

(viii) Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of radioactive material, provided that:

(a) Each source contains no more than one exempt quantity set forth in Appendix B of this part, and

(b) Each instrument contains no more than 10 exempt quantities. For purposes of this requirement, an instrument's source(s) may contain either one or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in Appendix B of this part, provided that the sum of such fractions shall not exceed unity.

(c) For americium-241, 0.05 microcurie (1.85 kBq) is considered an exempt quantity under C.4(c)(1)(viii).

(ix) Spark gap irradiators containing not more than 1 microcurie (37 kBq) of cobalt-60 per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate of at least 3 gallons (11.4 l) per hour.

(2) Self-Luminous Products Containing Radioactive Material.

(i) Tritium, Krypton-85, or Promethium-147. Except for persons who manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147, any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed, produced, imported, or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.22 of 10 CFR Part 32, which license authorizes the transfer of the product to persons who are exempt from regulatory requirements. The exemption in C.4(c)(2) does not apply to tritium, krypton-85, or promethium-147 used in products primarily for frivolous purposes or in toys or adornments.

(ii) Radium-226. Any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, or owns articles containing less than 0.1 microcurie (3.7 kBq) of radium-226 which were acquired prior to December 6, 1982.

(3) Gas and Aerosol Detectors Containing Radioactive Material.

(i) Except for persons who manufacture, process, or produce gas and aerosol detectors containing radioactive material, any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards provided that detectors containing radioactive material shall have been manufactured, imported, or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.26 of 10 CFR Part 32; or a Licensing State pursuant to C.28(c), which authorizes the transfer of the detectors to persons who are exempt from regulatory requirements.

(ii) Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by an Agreement State shall be considered exempt under C.4(c)(3)(i), provided that the device is labeled in accordance with the specific license authorizing distribution of the generally licensed device, and provided further that they meet the requirements of C.28(c).

(iii) Gas and aerosol detectors containing NARM previously manufactured and distributed in accordance with a specific license issued by a Licensing State shall be considered exempt under C.4(c)(3)(i), provided that the device is labeled in accordance with the specific license authorizing distribution, and provided further that they meet the requirements of C.28(c).

(4) Resins Containing Scandium-46 and Designed for Sand Consolidation in Oil Wells.

Any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns or acquires synthetic plastic resins containing scandium-46 which are designed for sand consolidation in oil wells. Such resins shall have been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or shall have been manufactured in accordance with the specifications contained in a specific license issued by the Agency or any Agreement State to the manufacturer of such resins pursuant to licensing requirements equivalent to those in Sections 32.16 and 32.17 of 10 CFR Part 32 of the regulations of the U.S. Nuclear Regulatory Commission. This exemption does not authorize the manufacture of any resins containing scandium-46.

(5) Radioactive Drug: Capsules Containing Carbon-14 Urea for "In vivo" Diagnostic Use for Humans.

(i) Except as provided in paragraphs (b) and (c) of this section, any person is exempt from the requirements for a license and from these regulations provided that such person receives, possesses, uses, transfers, owns, or acquires capsules containing 37 kBq (1 μ Ci) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each, for "in vivo" diagnostic use for humans.

(ii) Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license pursuant to Section C.

(iii) Any person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution such capsules shall apply for and receive a specific license pursuant to 10 CFR §32.21.

(iv) Nothing in this section relieves persons from complying with applicable FDA, Federal, and State requirements governing receipt, administration, and use of drugs.

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2/ Authority to transfer possession or control by the manufacturer, processor or producer of any equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(iv) within 30 days of any transfer, shall report in writing to the Agency the name and address of the person receiving the depleted uranium pursuant to such transfer; and

(v) shall not export such depleted uranium except in accordance with a license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 110.

(5) Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by C.21(e)(1) is exempt from the requirements of Parts D and J of these regulations with respect to the depleted uranium covered by that general license.

Sec. C.22 General Licenses* - Radioactive Material Other Than Source Material.

(a) Certain Devices and Equipment. A general license is hereby issued to transfer, receive, acquire, own, possess, and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission for use pursuant to Section 31.3 of 10 CFR Part 31. This general license is subject to the provisions of A.4 through A.9, C.4(a)(2), C.31, C.40, C.50 and Parts D^{4/}, J, and T of these regulations.

(1) Static Elimination Device. Devices designed for use as static eliminators which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries (18.5 MBq) of polonium-210 per device.

(2) Ion Generating Tube. Devices designed for ionization of air which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries (18.5 MBq) of polonium-210 per device or a total of not more than 50 millicuries (1.85 GBq) of hydrogen-3 (tritium) per device.

(b) General License to Install Devices Generally Licensed in Sec. C.22

Any person who holds a specific license issued by an Agreement State or the U.S. Nuclear Regulatory Commission authorizing the holder to manufacture, install, or service a device described in C.22 within such Agreement State is hereby granted a general license to install and service such device in the State of Maryland as defined in C.90 provided that:

(1) [Reserved]

(2) The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the U.S. Nuclear Regulatory Commission or Agreement State.

(3) Such person assures that any labels required to be affixed to the device under regulations of the U.S. Nuclear Regulatory Commission or Agreement State that licensed manufacture of the device bear a statement that removal of the label is prohibited.

(c) Reserved.

*Note: Different general licenses are issued in this section, each of which has its own specific conditions and requirements.

^{4/} Attention is directed particularly to the provisions of Part D of these regulations which relate to the labeling of containers.

(d) Certain Measuring, Gauging or Controlling Devices.

(1) A general license is hereby issued to commercial and industrial firms and to research, educational and medical institutions, individuals in the conduct of their business, and State or local government agencies to own, receive, acquire, possess, use or transfer in accordance with the provisions of C.22(d)(2), (3), and (4), radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

(2) The general license in C.22(d)(1) applies only to radioactive material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in a specific license issued by the Agency pursuant to C.28(d) or in accordance with the specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, which authorizes distribution of devices to persons generally licensed by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State and the device has been manufactured and installed so that:

(i) The dose rate in the radiation beam of the device at 18 inches (0.46 meters) from the radiation source with the device shutter in the open position does not exceed 125 millirem (1.25 mSv) per hour; and

(ii) There is not an accessible airgap of 18 inches (0.46 meters) or greater between the radiation source and detector which would allow insertion of a 12 inch (0.30 meters) diameter sphere into the radiation beam ^{5/}.

(3) The devices must have been received from one of the specific licensees described in C.22(d)(2)(i) or through a transfer made under C.22(d)(4)(vii).

(4) Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general license in C.22(d)(1):

(i) shall assure that all labels affixed to the device at the time of receipt, and bearing a statement that removal of the label is prohibited, are maintained thereon and shall comply with all instructions and precautions provided by such labels;

(ii) shall assure that the device is tested for leakage of radioactive material and proper operation of the "on-off" mechanism and indicator, if any, at no longer than 6-month intervals or at such other intervals as are specified in the label, however,

(a) devices containing only krypton need not be tested for leakage of radioactive material, and

^{5/} Regulations under the Federal Food, Drug, and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling thereon which is found in 21 CFR 179.21.

(b) devices containing only tritium or not more than 100 microcuries (3.7 MBq) of other beta- and/or gamma-emitting material or 10 microcuries (0.37 MBq) of alpha-emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;

(iii) shall assure that the tests required by C.22(d)(4)(ii) and other testing, installation, servicing, and removal from installation involving the radioactive material, its shielding or containment, are performed:

(a) in accordance with the instructions provided by the labels, or

(b) by a person holding an applicable specific license from the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to perform such activities;

(iv) shall maintain records showing compliance with the requirements of C.22(d)(4)(ii) and (iii). The records shall show the results of tests. The records also shall show the dates of performance of, and the names of persons performing, testing, installation, servicing, and removal from installation concerning the radioactive material, its shielding or containment. Records of tests for leakage of radioactive material required by C.22(d)(4)(ii) shall be maintained for 2 years after the next required leak test is performed or until the sealed source is transferred or disposed of. Records of tests of the "on-off" mechanism and indicator required by C.22(d)(4)(ii) shall be maintained for 2 years after the next required test of the "on-off" mechanism and indicator is performed or until the sealed source is transferred or disposed of. Records which are required by C.22(d)(4)(iii) shall be maintained for a period of 2 years from the date of the recorded event or until the device is transferred or disposed of;

(v) shall immediately suspend operation of the device if there is a failure of, or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 185 becquerel (0.005 microcurie) or more removable radioactive material. The device may not be operated until it has been repaired by the manufacturer or other person holding a specific license to repair such devices that was issued under Section C or by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State. The device and any radioactive material from the device may only be disposed of by transfer to a person authorized by a specific license to receive the byproduct material in the device or as otherwise approved by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State. A report containing a brief description of the event and the remedial action taken; and, in the case of detection of 0.005 microcurie or more removable radioactive material or failure of or damage to a source likely to result in contamination of the premises or the environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use; must be furnished to the Manager, Radiological Health Program, 1800 Washington Boulevard, Baltimore, Maryland 21230 within 30 days. Under these circumstances, the criteria set out in Section D.1402, "Radiological Criteria for Unrestricted Use", may be applicable, as determined by the Agency on a case-by-case basis;

(vi) shall not abandon the device containing radioactive material;

(vii) shall transfer or dispose of the device containing radioactive material by transfer to another general licensee as authorized in C.22(d)(4)(x), or to a person authorized to receive the device by a specific license issued under Section C that authorizes waste collection, or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State, or as otherwise approved under C.22(d)(4)(ix);

(viii) shall within 30 days after the transfer of a device to a specific licensee or export, furnish a report to: Manager, Radiological Health Program, 1800 Washington Boulevard, Baltimore, Maryland 21230. The report shall contain:

- (a) the identification of the device by manufacturer's (or initial transferor's) name, model number, and serial number,
- (b) the name, address, and license number of the person receiving the device (license number not applicable if exported), and
- (c) the date of the transfer;

(ix) shall obtain written Agency approval before transferring the device to any other specific licensee not specifically identified in C.22(d)(4)(vii);

(x) shall transfer the device to another general licensee only if:

(a) the device remains in use at a particular location. In this case, the transferor shall give the transferee a copy of Sections C.20(a), C.22(d), C.38, D.1201, and D.1202 and any safety documents identified in the label of the device. Within 30 days of the transfer, the transferor shall report to the Manager, Radiological Health Program, 1800 Washington Boulevard, Baltimore, Maryland 21230:

- (1) the manufacturer's (or initial transferor's) name,
- (2) the model number and the serial number of the device transferred,
- (3) the transferee's name and mailing address for the location of use, and
- (4) the name, title, and phone number of the responsible individual identified by the transferee in accordance with C.22(d)(4)(xii) to have knowledge of and authority to take actions to ensure compliance with the appropriate regulations and requirements; or

(b) the device is held in storage by an intermediate person in the original shipping container at its intended location of use prior to initial use by a general licensee;

(xi) shall comply with the provisions of Sections D.1201 and D.1202 for reporting radiation incidents, theft, or loss of licensed material, but shall be exempt from the other requirements of Parts D and J;

(xii) shall appoint an individual responsible for having knowledge of the appropriate regulations and requirements and the authority for taking required actions to comply with appropriate regulations and requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with appropriate regulations and requirements. This appointment does not relieve the general licensee of any of its responsibility in this regard;

(xiii) shall report changes to the mailing address for the location of use (including change in name of general licensee) to the Manager, Radiological Health Program, 1800 Washington Boulevard, Baltimore, Maryland 21230 within 30 days of the effective date of the change. For a portable device, a report of address change is only required for a change in the device's primary place of storage;

(xiv) may not hold devices that are not in use for longer than 2 years. If devices with shutters are not being used, the shutter must be locked in the closed position. The testing required by C.22(d)(4)(iii) need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage before use or transfer and the shutter tested before use. Devices kept in standby for future use are excluded from the two-year time limit if the general licensee performs quarterly physical inventories of these devices while they are in standby;

(xv) shall not export the device containing byproduct material except in accordance with 10 CFR Part 110; and

(xvi) shall respond to written requests from the Agency to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the Agency a written justification for the request.

(5) The general license in C.22(d)(1) does not authorize the manufacture of devices containing radioactive material.

(6) The general license provided in C.22(d)(1) is subject to the provisions of A.4 through A.9, C.31, C.40, C.50, and Part T of these regulations.

(e) Luminous Safety Devices for Aircraft.

(1) A general license is hereby issued to own, receive, acquire, possess, and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided:

(i) each device contains not more than 10 curies (370 GBq) of tritium or 300 millicuries (11.1 GBq) of promethium-147; and

(ii) each device has been manufactured, assembled or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the Agency or any Agreement State to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in Section 32.53 of 10 CFR Part 32.

(2) Persons who own, receive, acquire, possess, or use luminous safety devices pursuant to the general license in C.22(e)(1) are exempt from the requirements of Parts D and J of these regulations except that they shall comply with the provisions of D.1001, D.1201, D.1202 and D.1207.

(3) This general license does not authorize the manufacture, assembly, or repair of luminous safety devices containing tritium or promethium-147.

(4) This general license does not authorize the ownership, receipt, acquisition, possession or use of promethium-147 contained in instrument dials.

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

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 certification by the Board of Pharmaceutical Specialties, the NRC or Agreement State license, or the permit issued by a licensee of broad scope, and a copy of the 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 or Irradiation of Materials. 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 or reference source, or for diagnostic, brachytherapy or teletherapy sources for the uses listed in G.400, G.500, and G.600 of these regulations, or for use to irradiate materials 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 and G.600 and for use to irradiate materials 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,