

105 CMR: DEPARTMENT OF PUBLIC HEALTH

120.001: GENERAL PROVISIONS

120.005: Definitions

As used in 105 CMR 120.000, these terms have the definitions set forth in 105 CMR 120.005. Additional definitions used only in a certain Section will be found in that Section.

Total Effective Dose Equivalent (TEDE) means the sum of the effective deep dose equivalent (for external exposures) and the committed effective dose equivalent for (internal exposures).

Total Organ Dose Rquivalent (TODE) means the sum of the deep dose equivalent and the committed dose equivalent to the organ receiving the highest dose as described in 105 CMR 120.267(A)(6).

120.100: LICENSING OF RADIOACTIVE MATERIAL

120.101: Purpose and Scope

(A) 105 CMR 120.100, 120.500 and 120.770, provide for the licensing of radioactive material. No person shall manufacture, produce, receive, possess, use, transfer, own, or acquire radioactive material except as authorized pursuant to 105 CMR 120.100, 120.500 or 120.770, or as otherwise provided in 105 CMR 120.000.

(B) In addition to the requirements of 105 CMR 120.100, all licensees are subject to the requirements of 105 CMR 120.000, 120.200, 120.750, and 120.770. Furthermore, licensees engaged in industrial radiographic operations are subject to the requirements of 105 CMR 120.300; licensees using radionuclides in the healing arts are subject to the requirements of 105 CMR 120.500, licensees engaged in land disposal of radioactive material are subject to the requirements of 105 CMR 120.801 through 120.885, and licensees engaged in wireline and subsurface tracer studies are subject to the requirements of 105 CMR 120.900.

120.104: Radioactive Material Other Than Source Material

(A) Exempt Concentrations.

(1) Except as provided in 105 CMR 120.104(A)(3 ~~2~~), and (4), any person is exempt from 105 CMR 120.100 to the extent that such person receives, possesses, uses, transfers, owns or acquires products containing byproduct radioactive material introduced in concentrations not in excess of those listed in 105 CMR 120.195: *Appendix A*.

(2) 105 CMR 120.104(A) shall not be deemed to authorize the import of byproduct material or products containing byproduct material.

(3) A manufacturer, processor, or producer of a product or material is exempt from the requirements for a license set forth in 105 CMR 120.100 to the extent that this person transfers byproduct material contained in a product or material in concentrations not in excess of those specified in 105 CMR 120 195: *Appendix A* and introduced into the product or

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material by a licensee holding a specific license issued by NRC expressly authorizing such introduction. This exemption does not apply to the transfer of byproduct material contained in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

(4 ~~2~~) No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under 105 CMR 120.104(A)(1) or equivalent regulations of the NRC, ~~any~~ or an Agreement State ~~or Licensing State~~, except in accordance with a specific license issued pursuant to 10 CFR 32.11. ~~105 CMR 120.128(A) or the general license provided in 105 CMR 120.190.~~

(B) Exempt Quantities.

(1) Except as provided in 105 CMR 120.104(B)(2), (3), and (5), ~~A~~ any person is exempt from 105 CMR 120.100 to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct ~~radioactive~~ material in individual quantities each of which does not exceed the applicable quantity set forth in 105 CMR 120.196: *Appendix B* Table I provided they have been distributed pursuant to a license as described in 105 CMR 120.104(B)(3).

(2) 105 CMR 120.104(B) does not authorize the production, packaging or repackaging of byproduct ~~radioactive~~ material for purposes of commercial distribution, or the incorporation of byproduct ~~radioactive~~ material into products intended for commercial distribution.

(3) No person may, for purposes of commercial distribution, transfer byproduct ~~radioactive~~ material in the individual quantities set forth in 105 CMR 120.196: *Appendix B, Table I*, knowing or having reason to believe that such quantities of byproduct ~~radioactive~~ material will be transferred to persons exempt under 105 CMR 120.104(B) or equivalent regulations of the NRC, any Agreement State or Licensing State, except in accordance with a specific license issued by the NRC pursuant to 10 CFR Part 32, § 32.18 ~~or by the Agency pursuant to 105 CMR 120.128(B)~~ which license states that the byproduct ~~radioactive~~ material may be transferred by the licensee to persons exempt under 105 CMR 120.104(B) or the equivalent regulations of the NRC, an Agreement State, ~~or Licensing State.~~²

(4) Any person who possesses byproduct ~~radioactive~~ material received or acquired prior to September 25, 1971 under the general license then provided in 10 CFR 31.4 or similar general license of a State, is exempt from the requirements for a license set forth in 105 CMR 120.100 if such person possesses, uses, transfers, or owns such byproduct ~~radioactive~~ material.

(5) No person may, for purposes of producing an increased radiation level, combine quantities of byproduct material covered by the exemption in 105 CMR 120.104(B) so that the aggregate quantity exceeds the limits set forth in 105 CMR 120.196: *Appendix B*, except for byproduct material combined within a device placed in use before May 3, 1999, or as otherwise permitted by regulation in 105 CMR 120.100.

(C) Exempt Items.

(1) Certain Items Containing Byproduct ~~Radioactive~~ Material. Except for persons who apply radioactive material to, or persons who incorporate radioactive material into the following products, any person is exempt from 105 CMR 120.000 to the extent that he receives, possesses, uses, transfers, owns, or acquires the following products:

(a) Timepieces or hands or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified radiation dose rate:

1. 25 millicuries (925 MBq) of tritium per timepiece.
2. five millicuries (185 MBq) of tritium per hand.
3. 15 millicuries (555 MBq) of tritium per dial (bezels when used shall be considered as part of the dial).
4. 100 microcuries (3.7 MBq) of promethium-147 per watch or 200 microcuries (7.4 MBq) of promethium-147 per any other timepiece.

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 Nuclear Regulatory Commission (NRC), Washington, D.C.

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120.104: continued

5. 20 microcuries (0.74 MBq) of promethium-147 per watch hand or 40 microcuries (1.48 MBq) of promethium-147 per other timepiece hand.
6. 60 microcuries (2.22 MBq) of promethium-147 per watch dial or 120 microcuries (4.44 MBq) of promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial).
7. The radiation dose rate from hands and dials containing promethium-147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:
 - a. For wrist watches, 0.1 millirad (1 μ Gy) per hour at ten centimeters from any surface.
 - b. For pocket watches, 0.1 millirad (1 μ Gy) per hour at one centimeter from any surface.
 - c. For any other timepiece, 0.2 millirad (2 μ Gy) per hour at ten centimeters from any surface.
8. One microcurie (37 kBq) of radium-226 per timepiece in timepieces acquired prior to November 30, 2007. ~~the effective date of 105 CMR 120.100.~~
- (b) ~~[Reserved] Lock illuminators containing not more than 15 millicuries (555 MBq) of tritium or not more than two millicuries (74 MBq) of promethium-147 installed in automobile locks. The radiation dose rate from each lock illuminator containing promethium-147 will not exceed one millirad (10 μ Gy) per hour at one centimeter from any surface when measured through 50 milligrams per square centimeter of absorber.~~
- (c) Precision balances containing not more than one millicurie (37 MBq) of tritium per balance or not more than 0.5 millicurie (18.5 MBq) of tritium per balance part manufactured before December 17, 2007.
- (d) ~~[Reserved] Automobile shift quadrants containing not more than 25 millicuries (925 MBq) of tritium.~~
- (e) Marine compasses containing not more than 750 millicuries (27.8 GBq) of tritium gas and other marine navigational instruments containing not more than 250 millicuries (9.25 GBq) of tritium gas manufactured before December 17, 2007.
- (f) ~~[Reserved] Thermostat dials and pointers containing not more than 25 millicuries (925 MBq) of tritium per thermostat.~~
- (g) Ionization chamber smoke detectors containing not more than 1 microcurie (μ Ci) of americium-241 per detector in the form of a foil and designed to protect life and property from fires
- (h ~~-g~~) Electron tubes; provided, that each tube does not contain more than one of the following specified quantities of byproduct ~~radioactive~~ material:
 1. 150 millicuries (5.55 GBq) of tritium per microwave receiver protector tube or 10 millicuries (370 MBq) of tritium per any other electron tube.
 2. 1 microcurie (37 kBq) of cobalt-60.
 3. 5 microcuries (185 kBq) of nickel-63.
 4. 30 microcuries (1.11 MBq) of krypton-85.
 5. 5 microcuries (185 kBq) of cesium-137.
 6. 30 microcuries (1.11 MBq) of promethium-147.And provided further, that the radiation dose rate from each electron tube containing byproduct ~~radioactive~~ material will not exceed one millirad (ten μ Gy) per hour at one centimeter from any surface when measured through seven milligrams per square centimeter of absorber. For purposes of 105 CMR 120.104(C)(1)(g), "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pick-up tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents.
- (i ~~-h~~) Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of radioactive material, provided that:
 1. Each source contains no more than one exempt quantity set forth in 105 CMR 120.196: *Appendix B, Table I*; and

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2. Each instrument contains no more than ten 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 105 CMR 120.196: *Appendix B, Table 1*, provided that the sum of such fractions shall not exceed unity.

3. For americium-241, 0.05 microcurie (1.85 kBq) is considered an exempt quantity under 105 CMR 120.104(C)(1)(h).

~~(j i) [Reserved] Spark gap irradiators containing not more than one 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 three gallons (11.4 l) per hour.~~

(2) Self-luminous Products Containing Radioactive Material.

(a) 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 105 CMR 120.000 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 NRC pursuant to 10 CFR Part 32, § 32.22 which license authorizes the transfer of the product to persons who are exempt from regulatory requirements. The exemption in 105 CMR 120.104(C)(2) does not apply to tritium, krypton-85, or promethium-147 used in products primarily for frivolous purposes or in toys or adornments.

(b) Radium-226. Any person is exempt from 105 CMR 120.000 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 March 11, 1994.

(3) Gas and Aerosol Detectors Containing Radioactive Material.

(a) Except for persons who manufacture, process, ~~or produce,~~ or initially transfer for sale or distribution gas and aerosol detectors containing radioactive byproduct material, any person is exempt from the requirement of a license set forth in 105 CMR 120.1000 to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards provided that detectors containing radioactive byproduct material shall have been manufactured, ~~imported,~~ processed, produced, or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission² pursuant to 10 CFR Part 32, § 32.26, ~~; or a Licensing State pursuant to 105 CMR 120.128(C), which authorizes the~~ license authorizes the initial transfer of the detectors to persons who are exempt from regulatory requirements. product for use under 105 CMR 120.105(C)(3). This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007 in accordance with a specific license issued by a State under comparable provisions to 10 CFR 32.28 authorizing distribution to persons exempt from regulatory requirements.

(b) 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 105 CMR 120.104(C)(3)(a), 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 105 CMR 120.128(C).

(c) 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 105 CMR 120.104(C)(3)(a), provided that the device is labeled in accordance with the specific license authorizing distribution, and provided further that they meet the requirements of 105 CMR 120.128(C).

~~(4) Resins Containing Scandium 46 and Designed for Sand Consolidation in Oil Wells. Any person is exempt from 105 CMR 120.000 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~~

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~~or any Agreement State to the manufacturer of such resins pursuant to licensing requirements equivalent to those in 10 CFR Part 32, §§ 32.16 and 32.17. 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.

- (a) Except as provided in 105 CMR 120.104(C)(5)(b) and (c), any person is exempt from the requirements for a license set forth in Section 5P of M.G.L. c. 111 and from the regulations in 105 CMR 120.100 and 105 CMR 120.500 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.
- (b) Any persons who desires to use the capsules for research involving human subjects shall apply for and receive a specific license pursuant to 105 CMR 120.500.
- (c) Any person who desires to manufacture, prepare, process, produce, package, or transfer for commercial distribution such capsules shall apply, to NRC, for and receive a specific license pursuant to 10 CFR 32.21.
- (d) Nothing in 105 CMR 120.104(C)(5) relieves persons from complying with applicable FDA, other Federal, and State requirements governing receipt, administration, and use of drugs.

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120.120: Types of Licenses

Licenses for radioactive materials are of two types: general and specific.

(A) The Agency issues a specific license to a named person who has filed an application for the license under the provisions of 105 CMR 120.124.

(B) A general license is provided by regulation, grants authority to a person for certain activities involving radioactive material, and is effective without the filing of an application with the Agency or the issuance of a licensing document to a particular person. However, registration with the Agency may be required by the particular general license.

120.121: General Licenses - Source Material

120.122: General Licenses - Radioactive Material Other Than Source Material

(D) Certain Detecting, Measuring, Gauging, or Controlling Devices and Certain Devices for Producing Light or an Ionized Atmosphere.

(1) A general license is hereby issued to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and State or local government agencies to acquire, receive, possess, use or transfer in accordance with the provisions of 105 CMR 120.122(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)(a) The general license in 105 CMR 120.122(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:

1. a specific license issued by the Agency pursuant to 105 CMR 120.128(D); or
2. an equivalent specific license issued by the U.S. Nuclear Regulatory Commission, an Agreement State; or ~~a Licensing State~~; an equivalent specific license issued by a State with provisions comparable to 105 CMR 120.128(D).

(b) The devices must have been received from one of the specific licensees described in 105 CMR 120.122(D)(2)(a) or through a transfer made under 105 CMR 120.122(D)(3)(i).

(3) Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general license in 105 CMR 120.122(D)(1):

(a) 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;

(b) 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 six-month intervals or at such other intervals as are specified in the label, however,

1. devices containing only krypton need not be tested for leakage of radioactive material; and
2. devices containing only tritium or not more than 100 microcuries (3.7 MBq) of other beta and/or gamma-emitting material or ten 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;

(c) shall assure that the tests required under 105 CMR 120.122(D)(3)(b) and other testing, installation, servicing, and removal from installation involving the radioactive material, its shielding or containment, are performed:

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1. in accordance with the instructions provided by the labels; or
 2. 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;
- (d) shall maintain records showing compliance with the requirements of 105 CMR 120.122(D)(3)(b) and (c). 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. The licensee shall retain these records as follows:
1. each record of a test for leakage of radioactive material required by 105 CMR 120.122(D)(3)(b) shall be retained for three years after the next required leak test is performed or until the sealed source is transferred or disposed of;
 2. each record of a test of the "on-off" mechanism and indicator required by 105 CMR 120.122(D)(3)(b) shall be retained for three 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; and
 3. each record that is required by 105 CMR 120.122(D)(3)(c) shall be maintained for a period of three years from the date of the recorded event or until the device is transferred or disposed of;
- (e) 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 Bq (0.005 microcurie) or more removable radioactive material. The device shall not be operated until it has been repaired by the manufacturer or other person holding an applicable specific license from the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to repair such devices. The device and any radioactive material from the device shall only be disposed of by transfer to a person authorized by an applicable specific license to receive the radioactive material contained in the device or as otherwise approved by the Agency. 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 Agency within 30 days. Under these circumstances, the criteria set out in 105 CMR 120.243: *Vacating Premises*, may be applicable, as determined by the Agency on a case-by-case basis;
- (f) shall not abandon the device containing radioactive material;
- (g) shall not export the device containing radioactive material except in accordance with 10 CFR 110;
- (h) 1. shall transfer or dispose of the device containing radioactive material only by export as provided in 105 CMR 120.122(D)(3)(g), by transfer to another general licensee as authorized in 105 CMR 120.122(D)(3)(i), or to a person authorized to receive the device by a specific license issued by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State that authorizes waste collection or as otherwise approved under 105 CMR 120.122(D)(3)(h)3.
2. shall furnish a report to the Agency within 30 days after the transfer of a device to a specific licensee or export. 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.
 3. shall obtain written Agency approval before transferring the device to any other specific licensee not specifically identified in 105 CMR 120.122(D)(3)(h)1.; however, a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if, the holder:
 - a. Verifies that the specific license authorizes the possession and use, or applies for and

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obtains an amendment to the license authorizing the possession and use;

b. Removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by paragraph (3)(a) of this section) so that the device is labeled in compliance with 105 CMR 120.240; however the manufacturer, model number, and serial number must be retained;

c. Obtains the manufacturer's or initial transferor's information concerning maintenance that would be applicable under the specific license (such as leak testing procedures); and

d. Reports the transfer under 105 CMR 120.122(D)(3)(h)2. of this section.

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

1. the device remains in use at a particular location. In this case, the transferor shall give the transferee a copy of 105 CMR 120.122(D), a copy of 120.122, 120.009, 120.281, and 120.282, and any safety documents identified in the label of the device. Within 30 days of the transfer, the transferor shall report to the Agency:

a. the manufacturer's (or initial transferor's) name;

b. the model number and the serial number of the device transferred;

c. the transferee's name and mailing address for the location of use; and

d. the name, title, and phone number of the responsible individual identified by the transferee in accordance with 105 CMR 120.122(D)(3)(l) to have knowledge of and authority to take actions to ensure compliance with the appropriate regulations and requirements; or

2. 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;

(j) shall comply with the provisions of 105 CMR 120.281 and 120.282 for reporting radiation incidents, theft, or loss of licensed material, but shall be exempt from the other requirements of 105 CMR 120.200 and 120.750;

(k) 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 submitting a letter to the Director, Radiation Control Program, Massachusetts Department of Public Health, and provide written justification as to why it cannot comply;

(l) 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;

(m)1. shall register, in accordance with 105 CMR 120.122(D)(3)(m)2. and 3., devices containing at least 370 MBq (10 mCi) of cesium-137, 3.7 MBq (0.1 mCi) of strontium-90, 37 MBq (1 mCi) of cobalt-60, 3.7 MBq (0.1 mCi) radium-226, or 37 MBq (1 mCi) of americium-241 or any other transuranic (i.e., element with atomic number greater than uranium (92)), based on the activity indicated on the label. Each address for a location of use, as described under 105 CMR 120.122(D)(3)(m)3.d. represents a separate general licensee and requires a separate registration and fee;

2. if in possession of a device meeting the criteria of 105 CMR 120.122(D)(3)(m)1., shall register

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these devices annually with the Agency and shall pay any prescribed fee. Registration must be done by verifying, correcting, and/or adding to the information provided in a request for registration received from the Agency. The registration information must be submitted to the Agency within 30 days of the date of the request for registration or as otherwise indicated in the request. In addition, a general licensee holding devices meeting the criteria of 105 CMR 120.122(D)(3)(m)1. is subject to the bankruptcy notification requirement in 105 CMR 120.131(E);

3. in registering devices, the general licensee shall furnish the following information and any other information specifically requested by the Agency:

- a. name and mailing address of the general licensee;
- b. information about each device: the manufacturer (or initial transferor), model number, serial number, the radioisotope and activity (as indicated on the label);
- c. name, title, and telephone number of the responsible person designated as a representative of the general licensee under 105 CMR 120.122(D)(3)(l);
- d. address or location at which the device(s) are used and/or stored. For portable devices, the address of the primary place of storage;
- e. certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and checking of label information;
- f. certification by the responsible representative of the general licensee that they are aware of the requirements of the general license.

4. persons generally licensed by an Agreement State, Licensing State or NRC with respect to devices meeting the criteria in 105 CMR 120.122(D)(3)(m)1. are not subject to registration requirements if the devices are used in areas subject to Agency jurisdiction for a period less than 180 days in any calendar year. The Agency will not request registration information from such licensees.

(n) shall report changes to the mailing address for the location of use (including change in name of general licensee) to the Director, Radiation Control Program, Massachusetts Department of Public Health, 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;

(o) may not hold devices that are not in use for longer than two years. If devices with shutters are not being used, the shutter must be locked in the closed position. The testing required by 105 CMR 120.122(D)(3)(b) 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.

(4) The general license in 105 CMR 120.122(D)(1) does not authorize the manufacture or import of devices containing radioactive material.

[*Note:* Persons possessing radioactive material in devices under a general license in 10 CFR 31.5 before January 15, 1975, may continue to possess, use, or transfer that material in accordance with the labeling requirements of 10 CFR. 31.5 in effect on January 14, 1975.]

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(E) General License for Certain Items and Self-Luminous Products Containing Radium-226 ~~Luminous Safety Devices for Aircraft~~

(1) A general license is hereby issued to any person to acquire, receive, possess, use, or transfer, in accordance with the provisions of paragraphs (2), (3), and (4) of 105 CMR120.122(E), radium-226 contained in the following products manufactured prior to November 30, 2007.

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

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

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

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

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

(2) Persons who acquire, receive, possess, use, or transfer byproduct material under the general license issued in paragraph (a) of this section are exempt from the provisions of 105CMR 120.750, 120.200, and 120.142 and 120.009, to the extent that the receipt, possession, use, or transfer of byproduct material is within the terms of the general license; provided, however, that this exemption shall not be deemed to apply to any such person specifically licensed under 105 CMR 120.000.

(3) Any person who acquires, receives, possesses, uses, or transfers byproduct material in accordance with the general license in paragraph (a) of this section:

(a) Shall notify the NRC should there be any indication of possible damage to the product so that it appears it could result in a loss of the radioactive material. A report containing a brief description of the event, and the remedial action taken, must be furnished to the Director of the Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555—0001 within 30 days.

(b) Shall not abandon products containing radium-226. The product, and any radioactive material from the product, may only be disposed of according to 105 CMR120.256 or by transfer to a person authorized by a specific license to receive the radium-226 in the product or as otherwise approved by the NRC.

(c) Shall not export products containing radium-226 except in accordance with 10 CFR 110.

(d) Shall dispose of products containing radium-226 at a disposal facility authorized to dispose of radioactive material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005, by transfer to a person authorized to receive radium-226 by a specific license issued by the Agency, Nuclear Regulatory Commission, or an Agreement State, or as otherwise approved by the NRC.

(e) Shall respond to written requests from the NRC to provide information relating to the general license within 30calendar days of the date of the request, or other time specified in the request. If the general

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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 Director of the Office of Federal and State Materials and Environmental Management Programs, by an appropriate method listed in 10 CFR 30.6(a), a written justification for the request.

(4) The general license in paragraph 105 CMR 120.122(E)(1) does not authorize the manufacture, assembly, disassembly, repair, or import of products containing radium-226, except that timepieces may be disassembled and repaired.

(5 ~~4~~) 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:

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

(b) 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 10 CFR Part 32, § 32.53.

(6 ~~2~~) Persons who own, receive, acquire, possess, or use luminous safety devices pursuant to the general license in 105 CMR 120.122(E)(1) are exempt from the requirements of 105 CMR 120.200 and 120.750 except that they shall comply with the provisions of 105 CMR 120.281 and 120.282.

(7 ~~3~~) This general license does not authorize the manufacture, assembly, or repair of luminous safety devices containing tritium or promethium-147.

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

(9 ~~5~~) This general license is subject to the provisions of 105 CMR 120.005 through 120.016, 120.131, 120.140, 120.150, and 120.770.

(F) Ownership of Radioactive Material. A general license is hereby issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of 105 CMR 120.122, this general license does not authorize the manufacture, production, transfer, receipt, possession or use of radioactive material.

120.124: Filing Application for Specific Licenses

(A) Applications for specific licenses shall be filed in duplicate on form MRCP 120.100-4 as prescribed by the Agency.

(B) The Agency may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the Agency to determine whether the application should be granted or denied or whether a license should be modified or revoked.

(C) Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on his behalf.

(D) An application for a license may include a request for a license authorizing one or more activities. The Agency will not grant the request if the proposed activities are not under the control of the same facility, administrator and radiation safety officer. In addition, when evaluating the request, the Agency will consider complexity, similarity and proximity of the proposed activities.

(E) In the application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the Agency provided such references are clear and specific.

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(F) Applications and documents submitted to the Agency may be made available for public inspection except that the Agency may withhold any document or part thereof from public inspection if disclosure of its content is not required in the public interest and would adversely affect the interest of a person concerned.

(G) An application for a specific license to authorize receipt, possession or use of radioactive material in the form of a sealed source or in a device that contains a sealed source shall either:

(1) identify the sealed source or device that contains a sealed source by manufacturer and model number as registered ~~filed in an evaluation sheet in the U.S. Department of Health and Human Services "Radioactive Material Reference Manual" or in the U.S. Nuclear Regulatory Commission "Registry of Radioactive Sealed Sources and Devices" under 10 CFR 32.210, with an Agreement State, or for a source or a device containing radium-226 or accelerator-produced radioactive material with a State under provisions comparable to~~105 CMR 120.128(N); ~~or~~

(2) contain the information identified in 105 CMR 120.128(N);

(3) for sources or devices containing naturally occurring or accelerator-produced radioactive material manufactured prior to November 30, 2007 that are not registered with NRC under 10 CFR 32.210 or with an Agreement State, and for which the applicant is unable to provide all categories of information specified in 105 CMR 120.128(N)(2) (b) or (c) as applicable, the applicant must provide:

(a) All available information identified in 105 CMR 120.128(N)(2)(b) or (c) concerning the source, and, if applicable, the device; and,

(b) Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test.

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120.128: Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute

Commodities, Products, or Devices which Contain Radioactive Material

(A) Licensing Requirements to Produce for Noncommercial Transfer Positron Emission Tomography (PET) Radioactive Drugs

An application from a medical facility, educational institution, or Federal facility to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use under 105 CMR 120.500, or equivalent Nuclear Regulatory Commission, or Agreement State requirements shall include:

- (1) A request for authorization for the production of PET radionuclides or evidence of an existing license issued under 105 CMR 120.100 or equivalent Nuclear Regulatory Commission, or Agreement State requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.
- (2) Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in 105 CMR 120.128(J)(1)(b).
- (3) Identification of individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in 105 CMR 120.128(J)(2)(b).
- (4) Information identified in 105 CMR 120.128(J)(1)(c) on the PET drugs to be noncommercially transferred to members of its consortium.

(E) Special Requirements for the Manufacture, Assembly, or Repair of Luminous Safety Devices for Use in Aircraft. An application for a specific license to manufacture, assemble, or repair luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under 105 CMR 120.122(E) will be approved if:

- (1) the applicant satisfies the general requirements specified in 105 CMR 120.125; and,
- (2) the applicant satisfies the requirements of 10 CFR Part 32 §§ 32.53, 32.54, 32.55, 32.56, and 32.101, or their equivalent.

(F) Special Requirements for License to Manufacture or Initially Transfer Calibration or Reference Sources Containing Americium-241, ~~Plutonium~~ or Radium-226 for Distribution to Persons Generally Licensed Under 105 CMR 120.122(G). An application for a specific license to manufacture or initially transfer calibration or ~~and~~ reference sources containing americium-241; ~~plutonium~~ or radium-226 to persons generally licensed under 105 CMR 120.122(G). will be approved if:

- (1) the applicant satisfies the general requirement of 105 CMR 120.125; and,
- (2) the applicant satisfies the requirements of 10 CFR Part 32, §§ 32.57, 32.58, 32.59, and 32.102 and 10 CFR Part 70, § 70.39 or their equivalent.

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(3) Each person licensed under 105 CMR 120.128(F) shall affix to each source, or storage container for the source, a label which shall contain sufficient information relative to safe use and storage of the source and shall include the following statement or a substantially similar statement which contains the information called for in the following statement:

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

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

Name of manufacturer or initial transferor

(4) Each person licensed under 105 CMR 120.128(F) shall perform a dry wipe test upon each source containing more than 3.7 kilobecquerels (0.1 microcurie) of americium-241 or radium-226 before transferring the source to a general licensee under 10 CFR 31.8. This test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure. The radioactivity on the paper shall be measured by using radiation detection instrumentation capable of detecting 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226. If this test discloses more than 0.185 kilobecquerel (0.005 microcurie) of radioactive material, the source shall be deemed to be leaking or losing americium-241 or radium-226 and shall not be transferred to a general licensee under 10 CFR 31.8.

(G) Requirements for Other Specific Licenses (Reserved).

(H) Manufacture and Distribution of Radioactive Material for Certain *In Vitro* Clinical or Laboratory Testing Under General License. An application for a specific license to manufacture or distribute radioactive material for use under the general license of 105 CMR 120.122(I) will be approved if:

- (1) the applicant satisfies the general requirements specified in 105 CMR 120.125.
- (2) the radioactive material is to be prepared for distribution in prepackaged units of:
 - (a) carbon-14 in units not exceeding ten microcuries (370 kBq) each.
 - (b) cobalt-57 in units not exceeding ten microcuries (370 kBq) each.
 - (c) hydrogen-3 (tritium) in units not exceeding 50 microcuries (1.85 MBq) each.
 - (d) iodine-125 in units not exceeding ten microcuries (370 kBq) each.
 - (e) Mock Iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each.
 - (f) iodine-131 in units not exceeding ten microcuries (370 kBq) each.

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- (g) iron-59 in units not exceeding 20 microcuries (740 kBq) each.
 - (h) selenium-75 in units not exceeding ten microcuries (370 kBq) each.
- (3) each prepackaged unit bears a durable, clearly visible label:
- (a) identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed ten microcuries (370 kBq) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 50 microcuries (1.85 MBq) of hydrogen-3 (tritium); 20 microcuries (740 kBq) of iron-59; or Mock Iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each; or cobalt-57 in units not exceeding 0.37 megabecquerel (10 microcuries) and,
 - (b) displaying the radiation caution symbol described in 105 CMR 120.237(A) and the words, "CAUTION, RADIOACTIVE MATERIAL", and "Not for Internal or External Use in Humans or Animals".
- (4) one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:
- (a) This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for *in vitro* clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the U.S. Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority.

Name of manufacturer

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

Name of manufacturer

- (5) the label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in 105 CMR 120.251.

(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 105 CMR 120.122(J) will be approved if:

- (1) the applicant satisfies the general requirements of 105 CMR 120.125; and,

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

(J) Manufacture, Preparation, or Transfer for Commercial Distribution of Drugs Containing Radioactive Material for Medical Use Under 105 CMR 120.500.

- (1) An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing radioactive material for use by persons authorized pursuant to 105 CMR 120.500 will be approved if:

- (a) the applicant satisfies the general requirements specified in 105 CMR 120.125;
- (b) the applicant submits evidence that the applicant is at least one of the following:
 - 1. registered or licensed with the U.S. Food and Drug Administration (FDA) as ~~a drug manufacturer~~ the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a); or
 - 2. registered or licensed with a state agency as a drug manufacturer; or,
 - 3. licensed as a pharmacy by a State Board of Pharmacy; or,
 - 4. operating as a nuclear pharmacy pursuant to 247 CMR 13.00.
 - 5. operating as a nuclear pharmacy within a Federal medical institution; or
 - 6. A Positron Emission Tomography (PET) drug production facility registered with a State agency.

- (c) 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 safe handling and storage of the radioactive drugs by medical use licensees; and,

- (d) the applicant satisfies the following labeling requirements:
 - 1. 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”, 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.
 - 2. 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 pursuant to 105 CMR 120.128(J)(1)(b)3. or (b)4.:

- (a) may prepare radioactive drugs for medical use, as defined 105 CMR 120.502, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in 105 CMR 120.128(J)(2)(b) and 120.128(J)(2)(c), or an individual under the supervision of an authorized nuclear pharmacist as specified in 105 CMR 120.519.
- (b) may allow a pharmacist to work as an authorized nuclear pharmacist if:

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1. if this individual qualifies as an authorized nuclear pharmacist as defined in 105 CMR 120.502; or,
2. this individual meets the requirements specified in 105 CMR 120.526(B) and 120.529 and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or,
3. this individual is designated as an authorized nuclear pharmacist in accordance with 105 CMR 120.128(J)(2)(d).

(c) the actions authorized in 105 CMR 120.128(J)(2)(a) and (2)(b) are permitted in spite of more restrictive language in license conditions.

(d) may designate a pharmacist, as defined in 105 CMR 120.005, 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 NRC under 10 CFR part 32.~~ 1. The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material, and

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

(e) shall provide to the Agency:

1. A ~~a~~ copy of each individual's certification by a specialty board whose certification process has been recognized by the Commission or an Agreement State as specified in 105 CMR 120.526(A) with the written attestation signed by a preceptor as required by 105 CMR 120.526(B) ; or ~~the Board of Pharmaceutical Specialties, the NRC or Agreement State or Licensing 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 105 CMR 120.128(J)(2)(b)1. and (2)(b)3., the individual to work as an authorized nuclear pharmacist.~~
2. Agreement State or Nuclear regulatory Commission license, or
3. Nuclear regulatory Commission master materials licensee permit, or
4. The permit issued by a licensee or Nuclear regulatory Commission master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist, or
5. Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC; and
6. A copy of the State pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, under paragraphs (2)(b)1. and (2)(b)3. of 105 CMR 120.128(J), 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:

- (a) perform tests before initial use, periodically, and following repair, on each instrument for accuracy,

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linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

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

(4) Nothing in 105 CMR 120.128(J) 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.⁵ 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 105 CMR 120.100 for the uses listed in 105 CMR 120.547 will be approved if:

- (1) the applicant satisfies the general requirements specified in 105 CMR 120.125;
- (2) the applicant submits evidence that:

⁵ 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 105 CMR 120.547 ~~33~~ may submit the pertinent information specified in 105 CMR 120.128(K).

(L) Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to 105 CMR 120.500 for use as a calibration, transmission, or reference source or for the uses listed in 105 CMR 120.559 and 120.568 and 120.570 and 120.589 will be approved if:

- (1) the applicant satisfies the general requirements in 105 CMR 120.125;
- (2) the applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:
 - (a) the radioactive material contained, its chemical and physical form, and amount;
 - (b) details of design and construction of the source or device;
 - (c) 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;
 - (d) for devices containing radioactive material, the radiation profile of a prototype device;
 - (e) details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests;
 - (f) procedures and standards for calibrating sources and devices;
 - (g) legend and methods for labeling sources and devices as to their radioactive content; and
 - (h) 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

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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 Agency has approved the distribution of the (name of source or device) to persons licensed to use radioactive material identified in 105 CMR 120.523, 120.559, 120.568, and 120.570 or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State;

(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 six 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:

- (a) primary containment or source capsule;
- (b) protection of primary containment;
- (c) method of sealing containment;
- (d) containment construction materials;
- (e) form of contained radioactive material;
- (f) maximum temperature withstood during prototype tests;
- (g) maximum pressure withstood during prototype tests;
- (h) maximum quantity of contained radioactive material;
- (i) radiotoxicity of contained radioactive material; and
- (j) operating experience with identical sources or devices or similarly designed and constructed sources or devices.

120.131: Specific Terms and Conditions of Licenses

(A) Each license issued pursuant to 105 CMR 120.000 shall be subject to all the provisions of M.G.L. c. 111, §§ 3, 5M, 5N, 5O and 5P, and to all rules, regulations, orders of the Agency and license conditions as provided for in 105 CMR 120.130(B).

(B) No license issued or granted under 105 CMR 120.000 and no right to possess or utilize radioactive material granted by any license issued pursuant to this Part shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the Agency shall, after securing full information find that the transfer is in accordance with the provisions of M.G.L. c. 111, §§ 3, 5M, 5N, 5O and 5P, and to all valid rules, regulations, and orders of the Agency, and shall give its consent in writing.

(C) Each person licensed by the Agency pursuant to 105 CMR 120.000 shall confine use and possession of the material licensed to the locations and purposes authorized in the license. Preparation for shipment and transport of byproduct material shall be in accordance with the provisions of 10 CFR part 71 and 105 CMR 120.770.

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

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

- (1) the licensee;
- (2) an entity (as that term is defined in 11 U.S.C. 101(14)) controlling the licensee or listing the license or licensee as property of the estate; or
- (3) an affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.

(F) The notification specified in 105 CMR 120.131(E) shall indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of the filing of the petition.

(G) Each portable gauge licensee shall use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

(H) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with 105 CMR 120.548. The licensee shall record the results of each test and retain each record for 3 years after the record is made.

(I)(1) Authorization under 105 CMR 120.128(B) to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

(2) Each licensee authorized under 105 CMR 120.128(B) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

(i) Satisfy the labeling requirements in 105 CMR 120.128(J)(1)(d) for each PET radioactive drug transport container and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.

(ii) Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in 105 CMR 120.128(J)(3).

(3) A licensee that is a pharmacy authorized under 105 CMR 120.128(B) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:

- (i) an authorized nuclear pharmacist that meets the requirements in 105 CMR 120.128(J)(2)(b), or
- (ii) an individual under the supervision of an authorized nuclear pharmacist as specified in 105 CMR 120.519.

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(4) A pharmacy, authorized under 105 CMR 120.128(B) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of 105 CMR 120.128(J)(2)(e).

120.190: 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 105 CMR 120.000, 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 to conduct the activities authorized in such licensing document within this State for a period not in excess of 180 days in any calendar year provided that:

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

(b) the out-of-state licensee notifies the Agency in writing at least three 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 three 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 105 CMR 120.190(A)(1);

(c) 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;

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

(e) the out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in 105 CMR 120.190(A)(1) except by transfer to a person:

1. specifically licensed by the Agency or by the U.S. Nuclear Regulatory Commission to receive such material; or,

2. exempt from the requirements for a license for such material under 105 CMR 120.104(A).

(2) Notwithstanding the provisions of 105 CMR 120.190(A)(1), any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement State authorizing the holder to manufacture, transfer, install, or service a device described in 105 CMR 120.122(D)(1) within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate, or service such a device in this State provided that:

(a) Filing a report with the Agency (Reserved);

(b) 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 an Agreement State;

(c) such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited"; and,

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(d) the holder of the specific license shall furnish to each general licensee to whom he transfers such device or on whose premises he installs such device a copy of the general license contained in 105 CMR 120.122(D) or in equivalent regulations of the Agency having jurisdiction over the manufacture and distribution of the device.

(3) The Agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by the U.S. Nuclear Regulatory Commission or an Agreement State, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

(C) Exceptions to the General License.

(1) The general license granted in 105 CMR 120.190(A) to conduct activities in the State does not include activities in areas of exclusive Federal jurisdiction within the State or offshore waters.

(2) Authorization for use of radioactive materials in areas of exclusive Federal jurisdiction within the State or offshore waters may be obtained from the U.S. Nuclear Regulatory Commission as provided for in 10 CFR 150.20.

(3) Before radioactive material can be used at a temporary job site in another State, authorization shall be obtained for the State if it is an Agreement State, or from the NRC for any non-Agreement State, either by filing for reciprocity or applying for a specific license.

120.200: STANDARDS FOR PROTECTION AGAINST RADIATION

120.211: Occupational Dose Limits for Adults

(A) The licensee or registrant shall control the occupational dose to individual adults, except for planned special exposures pursuant to 105 CMR 120.216, to the following dose limits:

(1) An annual limit, which is the more limiting of:

(a) the total effective dose equivalent being equal to .05 sievert (5 rems); or

(b) the sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 0.5 sievert (50 rems).

(2) The annual limits to the lens of the eye, to the skin, and to the extremities which are:

(a) a lens dose equivalent of 0.15 sievert (15 rems); and

(b) a shallow dose equivalent of 0.5 sievert (50 rems) to the skin or to any extremity.

(B) Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, shall be subtracted from the limits for planned special exposures that the individual may receive during the current year and during the individual's lifetime. See 105 CMR 120.216(E)(1) and (2).

(c) When the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent must be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the NRC. The assigned deep-dose equivalent must be for the part of the body receiving the highest exposure. The assigned shallow-dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure. The deep-dose equivalent, lens-dose

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equivalent, and shallow-dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

~~(C) The assigned deep dose equivalent and shallow dose equivalent shall be for the portion of the body receiving the highest exposure. The assigned shallow dose equivalent must be the dose averaged over the contiguous ten square centimeters of skin receiving the highest exposure:~~

~~(1) The deep dose equivalent, lens dose equivalent, and shallow dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable;~~

~~(2) When a protective apron is worn while working medical fluoroscopic equipment and monitoring is conducted as specified in 105 CMR 120.226(A)(5), the effective dose equivalent for external radiation shall be determined as follows:~~

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

~~(b) When only one individual monitoring device is used and it is located at the neck (collar) outside the protective apron, and the reported dose exceeds 25% of the limit specified in 105 CMR 120.211(A), the reported deep dose equivalent value multiplied by 0.3 shall be the effective dose equivalent for external radiation; or~~

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

(D) Derived air concentration (DAC) and annual limit on intake (ALI) values are specified in 105 CMR 120.296: *Appendix B*, Table I and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits. See 105 CMR 120.266.

(E) In addition to the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to ten milligrams in a week in consideration of chemical toxicity. See footnote 3 of 105 CMR 120.296: *Appendix B*.

(F) The licensee or registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person during the current year. See 105 CMR 120.214.

120.256: Transfer for Disposal and Manifests

(A) The requirements of 105 CMR 120.256 and Appendix G to 10 CFR 20, herein incorporated into 105 CMR 120.256 by reference are designed to:

- (1) Control transfers of low-level waste by any waste generator, waste collector, or waste processor licensee, as defined in Appendix G to 10 CFR 20, who ships low-level waste either directly, or indirectly through a waste collector or waste processor, to a licensed low-level waste land disposal facility as defined in 105 CMR 120.803;
- (2) Establish a manifest tracking system; and
- (3) Supplement existing requirements concerning transfers and recordkeeping for those wastes.

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(B) Any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility must document the information required on the U.S. Nuclear Regulatory Commission's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded information to the intended consignee in accordance with Appendix G to 10 CFR 20.

(C) Each shipment manifest shall include a certification by the waste generator as specified in Appendix G to 10 CFR 20.

(D) Each person involved in the transfer of waste for disposal or in the disposal of waste, including the waste generator, waste collector, and waste processor, shall comply with the requirements specified in 105 CMR 120.256 and Appendix to 10 CFR 20 as appropriate.

(E) Reports and notifications required to be made to the nearest NRC regional administrator by Appendix G to 10 CFR 20 shall, instead, be made to the Agency.

120.258: Disposal of Certain Byproduct Material

(A) Licensed material as defined in paragraphs (3) and (4) of the definition of *Byproduct material* set forth in 105 CMR 120.005 may be disposed of in accordance with part 61 of this chapter, even though it is not defined as low-level radioactive waste. Therefore, any licensed byproduct material being disposed of at a facility, or transferred for ultimate disposal at a facility licensed under 105 CMR 120.800 or equivalent Nuclear Regulatory Commission or Agreement State requirements, must meet the requirements of 105 CMR 120.256.

(B) A licensee may dispose of byproduct material, as defined in paragraphs (3) and (4) of the definition of *Byproduct material* set forth in 105 CMR 120.005, at a disposal facility authorized to dispose of such material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005.

120.285: Reports to Individuals of Exceeding Dose Limits

When a licensee or registrant is required, pursuant to 105 CMR 120.283, or 120.284 ~~or 120.287~~ to report to the Agency any exposure of an identified occupationally exposed individual, or an identified member of the public, to radiation or radioactive material, the licensee shall also provide a copy of the report submitted to the Agency to the individual. This report must be transmitted at a time no later than the transmittal to the Agency.

120.500: USE OF RADIONUCLIDES IN THE HEALING ARTS

120.524: Training for Radiation Safety Officer

Except as provided in 105 CMR 120.528, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer (RSO) as provided in 105 CMR 120.515 to be an individual who:

(A) Is certified by a speciality board whose certification process includes all of the requirements in 105 CMR 120.524(B) and (C)

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and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State. (The names of board certifications which have been recognized by the Commission 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)
 - (a) 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;
 - (b) Have five or more years of professional experience in health physics (graduate training may be substituted for no more than two years of the required experience) including at least three years in applied health physics; and
 - (c) 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)
 - (a) 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;
 - (b) Have two years of full-time practical training and/or supervised experience in medical physics.
 1. Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an Agreement State; or
 2. In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users in 105 CMR 120.528, 120.551 or 120.556;
 3. Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

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120.524: continued

(B) (1) Has completed a structured educational program consisting of both:

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

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Radiation biology; and,
5. Radiation dosimetry; and,

(b) One year of full time experience under the supervision of the individual identified as the Radiation Safety Officer on an Agency, Agreement State, Licensing State, or U.S. Nuclear Regulatory Commission license that authorizes similar type(s) of use(s) of radioactive material involving the following:

1. Shipping, receiving and performing related radiation surveys;
2. Using and performing checks for proper operation of dose calibrators, survey meters, and instruments used to measure radionuclides;
3. Securing and controlling radioactive material;
4. Using administrative controls to avoid mistakes in the administration of radioactive material;
5. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;
6. Using emergency procedures to control radioactive material;
7. Disposing of radioactive material; or ~~and~~

(2) Training and Experience for Radiation Safety Officer [Reserved]

(C)(1) Is a medical physicist who has been certified by a specialty board whose certification

process has been recognized by the Commission or an Agreement State under 105 CMR 120.525(A) and has experience in radiation safety for similar types of use of byproduct material for which the licensee is seeking the approval of the individual as Radiation Safety Officer and who meets the requirements in 105 CMR 120.524(D) and (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 byproduct 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 105 CMR 120.524(E) and in (a)(1)(i) and (a)(1)(ii) or (a)(2)(i) and (a)(2)(ii) or (b)(1) or (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,

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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.

120.525: Training for Authorized Medical Physicist

The licensee shall require the authorized medical physicist to be an individual who:

(A) Is certified by a speciality board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in 105 CMR 120.525(B)(2) and (C). (The names of board certifications which have been recognized by the Commission 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 two years of full-time practical training and/or supervised experience in medical physics;
 - (a) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an Agreement State; or
 - (b) 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 105 CMR 120.528, 120.566 or 120.587; ~~or, before October 24, 2005, authorized users who meet the requirements in 10 CFR 35.940 or 35.960;~~ 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 one year of full-time training in medical physics and an additional year of fulltime 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 one million electron volts) and brachytherapy services and must include:

- (a) Performing sealed source leak tests and inventories;
 - (b) Performing decay corrections;
 - (c) Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and
 - (d) Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and
- (2) Has obtained written attestation that the individual has satisfactorily completed the requirements in 105 CMR 120.525(C) and 105 CMR 120.525(A)(1) and (2), or 120.525(B)(1) and (C), and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which

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the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in 105 CMR 120.525, 120.528, ~~or, before October 24, 2005, 10 CFR 35.9604~~, or equivalent Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

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

120.526: Training for an Authorized Nuclear Pharmacist

Except as provided in 105 CMR 120.528, the licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

(A) Is certified by a specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State and who meets the requirements in 105 CMR 120.526(B)(2). (The names of board certifications which have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

- (1) Have graduated from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;
- (2) Hold a current, active license to practice pharmacy;
- (3) Provide evidence of having acquired at least 4000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2000 hours of the required training and experience; and
- (4) Pass an examination in nuclear pharmacy administered by diplomates of the specialty board, that assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or

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

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

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Radiation biology; and
5. Chemistry of radioactive material for medical use; and

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

1. Shipping, receiving, and performing related radiation surveys;
2. Using and performing checks for proper operation of dose calibrators, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

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3. Calculating, assaying, and safely preparing dosages for patients or human research subjects;
 4. Using administrative controls to avoid misadministrations in the administration of radioactive material; and
 5. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and
- (2) Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in 105 CMR 120.526(A)(1) through (3) or 120.526(B)(1) and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

120.528: Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Medical Physicist, Authorized User, Nuclear Pharmacist, and Authorized Nuclear Pharmacist

- (A)(1) An individual identified as a Radiation Safety Officer, a teletherapy or medical physicist, or a nuclear pharmacist on a Nuclear Regulatory Commission, an Agreement State license or on a permit issued by a Nuclear Regulatory Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope before October 24, 2002 need not comply with the training requirements of 105 CMR 120.524 through 120.526, respectively.
- (2) An individual identified as a Radiation Safety Officer, an authorized medical physicist, or an authorized nuclear pharmacist on a Nuclear Regulatory Commission, an Agreement State license or a permit issued by a Nuclear Regulatory Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope between October 24, 2002 and April 29, 2005 need not comply with the training requirements of 105 CMR 120.524 through 120.526, respectively.
- (3) A Radiation Safety Officer, a medical physicist, or a nuclear pharmacist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses or in the practice of nuclear pharmacy at a Federal Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of 105 CMR 120.524 through 120.526, respectively, when performing the same uses. A nuclear pharmacist, who prepared only radioactive drugs containing accelerator-produced radioactive materials, or a medical physicist, who used only accelerator-produced radioactive materials, at the locations and time period identified in 105 CMR 120.528, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates, for purposes of 105 CMR 120.500.
- (B)(1) Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a Nuclear Regulatory Commission or Agreement State license or on a permit issued by a Nuclear Regulatory Commission or Agreement State broad scope licensee, or a permit issued by a Nuclear Regulatory Commission master material license broad scope permittee before October 24, 2002 who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of 105 CMR 120.546, 120.551, 120.556 through 120.558, 120.566, 120.567, 120.569 and 120.587.
- (2) Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a Nuclear Regulatory Commission or Agreement State license or on a permit issued by a Nuclear Regulatory Commission or Agreement State broad scope licensee, or a permit issued by a Nuclear Regulatory Commission master material license broad scope permittee who perform only those medical uses for which they were authorized between October 24, 2002, and April 29, 2005, need not comply with the training requirements of 105 CMR 120.546, 120.551, 120.556 through

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120.558, 120.566, 120.567, 120.569 and 120.587.

(3) Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses performed at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of 105 CMR 120.546, 120.551, 120.556 through 120.558, 120.566, 120.567, 120.569 and 120.587 when performing the same medical uses. A physician, dentist, or podiatrist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses at the locations and time period identified in 105 CMR 120.528(B)(3), qualifies as an authorized user for those materials and uses performed before these dates, for purposes of 105 CMR 120.500.

(C) Individuals who need not comply with training requirements as described in 105 CMR 120.528 may serve as preceptors for, and supervisors of, applicants seeking authorization on Agency licenses for the same uses for which these individuals are authorized.

120.529: Recentness of Training

The training and experience specified in 105 CMR 120.500 must have been obtained within the seven 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

120.531: Quality Control of Diagnostic Equipment

Each licensee shall establish written quality control procedures for all diagnostic equipment used for radionuclide studies. As a minimum, quality control procedures and frequencies shall be those recommended by equipment manufacturers or procedures which have been approved by the Agency. The licensee shall conduct quality control procedures in accordance with written procedures.

120.532: Possession, Use, and Calibration of Instruments Used to Measure the Activity of Unsealed

Radioactive Material

(A) For direct measurements performed in accordance with 105 CMR 120.534, a licensee shall possess and use instrumentation to measure the activity of unsealed radioactive materials prior to administration to each patient or human research subject.

(B) A licensee shall calibrate the instrumentation required in 105 CMR 120.532(A) in accordance with nationally recognized standards or the manufacturer's instructions.

(C) A licensee shall retain a record of each instrument calibration required by 105 CMR 120.532 in accordance with 105 CMR 120.590(F).

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120.533: Calibration of Survey Instruments

- (A) A licensee shall ensure that the survey instruments used to show compliance with 105 CMR 120.200 and 120.500 have been calibrated before first use, annually, and following repair.
- (B) To satisfy the requirements of 105 CMR 120.533(A), the licensee shall:
- (1) Calibrate all required scale readings up to ten millisieverts (1000 mrem) per hour with a radiation source;
 - (2) Have each radiation survey instrument calibrated:
 - (a) At energies appropriate for use and at intervals not to exceed 12 months or after instrument servicing, except for battery changes;
 - (b) For linear scale instruments, at two points located approximately $\frac{1}{10}$ and $\frac{9}{10}$ of full-scale on each scale; for logarithmic scale instruments, at mid-range of each decade, and at two points of at least one decade; and for digital instruments, at three points between 0.02 and ten millisieverts (two and 1000 mrem) per hour; and
 - (c) For dose rate instruments, so that an accuracy within plus or minus 20% of the true radiation dose rate can be demonstrated at each point checked.
 - (3) Conspicuously note on the instrument the date of calibration.
- (C) The licensee shall not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is greater than 20%.
- (E) The licensee shall retain a record of each survey instrument calibration in accordance with 105 CMR 120.590(G).

120.534: Determination of Dosages of Unsealed Radioactive Material for Medical Use

- (A) A licensee shall determine and record the activity of each dosage prior to medical use.
- (B) For a unit dosage, this determination must be made either by direct measurement or by a decay correction, based on the measurement made by a manufacturer or preparer licensed pursuant to 105 CMR 120.128(J) or equivalent provisions of the Nuclear Regulatory Commission, Agreement State or Licensing State.
- (C) For other than unit dosages, this determination must be made by direct measurement of radioactivity or by a combination of measurements of radioactivity and mathematical calculations or combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer or preparer licensed pursuant to 105 CMR 120.128(J) or equivalent provisions of the Nuclear Regulatory Commission, Agreement State or Licensing State.
- (D) Unless otherwise directed by the authorized user, a licensee shall not use a dosage if the dosage differs from the prescribed dosage by more than 20%.
- (E) A licensee shall retain a record of the dosage determination required by 105 CMR 120.534 in accordance with 105 CMR 120.590(H).

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120.535: Authorization for Calibration, Transmission and Reference Sources

Any person authorized by 105 CMR 120.506 ~~3~~ for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration and reference use:

- (A) Sealed sources manufactured and distributed by persons specifically licensed pursuant to 105 CMR 120.128(L) or equivalent provisions of the U.S. Nuclear Regulatory Commission, Agreement State or Licensing State and that do not exceed 1.11 gigabecquerels (30 mCi) each;
- (B) Any radioactive material with a half-life of 120 days or less in individual amounts not to exceed 555 megabecquerels (15 mCi);
- (C) Any radioactive material with a half life greater than 120 days in individual amounts not to exceed 7.4 megabecquerels (200 μ Ci) or 1000 times the quantity in 105 CMR 120.196: *Appendix B*, Table 1; and
- (D) Technetium-99m in amounts as needed.

120.536: Requirements for Possession of Sealed Sources and Brachytherapy Sources

- (A) A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer or equivalent instructions approved by the Agency.
- (B) A licensee in possession of a sealed source shall:
 - (1) Test the source for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within six months before transfer to the licensee; and,
 - (2) Test the source for leakage at intervals not to exceed six months or at intervals approved by the Agency, another Agreement State, a Licensing State or the U.S. Nuclear Regulatory Commission in the Sealed Source and Device Registry.
- (C) To satisfy the leak test requirements of 105 CMR 120.536(B), the licensee shall measure the sample so that the leak test can detect the presence of 185 becquerels (0.005 μ Ci) of radioactive material in the sample. If the leak test reveals the presence of 185 becquerels (0.005 μ Ci) or more of removable contamination, the licensee shall:
 - (1) Immediately withdraw the sealed source from use and store, repair or dispose of it in accordance with the requirements of 105 CMR 120.100 and 120.200; and,
 - (2) File a report with the Agency within five days of receiving the leak test results with the Agency describing the equipment involved, the test results, and the action taken.
- (D) A licensee shall retain leak test records in accordance with 105 CMR 120.590(I)(1).
- (E) A licensee in possession of a sealed source or brachytherapy source, except for gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such sources. The licensee shall retain each inventory record in accordance with

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105 CMR 120.590(I)(2).

120.537: Labeling of Vials and Syringes

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

120.539: Surveys for Ambient Radiation Dose Rate and Contamination

(A) In addition to the surveys required by 105 CMR 120.200, a licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where unsealed radioactive material requiring a written directive was prepared for use or administered.

(B) A licensee does not need to perform the surveys required in 105 CMR 120.539(A) in area(s) where patients or human research subjects are confined when they can not be released pursuant to 105 CMR 120.540.

(C) A licensee shall retain a record of each survey in accordance with 105 CMR 120.590(J).

120.540: 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 five millisievert (0.5 rem). [NOTE: NRC Regulatory Guide, NUREG-1566, 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 five millisieverts (0.5 rem).]

(B) For patients administered radioactive material for which a written directive is required, a licensee shall provide the released individual, or the individual's parent or guardian, with oral and written instructions 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 one millisievert (0.1 rem). If the total effective dose equivalent to a breast-feeding infant or child could exceed one millisievert (0.1 rem) assuming there were no interruption of breast-feeding, the instructions shall also include:

- (1) Guidance on the interruption or discontinuation of breast-feeding; and
- (2) Information on the potential consequences, if any, of failure to follow the guidance.

(C) The licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with 105 CMR 120.590(K)(1).

(D) The licensee shall maintain a record of instructions provided to breast-feeding women in accordance with 105 CMR 120.590(K)(2).

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(E) The licensee shall immediately notify the Agency in accordance with 105 CMR 120.594(D) if a patient departs prior to an authorized release.

120.541: Provision of Mobile Medical Service

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

(A) A licensee providing mobile medical service shall:

- (1) Obtain a letter signed by the management of each location where services are rendered that authorizes use of radioactive material at the client's address of use and clearly delineates the authority and responsibility of the licensee and the client. If the client is licensed, the letter shall document procedures for notification, receipt, storage and documentation of transfer of radioactive material delivered to the client's location for use by the mobile medical service;
- (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 105 CMR 120.541(A)(2) 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 105 CMR 120.200.

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

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

(D) A mobile medical service licensee shall maintain all records required by 105 CMR 120.200 and 120.500 at a location within the Agency's jurisdiction that is:

- (1) A single address:
 - (a) identified as the records retention location; and,
 - (b) staffed at all reasonable hours by individual(s) authorized to provide the Agency with access for purposes of inspection; or
- (2) When no address is identified on the license for records retention, the mobile unit:
 - (a) identified in the license; and,
 - (b) whose current client's address schedule and location schedule is reported to the Agency.

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(E) A licensee providing mobile medical services shall:

- (1) Retain the letter required in 105 CMR 120.541(A)(1) in accordance with 105 CMR 120.590(L); and
- (2) Retain a record of each survey required by 105 CMR 120.541(A)(4) in accordance with 105 CMR 120.590(L).

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

120.542: Storage of Volatiles and Gases

(A) A licensee shall store volatile radiopharmaceuticals and radioactive gases in a radiation shield and container.

(B) A licensee shall store and use a multidose container in a properly functioning fume hood.

(C) A licensee who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed in 105 CMR 120.200.

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

(E) A licensee shall check the operation of collection systems monthly. Records of these checks shall be maintained for three years.

120.543: Decay-in-storage

(A) A licensee may hold radioactive material with a physical half-life of less than 120 days (or longer, if the Agency has approved it) for decay-in-storage before disposal without regard to its radioactivity if the licensee:

- (1) Monitors radioactive material at the surface and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey instrument set on its most sensitive scale and with no interposed shielding;
- (2) Removes or obliterates all radiation labels except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee; and
- (3) Separates and monitors each generator column individually with all radiation shielding removed to ensure that its contents have decayed to background radiation level before disposal.

(B) For radioactive material disposed in accordance with 105 CMR 120.543(A), the licensee shall retain a record of each disposal in accordance with 105 CMR 120.590(M).

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SPECIFIC REQUIREMENTS FOR THE USE OF RADIOACTIVE MATERIAL FOR
UPTAKE, DILUTION, OR EXCRETION STUDIES

120.544: Use of Unsealed Radioactive Material for Uptake, Dilution, or Excretion Studies for which a

Written Directive is not Required

A licensee may use any unsealed radioactive material, in quantities that do not require a written directive, for a diagnostic use involving measurements of uptake, dilution, or excretion:

- (A)(1) Obtained from a manufacturer or preparer licensed pursuant to 105 CMR 120.128(J) or equivalent regulations of another Agreement State, a Licensing State, or the Nuclear Regulatory Commission; or
- (2) A PET radioactive drug producer licensed under 105 CMR 120.100 or equivalent regulations of the Nuclear Regulatory Commission or equivalent Agreement State requirements; or
- (B) Excluding production PET radionuclides, prepared by:
 - (1) an authorized nuclear pharmacist;
 - (2) A physician who is an authorized user and who meets the requirements specified in 105 CMR 120.551, or 105 CMR 120.556 and 105 CMR 120.551(C)(1)(b)7.; or
 - (3) An individual under the supervision, as specified in 105 CMR 120.519, of the authorized nuclear pharmacist in 105 CMR 120.544(B)(1); or
- (C) Obtained from and prepared by an Agency, Nuclear Regulatory Commission, Agreement State or Licensing State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or
- (D) Prepared by the licensee in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA for use in research.

120.545: Possession of Survey Instrument

A licensee authorized to use radioactive material for uptake, dilution, and excretion studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range one microsievert (0.1 mrem) per hour to 1000 microsieverts (100 mrems) per hour. The instrument shall be operable and calibrated in accordance with 105 CMR 120.533.

120.546: Training for Uptake, Dilution, and Excretion Studies

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user of an unsealed radioactive material for the uses authorized under 105 CMR 120.544 to be a physician who:

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(A) Is certified by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State and who meets the requirements in 105 CMR 120.546(C)(2). (The names of board certifications which have been recognized by the Nuclear Regulatory Commission 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 byproduct material for uptake, dilution, and excretion studies as described in 105 CMR 120.546(C)(1)(a) through (b)6.; 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 105 CMR 120.551 or 120.556, or equivalent Agreement State or Nuclear Regulatory Commission requirements; or

(C)(1) Has completed 60 hours of training and experience, including a minimum of eight

hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience must include:

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

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Chemistry of radioactive material for medical use; and
5. Radiation biology; and

(b) Work experience, under the supervision of an authorized user who meets the requirements 105 CMR 120.528, 120 546,120.551 or 120.556 or equivalent Agreement State, or Nuclear Regulatory Commission requirements, involving:

120.546: continued

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 2. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
 3. Calculating, measuring, and safely preparing patient or human research subject dosages;
 4. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
 5. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
 6. Administering dosages to patients or human research subjects; and
- (2) Has obtained written attestation, signed by a preceptor authorized user, who meets the requirements in 105 CMR 120.528, 120.546, 120.551 or 120.556 or equivalent Agreement State, or Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in 105 CMR 120.546(A)(1) or (C)(1) and has achieved a level of competency sufficient to independently function as an authorized user for the medical uses authorized under 105 CMR 120.544.

SPECIFIC REQUIREMENTS FOR THE USE OF UNSEALED BYPRODUCT MATERIAL

WRITTEN DIRECTIVE NOT REQUIRED

120.547: Use of Unsealed Byproduct Material for Imaging and Localization Studies for which a Written

Directive is not Required

A licensee may use, for imaging and localization studies, any radioactive material prepared for medical use, in quantities that do not require a written directive as described in 105 CMR 120.521 that is:

(A) Obtained from:

- (1) A manufacturer or preparer licensed pursuant to 105 CMR 120.128(J) or equivalent regulations of another Agreement State, a Licensing State, or the Nuclear Regulatory Commission;
- (2) A PET radioactive drug producer licensed under 105 CMR 120.100 or equivalent regulations of the Nuclear Regulatory Commission or equivalent Agreement State requirements; or

(B) Excluding production PET radionuclides prepared by:

- (1) An authorized nuclear pharmacist;
- (2) A physician who is an authorized user and who meets the requirements specified in 105 CMR 120.551 or 120.556 and 120.551(C)(1)(b)7.; or
- (3) An individual under the supervision, as specified in 105 CMR 120.519, of the authorized nuclear pharmacist in 105 CMR 120.547(B)(1) or the physician who is an authorized user in 105 CMR 120.547(B)(2); or

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

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

(E) Provided the conditions of 105 CMR 120.542 are met, a licensee may use radioactive aerosols or gases if specific application is made to and approved by the Agency.

120.548: Radionuclide Contaminants

(A) A licensee shall not administer to humans a radiopharmaceutical containing:

- (1) more than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 μ Ci of Mo-99 per mCi of Tc-99m);
- (2) more than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 μ Ci of Sr-82 per mCi of Rb-82 chloride);
- (3) more than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 μ Ci of Sr-85 per mCi of Rb-82).

(B) To demonstrate compliance with 105 CMR 120.548(A), the licensee preparing radioactive drugs from radionuclide generators shall:

- (1) Measure the concentration of radionuclide contaminant in the first eluate after receipt of a molybdenum-99/technetium-99m generator;
- (2) Measure the concentration of radionuclide contaminant in each eluate or extract, as appropriate for other generator systems.

(C) A licensee who must measure radionuclide contaminant concentration shall retain a record of each measurement in accordance with 105 CMR 120.590(N).

(D) A licensee shall report immediately to the Agency each occurrence of radionuclide contaminant concentration exceeding the limits specified in 105 CMR 120.548(A).

120.551: Training for Imaging and Localization Studies

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under 105 CMR 120.547 to be a physician who:

(A) Is certified by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory

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Commission or an Agreement State and who meets the requirements in 105 CMR 120.551(C)(2). (The names of board certifications which have been recognized by the Commission 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 byproduct material for imaging and localization studies as described in 105 CMR 120.551(C)(1)(a) through (b)7.; 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 105 CMR 120.556 and meets the requirements of 105 CMR 120.551(C)(1)(b)7., or equivalent Agreement State or Nuclear Regulatory Commission requirements; or

(C)(1) Has completed 700 hours of training and experience, including a minimum of 80

hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies; the training and experience must include, at a minimum:

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

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Chemistry of radioactive material for medical use;
5. Radiation biology; and

(b) Work experience, under the supervision of an authorized user who meets the requirements 105 CMR 120.528 ~~54~~ or 120.551(C)(1)(b)7. and 120.556 or equivalent Agreement State, or Nuclear Regulatory Commission requirements, involving:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
2. Performing quality control procedures on instruments ~~Calibrating instruments~~ used to determine the activity of dosages and performing checks for proper operation of survey meters;
3. Calculating, measuring, and safely preparing patient or human research subject dosages;
4. Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;
5. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
6. Administering dosages of radioactive drugs to patients or human research subjects;
7. 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 105 CMR 120.528, 120.551 or 120.556 and 120.551(C)(1)(b)7., or equivalent Agreement State, or Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in 105 CMR 120.551(A)(1) or (C)(1) and

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has achieved a level of competency sufficient to independently function as an authorized user for the medical uses authorized under 105 CMR 120.544 and 120.547.

SPECIFIC REQUIREMENTS FOR THE USE OF UNSEALED BYPRODUCT MATERIAL

WRITTEN DIRECTIVE REQUIRED

120.552: Use of Unsealed Byproduct Material for which a Written Directive is Required

A licensee may use any unsealed radioactive material for diagnostic or therapeutic medical use for which a written directive is required that has been:

- (A) Obtained from a manufacturer or preparer licensed in accordance with 105 CMR 120128(J); or
- (B) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in 105 CMR 120.551 or 120.556, or an individual under the supervision of either as specified in 105 CMR 120 519; or
- (C) Obtained from and prepared by an Agency, Nuclear Regulatory Commission, Agreement State, or Licensing State licensee in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by the FDA for use in research; or
- (D) Prepared by the licensee in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA for use in research.

120.553: Safety Instruction

In addition to the requirements of 105 CMR 120.753:

- (A) A licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who have received therapy with with a radioactive drug, and cannot be released in accordance with 105 CMR 120.540. To satisfy the requirement in 105 CMR 120.553(A), the instruction must be commensurate with the duties of the personnel and include:
 - (1) Patient or human research subject control;
 - (2) Visitor control to include the following:
 - (a) Routine visitation to hospitalized individuals in accordance with 105 CMR 120.221(A)(1) and (C);
 - (b) Contamination control;
 - (c) Waste control; and
 - (d) Notification of the RSO, or his or her designee, and the authorized user if the patient or the human research subject has a medical emergency or dies.

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(B) A licensee shall retain a record of individuals receiving instruction in accordance with 105 CMR 120.590(P).

120.554: Safety Precautions

(A) For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with 105 CMR 120.540, a licensee shall:

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

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

(b) A room, with a private sanitary facility, with another individual who also has received similar radiopharmaceutical therapy and who cannot be released in accordance with 105 CMR 120.540; and

(2) Visibly post the patient's or human research subject's door with a "Radioactive Materials" sign and note on the door or on the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room; and

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

(B) The Radiation Safety Officer, or his or her designee, and the authorized user shall be notified immediately if the hospitalized patient or human research subject dies or has a medical emergency.

120.556: Training for Use of Unsealed Byproduct Material for which a Written Directive is Required

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user of radioactive material for the uses authorized under 105 CMR 120.552 to be a physician who:

(A) Is certified by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State and who meets the requirements in 105 CMR 120.556(B)(1)(b)7. and (B)(2). (Specialty boards whose certification processes have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's Web page.) To be recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in 105 CMR 120.556(B)(1)(a) through (b)5.. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-graduate Training of the American Osteopathic Association; and

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

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(B)(1) Has completed 700 hours of training and experience, including a minimum of 200

hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive. The training and experience must include:

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

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Chemistry of byproduct material for medical use;
5. Radiation biology; and

(b) Work experience, under the supervision of an authorized user who meets the requirements in 105 CMR 120.528, 120.556 or equivalent Agreement State, or Nuclear Regulatory Commission requirements. A supervising authorized user, who meets the requirements in 105 CMR 120.556(B), must also have experience in administering dosages in the same dosage category or categories (*i.e.*, 105 CMR 120.556(B)(1)(b)7.) as the individual requesting authorized user status. The work experience must involve:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
2. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
3. Calculating, measuring, and safely preparing patient or human research subject dosages;
4. Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;
5. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
7. Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status.
 - a. Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131, for which a written directive is required;
 - b. Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 [Note: *Experience with at least three cases of in category (b) also satisfies the requirement in category (a)*];
 - c. Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required; and/or
 - d. Parenteral administration of any other radionuclide, for which a written directive is required; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in 105 CMR 120.556(A)(1) and (B)(1)(b)7. and has achieved a level of competency sufficient to independently function as an authorized user for the medical uses authorized under 105 CMR 120.552. The written attestation must be signed by a preceptor authorized user, who meets the requirements of 105 CMR 120.528, 120.556 or equivalent Nuclear Regulatory Commission or Agreement State requirements. The preceptor authorized user, who meets the requirements of 105 CMR 120.556(B), must have experience in administering dosages in the same dosage category or categories listed in 105 CMR

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120.556(B)(1)(b)7. as the individual requesting authorized user status.

120.557: Training for the Oral Administration of Sodium Iodide I-131 in Quantities Less than or Equal to 1.22 Gigabecquerels (33 millicurie) for which a Written Directive is Required

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 in quantities less than or equal to 1.22 gigabecquerels (33 millicuries), for which a written directive is required, to be a physician who:

(A) Is certified by a medical specialty board whose certification process includes all of the requirements in 105 CMR 120.557(C)(1) and (2) and whose certification has been recognized by an Agreement State or the Nuclear Regulatory Commission and who meets the requirements in 105 CMR 120.557(C)(3). (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.); or

(B) Is an authorized user under 105 CMR 120.556, for uses listed in 105 CMR 120.556(B)(1)(b)7.b. or equivalent Agreement State or Nuclear Regulatory Commission requirements; or

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

- (a) Radiation physics and instrumentation;
- (b) Radiation protection;
- (c) Mathematics pertaining to the use and measurement of radioactivity;
- (d) Chemistry of radioactive material for medical use; and,
- (e) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in 105 CMR 120.528, 120.556, 120.558, or equivalent Agreement State, or Nuclear Regulatory Commission requirements. A supervising authorized user who meets the requirements of 105 CMR 120.556(B) must also have experience in administering dosages as specified in 105 CMR 120.556(B)(1)(b)7.b. The work experience must involve:

- (a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- (b) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
- (c) Calculating, measuring, and safely preparing patient or human research subject dosages;
- (d) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;
- (e) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures;
- (f) Administering dosages to patients or human research subjects that includes at least three cases involving the oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

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(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 105 CMR 120.557(C)(1) and (2), and has achieved a level of competency sufficient to independently function as an authorized user for medical uses authorized under 105 CMR 120.552. The written attestation must be signed by a preceptor authorized user, who meets the requirements of 105 CMR 120.528, 120.556 through 120.558, or equivalent Agreement State or Nuclear Regulatory Commission requirements. A preceptor authorized user who meets the requirements of 105 CMR 120.556(B)(1)(b)7.b.

120.558: Training for the Oral Administration of Sodium Iodide I-131 in Quantities Greater than 1.22

Gigabecquerels (33 millicurie) for which a Written Directive is Required

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 in quantities greater than 1.22 gigabecquerels (33 millicuries), for which a written directive is required, to be a physician who:

(A) Is certified by a medical specialty board whose certification process includes all of the requirements in 105 CMR 120.558(C)(1) and (2) and whose certification has been recognized by an Agreement State or the Nuclear Regulatory Commission, and who meets the requirements in 120.558(C)(3). (The names of board certifications which have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's Web page.); or

(B) Is an authorized user under 105 CMR 120.556, for uses listed in 105 CMR 120.556(B)(1)(b)7.b., or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements; or

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

- (a) Radiation physics and instrumentation;
- (b) Radiation protection;
- (c) Mathematics pertaining to the use and measurement of radioactivity;
- (d) Chemistry of radioactive material for medical use; and,
- (e) Radiation biology; and,

(2) Has work experience, under the supervision of an authorized user who meets the requirements in 105 CMR 120.528, 120.556, or 120.558, or equivalent Agreement State, or Nuclear Regulatory Commission requirements. A supervising authorized user who meets the requirements of 105 CMR 120.556(B), must also have experience in administering dosages as specified in 105 CMR 120.556(B)(1)(b)7.b.; the work experience must involve:

- (a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- (b) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
- (c) Calculating, measuring, and safely preparing patient or human research subject dosages;
- (d) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;
- (e) Using procedures to contain spilled radioactive material safely and using proper decontamination

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procedures;

(f) Administering dosages to patients or human research subjects that includes at least three cases involving the oral administration 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 105 CMR 120.558(C)(1) and (2), and has achieved a level of competency sufficient to independently function as an authorized user for medical uses authorized under 105 CMR 120.552. The written attestation must be signed by a preceptor authorized user, who meets the requirements of 105 CMR 120.528, 120.556 (~~B~~), 120.558, or equivalent Agreement State or Nuclear Regulatory Commission requirements. ~~The A~~ A preceptor authorized user, who meets the requirements of 105 CMR 120.556(B), must also have experience in administering dosages as specified in 105 CMR 120.556(B)(1)(b)7.b.

120.558A: Training for the Parenteral Administration of Unsealed Byproduct Material Requiring a Written

Directive

Except as provided in 105 CMR 120.528, 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 105 CMR 120.556-~~8A~~ for uses listed in 105 CMR 120.556(B)(1)(b)7.c. or d., or equivalent Agreement State, or Nuclear Regulatory Commission requirements; or

(B) Is an authorized user under 105 CMR 120.566, 120.587, or equivalent Agreement State, or Nuclear Regulatory Commission requirements and who meets the requirements in 105 CMR 120.558A(D); or

(C) Is certified by a medical specialty board whose certification process has been recognized under 105 CMR 120.566 or 120.587 or by the Nuclear Regulatory Commission or an Agreement State, and who meets the requirements in 105 CMR 120.558A(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:

- (a) Radiation physics and instrumentation;
- (b) Radiation protection;
- (c) Mathematics pertaining to the use and measurement of radioactivity;
- (d) Chemistry of byproduct material for medical use; and
- (e) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in 105 CMR 120.528, 120.556, 120.558A, or equivalent Agreement State, or Nuclear Regulatory Commission 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 105 CMR 120.556 must have experience in administering dosages as specified in 105 CMR 120.556(B)(1)(b)7.c.. and/or d. The work experience must involve:

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- (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 medical event involving the use of unsealed byproduct material;
 - (e) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures;
 - (f) Administering dosages to patients or human research subjects that includes at least three 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 three 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 105 CMR 120.558A(B) or (C), and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in 105 CMR 120.528, 120.556, 120.558A, or equivalent Agreement State, or Nuclear Regulatory Commission requirements. A preceptor authorized user, who meets the requirements in 105 CMR 120.556 must have experience in administering dosages as specified in 105 CMR 120.556(B)(1)(b)7.c.. and/or d..

MANUAL BRACHYTHERAPY

120.559: Use of Sealed Sources for Manual Brachytherapy

A licensee shall use only brachytherapy sources for therapeutic medical uses:

- (A) As approved in the Sealed Source and Device Registry; or
- (B) In research in accordance with an effective Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of 105 CMR 120.523(A) are met.

120.560: Surveys After Source Implant and Removal

- (A) Immediately after implanting sources in a patient or a human research subject, the licensee shall perform a survey to locate and account for all sources that have not been implanted.
- (B) Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed.

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(C) A licensee shall retain a record of the surveys in accordance with 105 CMR 120.592(A).

120.561: Brachytherapy Sources Accountability

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

(B) Promptly after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.

(C) A licensee shall maintain a record of the brachytherapy source accountability in accordance with 105 CMR 120.592(A).

120.562: Safety Instruction

In addition to the requirements of 105 CMR 120.753:

(A) The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subject that are undergoing implant therapy and cannot be released in accordance with 105 CMR 120.540. Instruction must be commensurate with the duties of the personnel and shall include the following:

- (1) Size and appearance of the brachytherapy sources;
- (2) Safe handling and shielding instructions;
- (3) Patient or human research subject control;
- (4) Visitor control, including both; and
 - (a) Routine visitation of hospitalized individuals in accordance with 105 CMR 120.221(A)(1); and
 - (b) Visitation authorized in accordance with 105 CMR 120.221(C); and
- (5) Notification of the Radiation Safety Officer, or his or her designee, and an authorized user if the patient or human research subject dies or has a medical emergency.
- (6) A licensee shall retain a record of individuals receiving instruction in accordance with 105 CMR 120.590(P).

120.563: Safety Precautions for Patients or Human Research Subjects Receiving Brachytherapy

(A) For each patient or human research subject receiving brachytherapy therapy and cannot be released in accordance with 105 CMR 120.540, a licensee shall:

- (1) Not place the patient or human research subject in the same room as an individual who is not receiving brachytherapy therapy;
- (2) Visibly post the patient's or human research subject's door with a "Radioactive Materials" sign and note on the door or the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room.

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(B) A licensee shall have emergency response equipment available near each treatment room to respond to a source that inadvertently becomes:

- (1) Dislodged from the patient; or
- (2) Lodged within the patient following removal of the source applicators.

(C) The Radiation Safety Officer, or his or her designee, and the authorized user shall be notified immediately if the hospitalized patient or human research subject dies or has a medical emergency.

120.564: Calibration Measurement of Brachytherapy Sealed Sources

(A) Prior to the first medical use of a brachytherapy sealed source on or after October 6, 2006, a licensee shall perform the following:

- (1) Determine the source output or activity using a dosimetry system that meets the requirements of 105 CMR 120.575(A);
- (2) Determine source positioning accuracy within applicators; and
- (3) Use published protocols accepted by nationally recognized bodies to meet the requirements of 105 CMR 120.564(A)(1) and (2).

(B) A licensee may use measurements provided by the source manufacturer [or by a calibration laboratory accredited by the American Association of Physicists in Medicine] that are made in accordance with 105 CMR 120.564(A).

(C) A licensee shall mathematically correct the outputs or activities determined in 105 CMR 120.564(A) of this section for physical decay at intervals consistent with 1.0% physical decay.

(D) An authorized medical physicist shall perform or review the calculation measurements made pursuant to 105 CMR 120.564(A), (B), or (C).

(E) Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined in accordance with paragraphs 105 CMR 120.564(A) through (C).

(F) A licensee shall retain a record of each calibration in accordance with 105 CMR 120.592(B).

(G) A licensee shall retain a record of decay calculations required by 105 CMR 120.564(E) in accordance with 105 CMR 120.592(C).

120.565: Therapy-related Computer Systems

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

- (A) The source-specific input parameters required by the dose calculation algorithm;
- (B) The accuracy of dose, dwell time, and treatment time calculations at representative points. The licensee shall perform regular quality assurance testing on the treatment planning computer. Said testing shall be in accordance with TG40 or current AAPM recommendation.
- (C) The accuracy of isodose plots and graphic displays; and
- (D) The accuracy of the software used to determine radioactive source positions from radiographic images.

120.566: Training for Use of Manual Brachytherapy Sources

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under 105 CMR 120.559 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 Nuclear Regulatory Commission, and who meets the requirements in 105 CMR 120.566(B)(3) (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

- (1) Successfully complete a minimum of three years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and
- (2) Pass an examination, administered by diplomates of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or

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

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

- 1. Radiation physics and instrumentation;
- 2. Radiation protection;
- 3. Mathematics pertaining to the use and measurement of radioactivity; and,
- 4. Radiation biology; and

(b) 500 hours work experience, under the supervision of an authorized user who meets the requirements in 105 CMR 120.528, 120.566 or equivalent Agreement State, or Nuclear Regulatory Commission requirements at a medical institution, involving:

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1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 2. Checking survey meters for proper operation;
 3. Preparing, implanting, and removing brachytherapy sources;
 4. Maintaining running inventories of material on hand;
 5. Using administrative controls to prevent a medical event involving the use of byproduct material;
 6. Using emergency procedures to control byproduct material; and

(2) Has completed three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in 105 CMR 120.528, 120.566 or equivalent Agreement State or Nuclear Regulatory Commission requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by 105 CMR 120.566(B)(1)(b); and

(3) Has obtained written attestation, signed by a preceptor authorized user, who meets the requirements in 105 CMR 120.528, 120.566 or equivalent Agreement State or Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in 105 CMR 120.566(A)(1), or 120.566(B)(1) and (2) and has achieved a level of competency sufficient to independently function as an authorized user of manual brachytherapy sources for the medical uses authorized under 105 CMR 120.559.

120.567: Training for Ophthalmic Use of Strontium-90

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user of a strontium-90 source for ophthalmic uses authorized under 105 CMR 120.559 to be a physician who:

(A) Is an authorized user under 105 CMR 120.566 or equivalent Agreement State or Nuclear Regulatory Commission 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:

- (a) Radiation physics and instrumentation;
- (b) Radiation protection;
- (c) Mathematics pertaining to the use and measurement of radioactivity;
- (d) Radiation biology; and

(2) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user who meets the requirements in 105 CMR 120.566 or 120.567, and that includes the use of strontium-90 for ophthalmic treatment of five individuals that includes:

- (a) Examination of each individual to be treated;
- (b) Calculation of the dose to be administered;
- (c) Administration of the dose;

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(d) 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 105 CMR 120.528, 120.566, ~~or~~ 120.567 or equivalent Agreement State or Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in 105 CMR 120.567(A) and (B) and has achieved a level of competency sufficient to independently function as an authorized user of strontium-90 for ophthalmic use.

SEALED SOURCES FOR DIAGNOSIS

120.568: Sealed Sources for Diagnosis

A licensee shall use only sealed source for diagnostic medical uses.

(A) Approved in the Sealed Source and Device Registry; and

(B) Handled in accordance with the manufacturer's radiation safety instructions.

120.569: Training for Use of Sealed Sources for Diagnosis

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user of a diagnostic sealed source for use in a device authorized under 105 CMR 120.568 to be a physician, dentist, or podiatrist who:

(A) Is certified by a medical specialty board whose certification process includes all of the requirements in 105 CMR 120.569(B) and (C) and whose certification has been recognized by an Agreement State or the Nuclear Regulatory Commission. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.); or

(B) Has completed eight hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device that includes:

- (1) Radiation physics and instrumentation;
- (2) Radiation protection;
- (3) Mathematics pertaining to the use and measurement of radioactivity; and,
- (4) Radiation biology; and,
- (5) Has completed training in the use of the device for the uses requested.

PHOTON EMITTING REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS

120.570: Use of Sealed Sources in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic

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Radiosurgery Unit

A licensee shall use sealed sources in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic units for therapeutic medical uses:

(A) As approved in the Sealed Source and Device Registry; or

(B) In research in accordance with an effective Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of 105 CMR 120.523(A) are met.

120.571: Surveys of Patients and Human Research Subjects Treated with Remote Afterloader Unit

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

(B) A licensee shall retain a record of the surveys in accordance with 105 CMR 120.590(Q).

120.572: Installation, Maintenance, Adjustment, and Repair

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

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

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

(D) A licensee shall retain a record of the installation, maintenance, adjustment and repair done on remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with 105 CMR 120.592(D).

120.573: Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma

Stereotactic Radiosurgery Units

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- (A) A licensee shall:
- (1) Secure the unit, the console, the console keys, and the treatment room when not in use or is unattended;
 - (2) Permit only individuals approved by authorized user, Radiation Safety Officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s);
 - (3) Prevent dual operation of more than one radiation producing device in a treatment room, if applicable; and
 - (4) Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. This procedure must include:
 - (a) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;
 - (b) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and
 - (c) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.
- (B) A copy of the procedures required by 105 CMR 120 573(A)(4) must be physically located at the unit console.
- (C) A licensee shall post instructions at the unit console to inform the operator of:
- (1) The location of the procedures required by 105 CMR 120 573(A)(4); and
 - (2) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.
- (D) A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in:
- (1) The procedures identified in 105 CMR 120 573(A)(4); and
 - (2) the operating procedures for the unit.
- (E) A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.
- (F) A licensee shall retain a record of individuals receiving instruction required by 105 CMR 120.573(D), in accordance with 105 CMR 120.590(D).

120.574: Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

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

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

- (1) Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;
- (2) Cause the source(s) to be shielded promptly when an entrance door is opened; and
- (3) Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.

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

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

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

(F) In addition to the requirements specified in 105 CMR 120.574(A) through (E), a licensee shall:

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

- (a) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and
- (b) An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.

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

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

(3) For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.

(4) Notify the Radiation Safety Officer, or his or her designee, and an authorized user as soon as possible, if the patient or human research subject has a medical emergency and, immediately, if the patient dies.

(G) A licensee shall have emergency response equipment available near each treatment room, to respond to a source that inadvertently:

- (1) Remains in the unshielded position; or
- (2) Lodges within the patient following completion of the treatment.

120.575: Dosimetry Equipment

(A) Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met.

(1) The system must have been calibrated using a system or source traceable to the National Institute of Standards and Technology (NIST) and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous two years and after any servicing that may have affected system calibration; or

(2) The system must have been calibrated within the previous four years; 18 to 30 months after that calibration, the system must have been intercompared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison must have indicated that the calibration factor of the licensee's system had not changed by more than 2%. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.

(B) The licensee shall have available for use a dosimetry system for spot-check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with 105 CMR 120.575(A). This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in 105 CMR 120.575(A).

(C) The licensee shall retain a record of each calibration, intercomparison, and comparison in accordance with 105 CMR 120.592(D).

120.576: Full Calibration Measurements on Teletherapy Units

(A) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:

(1) Before the first medical use of the unit; and

(2) Before medical use under the following conditions:

(a) Whenever spot-check measurements indicate that the output differs by more than 5% from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(b) Following replacement of the source or following reinstallation of the teletherapy unit in a new location; and,

(c) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and,

(3) At intervals not exceeding one year.

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(B) To satisfy the requirement of 105 CMR 120.576(A), full calibration measurements shall include determination of:

- (1) The output within 3% for the range of field sizes and for the distance or range of distances used for medical use;
- (2) The coincidence of the radiation field and the field indicated by the light beam localizing device;
- (3) The uniformity of the radiation field and its dependence on the orientation of the useful beam;
- (4) Timer accuracy;
- (5) "On-off" error; and,
- (6) The accuracy of all distance measuring and localization devices in medical use.

(C) A licensee shall use the dosimetry system described in 105 CMR 120.575 to measure the output for one set of exposure conditions. The remaining radiation measurements required in 105 CMR 120.576(B)(1) may then be made using a dosimetry system that indicates relative dose rates.

(D) A licensee shall make full calibration measurements required by 105 CMR 120.576(A) in accordance with published protocols accepted by nationally recognized bodies.

(E) A licensee shall correct mathematically the outputs determined in 105 CMR 120.576(B)(1) for physical decay for intervals not exceeding one month for cobalt-60 and intervals not exceeding six months for cesium-137, or at intervals consistent with 1% decay for all other nuclides.

(F) Full calibration measurements required by 105 CMR 120.576(A) and physical decay corrections required by 105 CMR 120.576(E) shall be performed by the authorized medical physicist.

(G) A licensee shall retain a record of each calibration in accordance with 105 CMR 120.592(F).

120.577: Full Calibration Measurements on Remote Afterloader Units

(A) A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit:

- (1) Before the first medical use of the unit; and
- (2) Before medical use under the following conditions:
 - (a) Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and
 - (b) Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and
- (3) At intervals not exceeding one quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and
- (4) At intervals not exceeding one year for low dose-rate remote afterloader units.

(B) To satisfy the requirement of 105 CMR 120.577(A), full calibration measurements shall include, as applicable, determination

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of:

- (1) the output within +/- 5%;
- (2) Source position accuracy to within +/- 1 millimeter;
- (3) Source retraction with backup battery upon power failure;
- (4) Length of the source transfer tubes;
- (5) Timer accuracy and linearity over the typical range of use;
- (6) Length of applicators; and
- (7) Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

(C) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in 105 CMR 120.577(B), a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding one quarter.

(D) A licensee shall use the dosimetry system described in 105 CMR 120.575(A) to measure the output.

(E) A licensee shall make full calibration measurements required by 105 CMR 120.577(A) in accordance with published protocols accepted by nationally recognized bodies.

(F) For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with 105 CMR 120.577(A) through (E).

(G) A licensee shall mathematically correct the outputs determined in 105 CMR 120.577(B)(1) for physical decay at intervals consistent with 1% physical decay.

(H) Full calibration measurements required by 105 CMR 120.577(A) and physical decay corrections required by 105 CMR 120.577(G) must be performed by the authorized medical physicist.

(I) A licensee shall retain a record of each calibration in accordance with 105 CMR 120.592(F).

120.578: Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units

(A) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit:

- (1) Before the first medical use of the unit; and
- (2) Before medical use under the following conditions:

(a) Whenever spot-check measurements indicate that the output differs by more than 5% from the output

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obtained at the last full calibration corrected mathematically for radioactive decay;

(b) Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and,

(c) Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and,

(3) At intervals not exceeding one year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

(B) To satisfy the requirement of 105 CMR 120.578(A), full calibration measurements shall include determination of:

- (1) The output within $\pm 3\%$;
- (2) Relative helmet factors;
- (3) Isocenter coincidence;
- (4) Timer accuracy and linearity over the range of use;
- (5) On-off error;
- (6) Trunnion centricity;
- (7) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;
- (8) Helmet microswitches;
- (9) Emergency timing circuits; and,
- (10) Stereotactic frames and localizing devices (trunnions).

(C) A licensee shall use the dosimetry system described in 105 CMR 120.575(A) to measure the output for one set of exposure conditions. The remaining radiation measurements required in 105 CMR 120.578(B)(1) may be made using a dosimetry system that indicates relative dose rates.

(D) A licensee shall make full calibration measurements required by 105 CMR 120.578(A) in accordance with published protocols accepted by nationally recognized bodies.

(E) A licensee shall mathematically correct the outputs determined in 105 CMR 120.578(B)(1) at intervals not exceeding one month for cobalt-60 and at intervals consistent with 1% physical decay for all other radionuclides.

(F) Full calibration measurements required by 105 CMR 120.578(A) and physical decay corrections required by 105 CMR 120.578(E) must be performed by the authorized medical physicist.

(G) A licensee shall retain a record of each calibration in accordance with 105 CMR 120.592(F).

120.579: Periodic Spot-checks for Teletherapy Units

(A) A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit once in each calendar month that include determination of:

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- (1) Timer accuracy, and timer linearity over the range of use;
- (2) "On-off" error;
- (3) The coincidence of the radiation field and the field indicated by the light beam localizing device;
- (4) The accuracy of all distance measuring and localization devices used for medical use;
- (5) The output for one typical set of operating conditions; and,
- (6) The difference between the measurement made in 105 CMR 120.579(A)(5) and the anticipated output, expressed as a percentage of the anticipated output (*i.e.*, the value obtained at last full calibration corrected mathematically for physical decay).

(B) A licensee shall perform measurements required by 105 CMR 120.579(A) in accordance with procedures established by the authorized medical physicist. That individual need not actually perform the output spot-check measurements.

(C) A licensee shall have the authorized medical physicist review the results of each output spot-check within 15 days. The authorized medical physicist shall promptly notify the licensee in writing of the results of each output spot-check.

(D) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility once in each calendar month and after each source installation to assure proper operation of:

- (1) Electrical interlocks at each teletherapy room entrance;
- (2) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation restriction of source housing angulation or elevation, carriage or stand travel, and operation of the beam "on-off" mechanism;
- (3) Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;
- (4) Viewing and intercom systems;
- (5) Treatment room doors from inside and outside the treatment room; and,
- (6) Electrically assisted treatment room doors with the teletherapy unit electrical power turned "off".

(E) If the results of the checks required in 105 CMR 120.579(D) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(F) A licensee shall retain a record of each spot-check required by 105 CMR 120.579(A) and (D), in accordance with 105 CMR 120.592(G).

120.580: Periodic Spot-checks for Remote Afterloader Units

(A) A licensee authorized to use remote afterloader units for medical use shall perform spot-checks on each remote afterloader facility and on each unit:

- (1) At the beginning of each day of use of a high dose-rate, medium dose-rate or pulsed dose-rate remote afterloader unit;
- (2) Prior to each patient treatment with a low dose-rate remote afterloader unit; and

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- (3) After each source installation.
- (B) A licensee shall have the authorized medical physicist establish written procedures for performing the spot-checks required in 105 CMR 120.580(A). The authorized medical physicist need not actually perform the spot-check measurements.
- (C) A licensee shall have the authorized medical physicist review the results of each output spot-check within 15 days. The authorized medical physicist shall promptly notify the licensee in writing of the results of each output spot-check.
- (D) To satisfy the requirement of 105 CMR 120.580(A), spot-checks must, at a minimum, assure proper operation of:
- (1) Electrical interlocks at each remote afterloader unit room entrance;
 - (2) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
 - (3) Viewing and intercom systems in each high dose-rate, medium dose-rate and pulsed dose-rate remote afterloader facility;
 - (4) Emergency response equipment;
 - (5) Radiation monitors used to indicate the source position;
 - (6) Timer accuracy;
 - (7) Clock (date and time) in the unit's computer; and
 - (8) Decayed source(s) activity in the unit's computer.
- (E) If the results of the checks required in 105 CMR 120.580(D) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.
- (F) A licensee shall retain a record of each spot-check required by 105 CMR 120.580(D), in accordance with 105 CMR 120.592(H).

120.581: Periodic Spot-checks for Gamma Stereotactic Radiosurgery Units

- (A) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot-checks on each gamma stereotactic radiosurgery facility and on each unit:
- (1) Monthly;
 - (2) At the beginning of each day of use; and
 - (3) After each source installation.
- (B) A licensee shall have the authorized medical physicist:
- (1) Establish written procedures for performing the spot-checks required in 105 CMR 120.581(A); and
 - (2) Review the results of each spot-check required by 105 CMR 120.581(A)(1) within 15 days of the check. The authorized medical physicist need not actually perform the spot-check measurements. The authorized medical physicist

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shall notify the licensee as soon as possible, in writing, of the results of the spot check.

(C) To satisfy the requirement of 105 CMR 120.581(A)(1), spot-checks must, at a minimum:

(1) Assure proper operation of:

- (a) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;
- (b) Helmet microswitches;
- (c) Emergency timing circuits; and
- (d) Stereotactic frames and localizing devices (trunnions).

(2) Determine:

- (a) The output for one typical set of operating conditions measured with the dosimetry system described in 105 CMR 120.575(B);
- (b) The difference between the measurement made in 105 CMR 120.581(C)(2)(a) and the anticipated output, expressed as a percentage of the anticipated output (*i.e.*, the value obtained at last full calibration corrected mathematically for physical decay);
- (c) Source output against computer calculation;
- (d) Timer accuracy and linearity over the range of use;
- (e) On-off error; and
- (f) Trunnion centricity.

(D) To satisfy the requirements of 105 CMR 120.581(A)(2) and (3), spot-checks must assure proper operation of:

- (1) Electrical interlocks at each gamma stereotactic radiosurgery room entrance
- (2) Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;
- (3) Viewing and intercom systems;
- (4) Timer termination;
- (5) Radiation monitors used to indicate room exposure; and,
- (6) Emergency off buttons.

(E) A licensee shall arrange for prompt repair of any system identified in 105 CMR 120.581(C) that is not operating properly.

(F) If the results of the checks required in 105 CMR 120.581(D) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(G) A licensee shall retain a record of each check required by 105 CMR 120.581(C) and (D) in accordance with 105 CMR 120.592(I).

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120.582: Additional Technical Requirements for Mobile Remote Afterloader Units

- (A) A licensee providing mobile remote afterloader service shall:
- (1) Check survey instruments for consistent response before medical use at each address of use or on each day of use, whichever is more frequent; and
 - (2) Account for all sources before departure from a client's address of use.
- (B) In addition to the periodic spot-checks required by 105 CMR 120.580, a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the operation of:
- (1) Electrical interlocks on treatment area access points;
 - (2) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
 - (3) Viewing and intercom systems;
 - (4) Applicators, source transfer tubes, and transfer tube-applicator interfaces;
 - (5) Radiation monitors used to indicate room exposures;
 - (6) Source positioning (accuracy); and
 - (7) Radiation monitors used to indicate whether the source has returned to a safe shielded position.
- (C) In addition to the requirements for checks in 105 CMR 120.582(B), a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.
- (D) If the results of the checks required in 105 CMR 120.582(B) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.
- (E) A licensee shall retain a record of each check required by 105 CMR 120.582(B) in accordance with 105 CMR 120.592(J).

120.583: Radiation Surveys

- (A) In addition to the survey requirements in 105 CMR 120.225, a person licensed pursuant to 105 CMR 120.500 shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position does not exceed the levels stated in the Sealed Source and Device Registry.
- (B) The licensee shall make the survey required by 105 CMR 120.583(A) at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).
- (C) A licensee shall retain a record of the radiation surveys required in 105 CMR 120.583(A) in accordance with 105 CMR

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120.592(K).

120.584: Five Year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units

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

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

(C) A licensee shall maintain a record of the inspection and servicing in accordance with 105 CMR 120.592(L).

120.585: Therapy-related Computer Systems

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

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

(B) The accuracy of dose, dwell time, and treatment time calculations at representative points. The licensee shall perform regular quality assurance testing on the treatment planning computer. Said testing shall be in accordance with TG40 or current AAPM recommendation.

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

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

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

120.587: Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user of a sealed source for a use authorized under 105 CMR 120.570 to be a physician who:

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(A) Is certified by a medical specialty board whose certification process has been recognized by an Agreement State or the Nuclear Regulatory Commission and who meets the requirements in 105 CMR 120.587(B)(3) and (C). (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

- (1) Successfully complete a minimum of three years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-graduate Training of the American Osteopathic Association; and
- (2) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy; or

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

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

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Radiation biology; and

(b) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in 105 CMR 120.528, 120.587 or equivalent Agreement State or Nuclear Regulatory Commission requirements at a medical institution, involving:

1. Reviewing full calibration measurements and periodic spot checks;
2. Preparing treatment plans and calculating treatment doses and times;
3. Using administrative controls to prevent a misadministration involving the use of radioactive material;
4. Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;
5. Checking and using survey meters;
6. Selecting the proper dose and how it is to be administered; and

(2) Has completed three years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in 105 CMR 120.528, 120.587 or equivalent Agreement State or Nuclear Regulatory Commission requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by 105 CMR 120.587(B)(1)(b); and

(3) Has obtained written attestation, that the individual has satisfactorily completed the requirements in 105 CMR 120.587(A)(1) or (B)(1) and (2), and 120.587(C) and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorize user status. The written attestation must be signed by a preceptor authorized user, who meets the requirements in

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105 CMR 120.528, 120.587, or equivalent Agreement State or Nuclear Regulatory requirements for an authorized user for each type therapeutic medical unit for which the individual is requesting authorized user status; and

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

120.754: 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 105 CMR 120.750. The information reported shall include data and results obtained pursuant to 105 CMR 120.000, orders, or license conditions, as shown in records maintained by the licensee or registrant pursuant to 105 CMR 120.267.

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 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 105 CMR 120.750. You should preserve this report for future reference."

(B) Each licensee or registrant shall furnish to each worker annually a written report of the worker's exposure to radiation or radioactive material as shown in records maintained by the licensee or registrant pursuant to 105 CMR 120.267. The licensee shall provide an annual report to each individual monitored under 105 CMR 120.226 of the dose received in that monitoring year if:

- (1) The individual's occupational dose exceeds 1 mSv (100 mrem) TEDE or 1 mSv (100 mrem) to any individual organ or tissue; or
- (2) The individual requests his or her annual dose report.

(C) Each licensee or registrant shall furnish a written report of the worker's exposure to sources of radiation at the request of a worker formerly 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 105 CMR 120.226. Such report shall be furnished within 30 days from the date of the request, or within 30 days after the dose of the individual has been determined by the licensee or registrant, whichever is later. The report shall cover the period of time that the worker's activities involved exposure to sources of radiation and shall include the dates and locations of work under the license or registration in which the worker participated during this period.

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(D) When a licensee or registrant is required pursuant to 105 CMR 120.282, 120.283, or 120.284, ~~120.285, or 120.286~~ to report to the Agency any exposure of an individual to radiation or radioactive material, ~~sources of radiation,~~ the licensee or the registrant shall also provide the individual a ~~written~~ report on his or her ~~the~~ exposure data included in the report to the Agency ~~therein~~. Such reports shall be transmitted at a time not later than the transmittal to the Agency.

(E) At the request of a worker who is terminating employment with the licensee or registrant in work involving exposure to radiation or radioactive material, during the current year, each licensee or registrant shall provide at termination to each such worker, or to the worker's designee, a written report regarding the radiation dose received by that worker from operations of the licensee or registrant during the current year or fraction thereof. If the most recent individual monitoring results are not available at that time, a written estimate of the dose shall be provided together with a clear indication that this is an estimate.

