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PART A

GENERAL PROVISIONS

Sec. A.1 Scope. Except as otherwise specifically provided, these regulations apply to all persons who receive, possess, use, transfer, own, or acquire any source of radiation; provided, however, that nothing in these regulations shall apply to any person to the extent such person is subject to regulation by the U.S. Nuclear Regulatory Commission./[1] This part also gives notice to all persons who knowingly provide to any licensee, applicant, certificate of registration holder, contractor, or subcontractor, components, equipment, materials, or other goods or services, that relate to a licensee's, applicant's or certificate of registration holder's activities subject to these regulations, that they may be individually subject to Maryland Department of the Environment enforcement actions for violation of A.16.

Sec. A.2 Definitions. As used in these regulations, these terms have the definitions set forth below. Additional definitions used only in a certain part will be found in that part.

"A1" means the maximum activity of special form radioactive material permitted in a Type A package. "A2" means the maximum activity of radioactive material, other than special form radioactive material, permitted in a Type A package. These values are either listed in Appendix A of Part T of these regulations, Table I, or may be derived in accordance with the procedure prescribed in Appendix A of Part T of these regulations.

"Absorbed dose" [See "Dose"]

"Accelerator-produced material" means any material made radioactive by a particle accelerator.

"Act" means the Annotated Code of Maryland, Environment Article, Title 8 "Radiation."

"Activity" means the rate of disintegration (or transformation) or decay of radioactive material. The units of activity are the becquerel (Bq) and the curie (Ci).

"Adult" means an individual 18 or more years of age.

"Agency" means the Maryland Department of Environment, Radiological Health Program.

"Agreement State" means any State with which the U.S. Nuclear Regulatory Commission or the U.S. Atomic Energy Commission has entered into an effective agreement under subsection 274b. of the Atomic Energy Act of 1954, as amended.

"Airborne radioactive material" means any radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

"Airborne radioactivity area" means a room, enclosure, or area in which airborne radioactive material exists in concentrations:

(1) In excess of the derived air concentrations (DACs) specified in Appendix B, Table I of Part D of these regulations, or

(2) To such a degree that an individual present in the area without respirator protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC hours.

1/ Attention is directed to the fact that regulation by the State of source material, byproduct material, and special nuclear material in quantities not sufficient to form a critical mass is subject to the provisions of the agreement between the State and the U.S. Nuclear Regulatory Commission and to 10 CFR Part 150 of the Commission's regulations.

"Annually" means either (1) at intervals not to exceed 1 year or (2) once per year, at about the same time per year (plus or minus 1 month).

"As low as reasonably achievable (ALARA)" means making every reasonable effort to maintain exposures to radiation as far below the dose limits in these regulations as is practical, consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed or registered sources of radiation in the public interest.

"Authorized nuclear pharmacist" means a pharmacist who:

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

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

(i) A specific license issued by the Agreement State or NRC that authorizes medical use or the practice of nuclear pharmacy;

(ii) A permit issued by an NRC master material licensee that authorizes medical use or the practice of nuclear pharmacy;

(iii) An authorization issued by an Agreement State or NRC broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or

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

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

(4) Is designated as an authorized nuclear pharmacist in accordance with Sec. C.28(j)(2)(iv).

"Background radiation" means radiation from cosmic sources; naturally occurring radioactive materials, including radon, except as a decay product of source or special nuclear material, and including global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the licensee. "Background radiation" does not include sources of radiation from radioactive materials or radiation producing machines regulated by the Agency.

"Becquerel" (Bq) means the SI unit of activity. One becquerel is equal to 1 disintegration or transformation per second (S-1).

"Bioassay" means the determination of kinds, quantities or concentrations and, in some cases, the locations of radioactive material in the human body, whether by direct measurement, in vivo counting, or by analysis and evaluation of materials excreted or removed from the human body. For purposes of these regulations, "radiobioassay" is an equivalent term.

"Byproduct material" means:

(1) Any radioactive material, except special nuclear material, yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material; and

(2) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium or thorium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition.

"Public dose" means the dose received by a member of the public from exposure to radiation and/or to radioactive material released by a licensee or registrant, or to any other source of radiation under the control of the licensee or registrant. Public dose does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with Sec. G.75, or dose from voluntary participation in medical research programs.

"Pyrophoric liquid" means any liquid that ignites spontaneously in dry or moist air at or below 130 F (54.4 C). A pyrophoric solid is any solid material, other than one classed as an explosive, which under normal conditions is liable to cause fires through friction, retained heat from manufacturing or processing, or which can be ignited readily and, when ignited, burns so vigorously and persistently as to create a serious transportation, handling, or disposal hazard. Included are spontaneously combustible and water-reactive materials.

"Quality factor" (Q) means the modifying factor, listed in Tables 1 and 2 of A.13, that is used to derive dose equivalent from absorbed dose.

"Rad" means the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg/gram or 0.01 joule/kilogram (0.01 gray).

"Radiation" means alpha particles, beta particles, gamma rays, x-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. For purposes of these regulations, ionizing radiation is an equivalent term. Radiation, as used in these regulations, does not include non-ionizing radiation, such as radiowaves or microwaves, visible, infrared, or ultraviolet light.

"Radiation area" means any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in 1 hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

"Radiation machine" means any assemblage of components capable of producing radiation except those devices with radioactive material as the only source of radiation. This assemblage may include, as determined by the Agency:

(1) Not more than one control panel;

(2) The necessary supporting structures; and

(3) Any additional components or auxiliary equipment that function with the assemblage to produce the result desired by using the machine.

"Radiation safety officer" means an individual who:

(1) Meets the requirements in Secs. G.50(a) or (c)(1) and G.59; or

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

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

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

(3) Has been determined by a registrant as an individual who has the knowledge and responsibility to apply appropriate radiation protection regulations.

"Radioactive material" means any solid, liquid, or gas which emits radiation spontaneously.

"Radioactivity" means the transformation of unstable atomic nuclei by the emission of radiation.

"Registrant" means any person who is registered with the Agency or is legally obligated to register with the Agency pursuant to these regulations and Act.

"Registration" means registration with the Agency in accordance with the regulations adopted by the Agency.

"Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR Parts 100-189.

"Rem" means the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 sievert).

"Research and development" means (1) theoretical analysis, exploration, or experimentation; or (2) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes. Research and development does not include the internal or external administration of radiation or radioactive material to human beings.

“Residual Radioactivity” means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee’s control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site, and previous burials at the site, even if those burials were made in accordance with the provisions of Part D.

"Restricted area" means an area, access to which is limited by the licensee or registrant for the purpose of protecting individuals against undue risks from exposure to sources of radiation. A restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

"Roentgen" means the special unit of exposure. One roentgen (R) equals 2.58×10^{-4} coulombs/kilogram of air (see "Exposure").

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

"Shallow dose equivalent" [See "Dose"]

"SI" means the abbreviation for the International System of Units.

"Sievert" means the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).

"Site Boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee or registrant.

"Source material" means:

(1) Uranium or thorium, or any combination thereof, in any physical or chemical form; or

(2) Ores that contain by weight one-twentieth of 1 percent (0.05 percent) or more of uranium, thorium, or any combination of uranium and thorium. Source material does not include special nuclear material.

TABLE 2
MEAN QUALITY FACTORS, Q, AND FLUENCE PER UNIT DOSE EQUIVALENT FOR MONOENERGETIC NEUTRONS

	Neutron Energy (MeV)	Quality Factor[a] (Q)	Fluence per unit Dose Equivalent[b] (neutrons $cm^{-2}rem^{-1}$)	Fluence per unit Dose Equivalent[b] (neutrons $cm^{-2}Sv^{-1}$)
(thermal)	$2.5x10^{-8}$	2	$980x10^{6}$	$980x10^{8}$
	$1x10^{-7}$	2	$980x10^{6}$	$980x10^{8}$
	$1x10^{-6}$	2	$810x10^{6}$	$810x10^{8}$
	$1x10^{-5}$	2	$810x10^{6}$	$810x10^{8}$
	$1x10^{-4}$	2	$840x10^{6}$	$840x10^{8}$
	$1x10^{-3}$	2	$980x10^{6}$	$980x10^{8}$
	$1x10^{-2}$	2.5	$1010x10^{6}$	$1010x10^{8}$
	$1x10^{-1}$	7.5	$170x10^{6}$	$170x10^{8}$
	$5x10^{-1}$	11	$39x10^{6}$	$39x10^{8}$
	1	11	$27x10^{6}$	$27x10^{8}$
	2.5	9	$29x10^{6}$	$29x10^{8}$
	5	8	$23x10^{6}$	$23x10^{8}$
	7	7	$24x10^{6}$	$24x10^{8}$
	10	6.5	$24x10^{6}$	$24x10^{8}$
	14	7.5	$17x10^{6}$	$17x10^{8}$
	20	8	$16x10^{6}$	$16x10^{8}$
	40	7	$14x10^{6}$	$14x10^{8}$
	60	5.5	$16x10^{6}$	$16x10^{8}$
	$1x10^{2}$	4	$20x10^{6}$	$20x10^{8}$
	$2x10^{2}$	3.5	$19x10^{6}$	$19x10^{8}$
	$3x10^{2}$	3.5	$16x10^{6}$	$16x10^{8}$
	$4x10^{2}$	3.5	$14x10^{6}$	$14x10^{8}$

[a]Value of quality factor (Q) at the point where the dose equivalent is maximum in a 30-centimeter diameter cylinder tissue-equivalent phantom.

[b]Monoenergetic neutrons incident normally on a 30-centimeter diameter cylinder tissue-equivalent phantom.

Sec. A.14 Units of Radioactivity. For purposes of these regulations, activity is expressed in the SI unit of becquerel (Bq) or in the special unit of curie (Ci), or their multiples, or disintegrations or transformations per unit of time.

(a) One becquerel (Bq) = 1 disintegration or transformation per second (s^{-1}) (dps or tps).

(b) One curie (Ci) = $3.7x10^{10}$ disintegrations or transformations per second = $3.7x10^{10}$ becquerel (Bq) = $2.22x10^{12}$ disintegrations or transformations per minute.

Sec. A.15 False Statements, Representations and Certifications.

No person shall:

(a) make a false statement, representation, or certification in any application, record, report, plan or other document regarding radiation levels, tests performed, radiation safety conditions, practices or notices, or

(b) falsify, tamper with or render inaccurate any monitoring device or method for data collection if the data collected by that device or method is required by these regulations, or by any license or registration condition.

Sec. A.16 Deliberate Misconduct.

(a) Any licensee, certificate of registration holder, applicant for a license or certificate of registration, employee of a licensee, certificate of registration holder or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any licensee or certificate of registration holder or applicant for a license or certificate of registration, who knowingly provides to any licensee, applicant, certificate holder, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's, certificate holder's or applicant's activities in this part, shall not:

(1) Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, certificate of registration holder, or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license issued by the Department; or

(2) Deliberately submit to the Department, a licensee, certificate of registration holder, an applicant, or a licensee's, certificate holder's or applicant's, contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the Department.

(b) A person who violates paragraph (a)(1) or (a)(2) of this section may be subject to enforcement action in accordance with Maryland Environmental Article, Sections 1-301, 8-101, 8-509(b) and 8-510(b).

(c) For the purposes of paragraph (a)(1) of this section, deliberate misconduct by a person means an intentional act or omission that the person knows:

(1) Would cause a licensee, certificate of registration holder or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation, of any license issued by the Department; or

(2) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, certificate of registration holder, applicant, contractor, or subcontractor.

Sec. A.17 Public Posting of Notices of Violation.

(a) A notice of violation issued by the Agency to a registered or licensed facility shall be conspicuously posted at the facility for public review within two (2) working days after receipt.

(b) A notice of violation 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.

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PART C

LICENSING OF RADIOACTIVE MATERIAL

Sec. C.1 Purpose and Scope.

(a) This part, and Parts G and T, of these regulations, provide for the licensing of radioactive material. No person shall receive, possess, use, transfer, own, or acquire radioactive material except as authorized pursuant to this part or Parts G or T, of these regulations, or as otherwise provided in these parts.

(b) In addition to the requirements of this part, all licensees are subject to the requirements of Parts A, D, J, and T of these regulations. Furthermore, licensees engaged in industrial radiographic operations are subject to the requirements of Part E of these regulations. Licensees using radionuclides in the healing arts are subject to the requirements of Part G of these regulations, and licensees engaged in wireline and subsurface tracer studies are subject to the requirements of Part W of these regulations.

Sec. C.2 Definitions.

"Nationally tracked source" means a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in Appendix H of this Part. In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

"Offshore waters" means that area of land and water, beyond Agreement States' Submerged Lands Act jurisdiction, on or above the U.S. Outer Continental Shelf.

"Principal activities" as used in this part, means activities authorized by the license, which are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

"Waste collector" means an entity, operating under a Commission or Agreement State license, whose principal purpose is to collect and consolidate waste generated by others, and to transfer this waste, without processing or repackaging the collected waste, to another licensed waste collector, licensed waste processor, or licensed land disposal facility.

"Waste processor" means an entity, operating under a Commission or Agreement State license, whose principal purpose is to process, repackage, or otherwise treat low-level radioactive material or waste generated by others prior to eventual transfer of waste to a licensed low-level radioactive waste land disposal facility.

Exemptions from the Regulatory Requirements

Sec. C.3 Source Material.

(a) Any person is exempt from this part to the extent that such person receives, possesses, uses, owns, or transfers source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than 1/20 of 1 percent (0.05 percent) of the mixture, compound, solution, or alloy.

(b) Any person is exempt from this part to the extent that such person receives, possesses, uses, or transfers unrefined and unprocessed ore containing source material; provided that, except as authorized in a specific license, such person shall not refine or process such ore.

(c) Any person is exempt from this part to the extent that such person receives, possesses, uses, or transfers:

(1) any quantities of thorium contained in

(i) incandescent gas mantles,

(ii) vacuum tubes,

(iii) welding rods,

(iv) electric lamps for illuminating purposes provided that each lamp does not contain more than 50 milligrams of thorium,

(v) germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting provided that each lamp does not contain more than 2 grams of thorium,

(vi) rare earth metals and compounds, mixtures, and products containing not more than 0.25 percent by weight thorium, uranium, or any combination of these, or

(vii) personnel neutron dosimeters, provided that each dosimeter does not contain more than 50 milligrams of thorium;

(2) source material contained in the following products:

(i) glazed ceramic tableware, provided that the glaze contains not more than 20 percent by weight source material,

(ii) glassware containing not more than 10 percent by weight source material, but not including commercially manufactured glass brick, pane glass, ceramic tile, or other glass or ceramic used in construction,

(iii) glass enamel or glass enamel frit containing not more than 10 percent by weight source material imported or ordered for importation into the United States, or initially distributed by manufacturers in the United States, before July 25, 1983, or

(iv) piezoelectric ceramic containing not more than 2 percent by weight source material;

(3) photographic film, negatives, and prints containing uranium or thorium;

(4) any finished product or part fabricated of, or containing, tungsten-thorium or magnesium-thorium alloys, provided that the thorium content of the alloy does not exceed 4 percent by weight and that this exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such product or part;

(5) uranium contained in counterweights installed in aircraft, rockets, projectiles, and missiles, or stored or handled in connection with installation or removal of such counterweights, provided that

(i) the counterweights are manufactured in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, authorizing distribution by the licensee pursuant to 10 CFR Part 40,

laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of a Licensing State.

Name of manufacturer

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

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

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

(2) the criteria of Sections 32.61, 32.62, and 32.103 of 10 CFR Part 32 are met.

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

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

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

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

(a) Registered or licensed with the U.S. Food and Drug Administration (FDA) as a drug manufacturer;

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

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

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

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

(iv) The applicant satisfies the following labeling requirements:

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

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

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

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

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

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

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

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

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

(iv) May designate a pharmacist (as defined in Sec. A.2) as an authorized nuclear pharmacist if the individual is identified as of December 2, 1994, as an "authorized user" on a nuclear pharmacy license issued by the Agency under this Part.

(v) Shall provide to the Agency a copy of each individual's:

(a) (*i*) certification by a specialty board whose certification process has been recognized by the Agency, NRC, or an Agreement State as specified in G.55(a) of this regulation with the written attestation signed by a preceptor as required by G.55(b)(2) of this regulation; or

(*ii*) Agency, NRC or Agreement State license; or

(*iii*) permit issued by a licensee of broad scope; and

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

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

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

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

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

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

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

(2) the applicant submits evidence that:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(i) primary containment or source capsule,

(ii) protection of primary containment,

(iii) method of sealing containment,

(iv) containment construction materials,

(v) form of contained radioactive material,

(vi) maximum temperature withstood during prototype tests,

(vii) maximum pressure withstood during prototype tests,

registration certificate number, issuing agency, and expiration date; provided, that the oral certification is confirmed in writing within 10 days.

(4) The transferor may obtain other information compiled by a reporting service from official records of the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State regarding the identity of licensees and the scope and expiration dates of licenses and registration.

(5) When none of the methods of verification described in C.40(d)(1) through (4) are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State, or a Licensing State that the transferee is licensed to receive the radioactive material.

(e) Shipment and transport of radioactive material shall be in accordance with the provisions of Part T of these regulations.

National Source Tracking System

C.41 Nationally Tracked Source Thresholds.

Nationally tracked source thresholds are specified in Appendix H of this Part.

C.42 Serialization of Nationally Tracked Sources.

Each licensee who manufactures a nationally tracked source shall assign a unique serial number to each nationally tracked source. Serial numbers must be composed only of alphanumeric characters.

C.43 Reports of Transactions Involving Nationally Tracked Sources. Each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report as specified in (a) through (e) of this section for each type of transaction.

(a) Each licensee who manufactures a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

(1) The name, address, and license number of the reporting licensee;

(2) The name of the individual preparing the report;

(3) The manufacturer, model, and serial number of the source;

(4) The radioactive material in the source;

(5) The initial source strength in becquerels (curies) at the time of manufacture; and

(6) The manufacture date of the source.

(b) Each licensee that transfers a nationally tracked source to another person shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

(1) The name, address, and license number of the reporting licensee;

(2) The name of the individual preparing the report;

(3) The name and license number of the recipient facility and the shipping address;

(4) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(5) The radioactive material in the source;

(6) The initial or current source strength in becquerels (curies);

(7) The date for which the source strength is reported;

(8) The shipping date;

(9) The estimated arrival date; and

(10) For nationally tracked sources transferred as waste under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the identification of the container with the nationally tracked source.

(c) Each licensee that receives a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

(1) The name, address, and license number of the reporting licensee;

(2) The name of the individual preparing the report;

(3) The name, address, and license number of the person that provided the source;

(4) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(5) The radioactive material in the source;

(6) The initial or current source strength in becquerels (curies);

(7) The date for which the source strength is reported;

(8) The date of receipt; and

(9) For material received under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container information with the nationally tracked source.

(d) Each licensee that disassembles a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

(1) The name, address, and license number of the reporting licensee;

(2) The name of the individual preparing the report;

(3) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(4) The radioactive material in the source;

(5) The initial or current source strength in becquerels (curies);

(6) The date for which the source strength is reported; and

(7) The disassemble date of the source.

(e) Each licensee who disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

(1) The name, address, and license number of the reporting licensee;

(2) The name of the individual preparing the report;

(3) The waste manifest number;

(4) The container identification with the nationally tracked source;

(5) The date of disposal; and

(6) The method of disposal.

(f) The reports discussed in C.43(a) through (e) must be submitted by the close of the next business day after the transaction. A single report may be submitted for multiple sources and transactions. The reports must be submitted to the National Source Tracking System by one of the following methods:

(1) Using the on-line National Source Tracking System;

(2) Electronically using a computer-readable format;

(3) By facsimile;

(4) By mail to the address on the National Source Tracking Transaction Report Form (NRC Form 748); or

(5) By telephone with follow-up by facsimile or mail.

(g) Each licensee shall correct any error in previously filed reports or file a new report for any missed transaction within 5 business days of the discovery of the error or missed transaction. Such errors may be detected by a variety of methods such as administrative reviews or by physical inventories required by regulation. In addition, each licensee shall reconcile the inventory of nationally tracked sources possessed by the licensee against that licensee's data in the National Source Tracking System. The reconciliation must be conducted during the month of January in each year. The reconciliation process must include resolving any discrepancies between the National Source Tracking System and the actual inventory by filing the reports identified by C.43(a) through (e). By January 31 of each year, each licensee must submit to the National Source Tracking System confirmation that the data in the National Source Tracking System is correct.

(h) Each licensee that possesses Category 1 nationally tracked sources shall report its initial inventory of Category 1 nationally tracked sources to the National Source Tracking System by January 1, 2009. Each licensee that possesses Category 2 nationally tracked sources shall report its initial inventory of Category 2 nationally tracked sources to the National Source Tracking System by January 1, 2009. The information may be submitted by using any of the methods identified by C.43(f)(1) through (f)(4). The initial inventory report must include the following information:

(1) The name, address, and license number of the reporting licensee;

(2) The name of the individual preparing the report;

(3) The manufacturer, model, and serial number of each nationally tracked source or, if not available, other information to uniquely identify the source;

(4) The radioactive material in the sealed source;

(5) The initial or current source strength in becquerels (curies); and

(6) The date for which the source strength is reported.

Secs. C.44 – C.49 Reserved.

Modification and Revocation of Licenses

Sec. C.50 Modification and Revocation of Licenses.

(a) The terms and conditions of all licenses shall be subject to amendment, revision, or modification or the license may be suspended or revoked by reason of amendments to the Act, or by reason of rules, regulations, and orders issued by the Agency.

(b) Any license may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of the Act, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means which would warrant the Agency to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of the Act, or of the license, or of any rule, regulation, or order of the Agency.

(c) Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefor, facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

(d) Each specific license revoked by the Agency expires at the end of the day on the date of the Agency's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by Agency order.

Sec. C.51 - C.89 Reserved.

RECIPROCITY

Sec. C.90 Reciprocal Recognition of Licenses.

(a) Licenses of Byproduct, Source, and Special Nuclear Material in Quantities Not Sufficient to Form a Critical Mass.

(1) Subject to these regulations, any person who holds a specific license from the U.S. Nuclear Regulatory Commission or an Agreement State, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license within this state, excluding offshore waters and areas of exclusive Federal jurisdiction, for a period not in excess of 180 days in any calendar year to possess radioactive material and/or to conduct the activities authorized in such licensing document provided that:

(i) the licensing document does not limit the activity authorized by such document to specified installations or locations;

(ii) the out-of-state licensee notifies the Agency in writing at least 3 days prior to engaging in such activity. Such notification shall indicate the location, period, and type of proposed possession and use within the State, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the 3 day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the Agency, obtain permission to proceed sooner. The Agency may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in C.90(a)(1);

(iii) the out-of-state licensee complies with all applicable regulations of the Agency and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable regulations of the Agency;

(iv) the out-of-state licensee supplies such other information as the Agency may request; and

(v) the out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in C.90(a)(1) except by transfer to a person:

(a) specifically licensed by the Agency or by the U.S. Nuclear Regulatory Commission to receive such material, or

(b) exempt from the requirements for a license for such material under C.4(a).

(2) Notwithstanding the provisions of C.90(a)(1), any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission or an

Appendix H

Nationally Tracked Source Thresholds

Radioactive Material	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)
Actinium-227	20	540	0.2	5.4
Americium-241	60	1600	0.6	16
Americium-241/Be	60	1600	0.6	16
Californium-252	20	540	0.2	5.4
Cobalt-60	30	810	0.3	8.1
Curium-244	50	1400	0.5	14
Cesium-137	100	2700	1	27
Gadolinium-153	1000	27000	10	270
Iridium-192	80	2200	0.8	22
Plutonium-238	60	1600	0.6	16
Plutonium-239/Be	60	1600	0.6	16
Polonium-210	60	1600	0.6	16
Promethium-147	40000	1100000	400	11000
Radium-226	40	1100	0.4	11
Selenium-75	200	5400	2	54
Strontium-90	1000	27000	10	270
Thorium-228	20	540	0.2	5.4
Thorium-229	20	540	0.2	5.4
Thulium-170	20000	540000	200	5400
Ytterbium-169	300	8100	3	81

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(3) X-Ray Log. Each facility shall maintain an x-ray log containing the patient's name, the type of examinations, and the dates the examinations were performed. When the patient or film must be provided with human auxiliary support, the name of the human holder shall be recorded.

(b) Processing of Film.

(1) All film shall be processed in such a fashion as to achieve adequate sensitometric performance. "Adequate sensitometric performance" means:

(i) A measured processing speed of greater than or equal to 80; and

(ii) That the base plus fog of the facility's film shall not exceed 0.3 OD; as measured by the Sensitometric Technique for the Evaluation of Processing (STEP) test[1].

(2) Manual Processing of Film.

(i) Where film is developed manually, a system shall be available which consists of at least one three-sectional tank made of mechanically rigid, corrosion resistant material (each section of which shall be constructed so as to retain its solution separate from the other two) and has the overall temperature controlling capability of maintaining each solution such that the temperature of each solution will always fall within the range of 60°F to 80°F (16-27°C).

(ii) Devices shall be available which will:

(a) Give the actual temperature of the developer, plus or minus 2°F (or 1°C if SI units are used), and

(b) Give an audible or visible signal after a preset time, plus or minus 10% of the preset time.

(3) Chemical-Film Processing Control.

(i) Chemicals shall be mixed in accord with the chemical manufacturer's recommendations.

(ii) Replenishing of chemicals shall be sufficient to maintain the standards of (b)(1) above.

(iii) All processing chemicals shall be completely replaced at least every 3 months.

(4) Automatic Processors and Other Closed Processing Systems. Preventive maintenance shall be performed on the unit, except for extended periods of non-use, on a frequency basis which is not less than that schedule recommended by the manufacturer. In the event that no schedule is available from the manufacturer, a maintenance schedule shall be established which will preserve good film quality.

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[1] This test is described by Suleiman, O.H. et al. in the article "Automatic Film Processing: Analysis of 9 Years of Observations". Radiology 1992 Vol. 185, pp. 25-28.

(5) Film Fog Prevention

(i) Film processing areas and devices shall be constructed so that film being processed, handled, or stored will be exposed only to light which has passed through a proper safelight filter.

(ii) That light which remains in a film processing area or device following compliance with F.3(b)(5)(i) shall, when exposed to film in a two minute fog test, produce an increase in fog of not more than 0.05 density units.

(iii) In determining compliance with F.3(b)(5)(ii), fog measurements are to be made at exposed film densities of 1.0 plus base plus fog.

(c) Quality Assurance.

The registrant shall be responsible for establishing and operating an effective program for radiographic imaging quality control. This program shall be designed to fulfill the following goals:

(1) That the diagnostic quality of radiographic images will be maintained at the highest level;

(2) That film processing systems will be maintained at the highest quality level;

(3) That radiographic images will be produced using the minimum radiation doses to patients; and

(4) That the above three goals will be consistently met.

(d) Machine Maintenance.

(1) A registrant shall maintain each radiation machine in accordance with the manufacturer's recommended maintenance specifications.

(2) A registrant shall maintain documentation, in the form of logs, service tickets, or work orders, that the machine manufacturer's recommended maintenance schedule has been met.

(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.290 or G.390; and

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

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

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

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

(iv) Radiation biology; and

(v) Radiation dosimetry; and

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

(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.

Sec. G.58 Reserved.

Sec. G.59 Recentness of Training.

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

General Technical Requirements

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

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

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

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

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

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

(a) A medical use licensee 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.

(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 is likely to exceed 1 mSv (0.1 rem). If the total effective dose equivalent to a nursing infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption of breast-feeding, the instructions must also include:

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

[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).

(2) Information on the potential consequences, if 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.

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

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

(4) Before leaving a client's address, survey all areas of use to ensure compliance with the requirements in COMAR 26.12.01.01 Part D.

(b) A mobile medical service may not have radioactive material delivered from the manufacturer or the distributor to the client unless the client has a license allowing possession of the radioactive material. Radioactive material delivered to the client must be received and handled in conformance with the client's license.

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

Secs. G.81 – G.99 Reserved.

Unsealed Radioactive Material—Written Directive Not Required

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

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

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

(b) Prepared by 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; or

(c) 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

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

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.190, G.290, G.390, or equivalent NRC or Agreement State requirements, involving:

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

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

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

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

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

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

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

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements specified in G.290, or G.390 and G.290(c)(1)(ii)(g); or

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

(c) Obtained from and prepared by an 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

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

Secs. G.201 – G.203 Reserved.

Sec. G.204 Permissible Molybdenum-99 Concentration.

(a) A licensee may not administer to humans a radiopharmaceutical that contains more than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m).

(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.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.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:

(1) An authorized nuclear pharmacist;

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

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

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

(d) 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);

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

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

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

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

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

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

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

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in G.394(c)(1) and G.394(c)(2), and 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.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

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

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in 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.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.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:

(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.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.

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:

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, 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;

(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