G.391 Reserved.

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

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

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

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

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

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

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

(v) Radiation biology; and

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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).

Sec. G.393 Reserved.

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

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

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

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

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

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

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

(v) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in G.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

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

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in G.394(c)(1) and G.394(c)(2), and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under G.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in G.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).

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) (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 cases involving the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV and/or at least 3 cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in G.396(b) or (c), and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in G.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).

Secs. G.397 – G.399 Reserved.

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(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, 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, signed by a preceptor authorized user who meets the requirements in G.57, G.490 or equivalent Agreement State or NRC requirements, that the individual has satisfactorily completed the requirements in G.490(a)(1), or G.490(b)(1) and G.490(b)(2), and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under G.400.

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

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

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

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

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(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(a) and G.491(b) and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

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Secs. G.492 – G.499 Reserved.

Sealed Sources for Diagnosis

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

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

Secs. G.501 – G.589 Reserved.

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

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

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Sec. G.652 Radiation Surveys.

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

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

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

Secs. G.653 – G.654 Reserved.

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

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

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

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

Sec. G.656 Reserved.

Sec. G.657 Therapy-Related Computer Systems.

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

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

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

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

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

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

Secs. G.658 – G.689 Reserved.

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

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

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

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

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

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

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

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

(d) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in G.57, G.690, or NRC or equivalent Agreement State requirements at a medical institution, involving:

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(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 independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user who meets the requirements in G.57, G.690, or NRC or equivalent Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and

(c) Has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

Secs. G.691 – G.999 Reserved.

Other Medical Uses of Radioactive Material or Radiation From Radioactive Material

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

A licensee may use radioactive material or a radiation source approved for medical use which is not specifically addressed in G.100 through G.690 if:

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

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

Secs. G.1001 – G.2023 Reserved.

Records

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

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

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

Secs. G.2025 – G.2039 Reserved.

Sec. G.2040 Records of Written Directives.

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

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

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

PART J

NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS; INSPECTIONS

Sec. J.1 Purpose and Scope. This part establishes requirements for notices, instructions and reports by licensees or registrants to individuals engaged in activities under a license or registration and options available to such individuals in connection with Agency inspections of licensees or registrants to ascertain compliance with the provisions of the Act and regulations, orders, and licenses issued thereunder regarding radiological working conditions. The regulations in this part apply to all persons who receive, possess, use, own, or transfer sources of radiation registered with or licensed by the Agency pursuant to Parts B and C of these regulations.

General Regulatory Provisions and Specific Requirements

Sec. J.11 Posting of Notices to Workers.

(a) Each licensee or registrant shall post current copies of the following documents:

(1) The regulations in this part, Part D and each applicable part of these regulations that apply to the activities authorized by the specific license or registration;

(2) The license, radiation machine certificate of registration, conditions or documents incorporated into the license by reference and amendments thereto;

(3) The operating procedures applicable to activities under the license or registration; and

(4) Any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued pursuant to Part A of these regulations, and any response from the licensee or registrant.

(b) If posting of a document specified in J.11(a)(1), (2), (3) or (4) is not practicable, the licensee or registrant may post a notice which describes the document and states where it may be examined.

(c) Agency MDE 279 "Notice to Employees" shall be posted by each licensee or registrant as required by these regulations.

(d) Agency documents posted pursuant to J.11(a)(4) shall be posted within two (2) working days after receipt of the documents from the Agency; the licensee's or registrant's response, if any, shall be posted within five (5) working days after dispatch from the licensee or registrant. Such documents shall remain posted for a minimum of 30 working days or until action correcting the violation has been completed and this correction has been verified by the Agency.

(e) Documents, notices, or forms posted pursuant to J.11 shall appear in a sufficient number of places to permit individuals engaged in work under the license or registration to observe them on the way to or from any particular work location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.

Sec. J.12 Instructions to Workers.

(a) All individuals who in the course of employment potentially may receive in a year an occupational dose in excess of 100 mrem (1 mSv):

(1) Shall be kept informed of the storage, transfer, or use of radiation or radioactive materials;

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(2) Shall be instructed in the health protection problems associated with exposure to radiation or radioactive material, in the precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed;

(3) Shall be instructed in, and required to observe, to the extent within the worker's control, the applicable provisions of these regulations and licenses for the protection of personnel from exposures to radiation or radioactive material;

(4) Shall be instructed of their responsibility to report promptly to the licensee or registrant any condition which may constitute, lead to, or cause a violation of the Act, these regulations, and licenses or unnecessary exposure to radiation or radioactive material;

(5) Shall be instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and

(6) Shall be advised as to the radiation exposure reports which workers may request pursuant to J.13.

(b) In determining those individuals subject to the requirements of paragraph (a) of this section, licensees or registrants must take into consideration assigned activities during normal and abnormal situations involving exposure to radiation and/or radioactive material which can reasonably be expected to occur during the life of a licensed or registered facility. The extent of these instructions shall be commensurate with potential radiological health protection problems in the work place.

Sec. J.13 Notifications and Reports to Individuals.

(a) Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual shall be reported to the individual as specified in J.13. The information reported shall include data and results obtained pursuant to these regulations, orders, or license conditions, as shown in records maintained by the licensee or registrant pursuant to D.1107 of these regulations. Each notification and report shall:

(1) Be in writing;

(2) Include appropriate identifying data such as the name of the licensee or registrant, the name of the individual, and the individual's identification number, preferably social security number;

(3) Include the individual's exposure information; and

(4) Contain the following statement:

"This report is furnished to you under the provisions of COMAR 26.12.01.01 Part J. You should preserve this report for further reference."

(b) Each licensee or registrant shall furnish a report to each worker annually, and within 90 days following termination, of the worker's dose as shown in records maintained by the licensee or registrant pursuant to D.1107 of these regulations.

(c) Each licensee or registrant shall furnish a report of the worker's exposure to sources of radiation at the request of a worker formerly or presently engaged in activities controlled by the licensee or registrant. The report shall include the dose record for each year the worker was required to be monitored pursuant to D.502 of these regulations. Such report shall be furnished within 30 days from date the request was made, or within 30 days after the dose of the individual has been determined by the licensee or registrant, whichever