

## 105 CMR: DEPARTMENT OF PUBLIC HEALTH

### 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 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.

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### 120.102: Definitions

As used in 105 CMR 120.100, the following definitions apply:

Alert means events may occur, are in progress, or have occurred that could lead to a release of radioactive material but that the release is not expected to require a response by offsite response organizations to protect persons offsite.

Decommissioning Funding Plan means a written document that contains a cost estimate for decommissioning and a description of the method for assuring for decommissioning, including means of adjusting cost estimates and associated funding levels periodically over the life of the facility.

Facility means the location within one building, vehicle, or under one roof and under the same administrative control:

- (1) at which the possession, use, processing or storage of radioactive material is or was authorized; or
- (2) at which one or more radioactivity-inducing machines are installed or located.

Facility may also mean multiple such locations at a site or part of a site.

Financial Surety means the method of assuring that sufficient funds will be available at the time of license termination and decommissioning of the facility to cover all costs associated with the decommissioning.

Site means the area contained within the boundary of a location under the control of persons generating or storing radioactive materials.

Site Area Emergency means events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a response by offsite response organizations to protect persons offsite.

### 120.103: Source Material

(A) Any person is exempt from 105 CMR 120.100 to the extent that such person receives, possesses, uses, owns, or transfers source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than 1/20 of 1% (0.05%) of the mixture, compound, solution, or alloy.

(B) Any person is exempt from 105 CMR 120.100 to the extent that such person receives, possesses, uses, or transfers unrefined and unprocessed ore containing source material; provided that, except as authorized in a specific license, such person shall not refine or process such ore.

(C) Any person is exempt from 105 CMR 120.103 to the extent that such person receives, possesses, uses, or transfers:

- (1) any quantities of thorium contained in:
  - (a) incandescent gas mantles;
  - (b) vacuum tubes;
  - (c) welding rods;
  - (d) electric lamps for illuminating purposes provided that each lamp does not contain more than 50 milligrams of thorium;
  - (e) germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting provided that each lamp does not contain more than two grams of thorium;
  - (f) rare earth metals and compounds, mixtures, and products containing not more than 0.25% by weight thorium, uranium, or any combination of these; or

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- (g) personnel neutron dosimeters, provided that each dosimeter does not contain more than 50 milligrams of thorium;
- (2) source material contained in the following products:
  - (a) glazed ceramic tableware, provided that the glaze contains not more than 20% by weight source material;
  - (b) glassware containing not more than 10% by weight source material, but not including commercially manufactured glass brick, pane glass, ceramic tile, or other glass or ceramic used in construction;

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- (c) glass enamel or glass enamel frit containing not more than 10% by weight source material imported or ordered for importation into the United States, or initially distributed by manufacturers in the United States, before July 25, 1983; or
  - (d) piezoelectric ceramic containing not more than 2% by weight source material.
- (3) photographic film, negatives, and prints containing uranium or thorium;
  - (4) any finished product or part fabricated of, or containing, tungsten-thorium or magnesium-thorium alloys, provided that the thorium content of the alloy does not exceed 4% by weight and that this exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such product or part;
  - (5) uranium contained in counterweights installed in aircraft, rockets, projectiles, and missiles, or stored or handled in connection with installation or removal of such counterweights, provided that:
    - (a) the counterweights are manufactured in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission (NRC), authorizing distribution by the licensee pursuant to 10 CFR Part 40;
    - (b) each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM";<sup>1</sup>
    - (c) each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED";<sup>1</sup> and
    - (d) this exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such counterweights other than repair or restoration of any plating or other covering;
  - (6) natural or depleted uranium metal used as shielding constituting part of any shipping container, provided that:
    - (a) the shipping container is conspicuously and legibly impressed with the legend "CAUTION - RADIOACTIVE SHIELDING - URANIUM"; and
    - (b) the uranium metal is encased in mild steel or equally fire resistant metal of minimum wall thickness of 1/8 inch (3.2 mm);
  - (7) thorium contained in finished optical lenses, provided that each lens does not contain more than 30% by weight of thorium, and that this exemption shall not be deemed to authorize either:
    - (a) the shaping, grinding, or polishing of such lens or manufacturing processes other than the assembly of such lens into optical systems and devices without any alteration of the lens; or
    - (b) the receipt, possession, use, or transfer of thorium contained in contact lenses, or in spectacles, or in eyepieces in binoculars or other optical instruments;
  - (8) uranium contained in detector heads for use in fire detection units, provided that each detector head contains not more than 0.005 microcurie of uranium; or
  - (9) thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that:
    - (a) the thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide); and
    - (b) the thorium content in the nickel-thoria alloy does not exceed 4% by weight.
- (D) The exemptions in 105 CMR 120.103(C) do not authorize the manufacture of any of the products described.

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<sup>1</sup> The requirements specified in 105 CMR 120.103(C)(5)(b) and (c) need not be met by counterweights manufactured prior to December 31, 1969; provided, that such counterweights are impressed with the legend, "CAUTION - RADIOACTIVE MATERIAL - URANIUM", as previously required by 105 CMR 120.000.

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### 120.104: Radioactive Material Other Than Source Material

#### (A) Exempt Concentrations.

- (1) Except as provided in 105 CMR 120.104(A)(2), any person is exempt from 105 CMR 120.100 to the extent that such person receives, possesses, uses, transfers, owns or acquires products containing radioactive material introduced in concentrations not in excess of those listed in 105 CMR 120.195: *Appendix A*.
- (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 Agreement State or Licensing State, except in accordance with a specific license issued pursuant to 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),~~ 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.~~<sup>2</sup>
- (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 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.

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<sup>2</sup> 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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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  $\mu$ Gy) per hour at ten centimeters from any surface.
    - b. For pocket watches, 0.1 millirad (1  $\mu$ Gy) per hour at one centimeter from any surface.
    - c. For any other timepiece, 0.2 millirad (2  $\mu$ Gy) per hour at ten centimeters from any surface.
  8. One microcurie (37 kBq) of radium-226 per timepiece in timepieces acquired prior to the effective date of 105 CMR 120.100.
- (b) 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  $\mu$ 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.
- (d) 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.
- (f) Thermostat dials and pointers containing not more than 25 millicuries (925 MBq) of tritium per thermostat.
- (g) Electron tubes; provided, that each tube does not contain more than one of the following specified quantities of 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 radioactive material will not exceed one millirad (ten  $\mu$ 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.
- (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
  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 I*, provided that the sum of such fractions shall not exceed unity.

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3. For americium-241, 0.05 microcurie (1.85 kBq) is considered an exempt quantity under 105 CMR 120.104(C)(1)(h).
- (i) 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 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 Commission<sup>2</sup> 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 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

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provided that such person receives, possesses, uses, transfers, owns, or acquires capsules containing 37 kBq (1 $\mu$  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

(A) A general license is hereby issued authorizing commercial and industrial firms, research, educational and medical institutions, and state and local government agencies to use and transfer not more than 15 pounds (6.82 kg) of source material at any one time for research, development, educational, commercial, or operational purposes. A person authorized to use or transfer source material, pursuant to this general license, may not receive more than a total of 150 pounds (68.2 kg) of source material in any one calendar year.

(B) Persons who receive, possess, use, or transfer source material pursuant to the general license issued in 105 CMR 120.121(A) are exempt from the provisions of 105 CMR 120.200 and 120.750 to the extent that such receipt, possession, use, or transfer is within the terms of such general license; provided, however, that this exemption shall not be deemed to apply to any such person who is also in possession of source material under a specific license issued pursuant to 105 CMR 120.100.

(C) Persons who receive, possess, use, or transfer source material pursuant to the general license in 105 CMR 120.121(A) are prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings except as may be authorized by the Agency in a specific license.

(D) A general license is hereby issued authorizing the receipt of title to source material without regard to quantity. This general license does not authorize any person to receive, possess, use, or transfer source material.

(E) Depleted Uranium in Industrial Products and Devices.

(1) A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of 105 CMR 120.121(E)(2), (3), (4), and (5), depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

(2) The general license in 105 CMR 120.121(E)(1) applies only to industrial products or devices which have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to 105 CMR 120.128(M) or in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission or an Agreement State which authorizes manufacture of the products or devices for distribution to persons generally licensed by the U.S. Nuclear Regulatory Commission or an Agreement State.

(3) (a) Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by 105 CMR 120.121(E)(1) shall file form MRCP 120.100-1 "Certificate - Use of Depleted Uranium Under General License", with the Agency. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium. The general licensee shall furnish on form MRCP 120.100-1 the following information and such other information as may be required by that form:

1. name and address of the general licensee;

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2. a statement that the general licensee has developed and will maintain procedures designed to establish physical control over the depleted uranium described in 105 CMR 120.121(E)(1) and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and
  3. name and title, address, and telephone number of the individual duly authorized to act for and on behalf of the general licensee in supervising the procedures identified in 105 CMR 120.121(E)(3)(a)2.
- (b) The general licensee possessing or using depleted uranium under the general license established by 105 CMR 120.121(E)(1) shall report in writing to the Agency any changes in information furnished by him in form MRCP 120.100-1 "Certificate - Use of Depleted Uranium Under General License". The report shall be submitted within 30 days after the effective date of such change.
- (4) A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by 105 CMR 120.121(E)(1):
- (a) shall not introduce such depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium;
  - (b) shall not abandon such depleted uranium;
  - (c) shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of 105 CMR 120.140. In the case where the transferee receives the depleted uranium pursuant to the general license established by 105 CMR 120.121(E)(1), the transferor shall furnish the transferee a copy of 105 CMR 120.100 and a copy of form MRCP 120.100-1. In the case where the transferee receives the depleted uranium pursuant to a general license contained in the U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to 105 CMR 120.121(E)(1), the transferor shall furnish the transferee a copy of 105 CMR 120.100 and a copy of form MRCP 120.100-1 accompanied by a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or Agreement State under requirements substantially the same as those in 105 CMR 120.100;
  - (d) within 30 days of any transfer, shall report in writing to the Agency the name and address of the person receiving the depleted uranium pursuant to such transfer; and,
  - (e) shall not export such depleted uranium except in accordance with a license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 110.
- (5) Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by 105 CMR 120.121(E)(1) is exempt from the requirements of 105 CMR 120.200 and 120.750 with respect to the depleted uranium covered by that general license.

### 120.122: General Licenses - Radioactive Material Other Than Source Material

(A) Certain Devices and Equipment. A general license is hereby issued to transfer, receive, acquire, own, possess, and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission for use pursuant to 10 CFR Part 31, § 31.3. This general license is subject to the provisions of 105 CMR 120.001 through 120.016, 120.104(A)(2), 120.131, 120.140, 120.150 and 120.200, 120.750, and 120.770. Attention is directed particularly to the provisions of 105 CMR 120.200 which relate to the labeling of containers.

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

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(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:
  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

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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.
- (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

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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 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.

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(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.]

(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 CMR 120.122(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 CMR 120.256 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

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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.

(c) Shall respond to written requests from the NRC to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the 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)~~ 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)~~ 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)~~ This general license does not authorize the manufacture, assembly, or repair of luminous safety devices containing tritium or promethium-147.

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

~~(9)~~ 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.

(G) Calibration and Reference Sources.

(1) A general license is hereby issued to those persons listed below to own, receive, acquire, possess, use, and transfer, in accordance with the provisions of 105 CMR 120.122(G)(4) and (5), americium-241 in the form of calibration or reference sources:

(a) any person who holds a specific license issued by the Agency which authorizes him to receive, possess, use, and transfer radioactive material; and

(b) any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission which authorizes him to receive, possess, use, and transfer special nuclear material.

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(2) A general license is hereby issued to own, receive, possess, use, and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of 105 CMR 120.122(G)(4) and (5) to any person who holds a specific license issued by the Agency which authorizes him to receive, possess, use, and transfer radioactive material.

(3) A general license is hereby issued to own, receive, possess, use, and transfer radium-226 in the form of calibration or reference sources in accordance with the provisions of 105 CMR 120.122(G)(4) and (5) to any person who holds a specific license issued by the Agency which authorizes him to receive, possess, use, and transfer radioactive material.

(4) The general licenses in 105 CMR 120.122(G)(1), (2) and (3) apply only to calibration or reference sources which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 32, § 32.57 or 10 CFR Part 70, § 70.39 or which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the Agency, any Agreement State or Licensing State pursuant to licensing requirements equivalent to those contained in 10 CFR Part 32, § 32.57 or 10 CFR Part 70, § 70.39.

(5) The general licenses provided in 105 CMR 120.122(G)(1), (2), and (3) are subject to the provisions of 105 CMR 120.005 through 120.016, 120.131, 120.140, 120.150, and 120.770. In addition, persons who own, receive, acquire, possess, use, or transfer one or more calibration or reference sources pursuant to these general licenses:

(a) shall not possess at any one time, at any one location of storage or use, more than five microcuries (185 kBq) of americium-241, five microcuries (185 kBq) of plutonium, or five microcuries (185 kBq) of radium-226 in such sources;

(b) shall not receive, possess, use, or transfer such source unless the source, or the storage container, bears a label which includes one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, as appropriate:

1. The receipt, possession, use and transfer of this source, Model \_\_\_\_\_, Serial No. \_\_\_\_\_, are subject to a general license and the regulations 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. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL

THIS SOURCE CONTAINS (AMERICIUM-241) (PLUTONIUM)<sup>3</sup>.

DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

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Name of Manufacturer or Importer

2. The receipt, possession, use and transfer of this source, Model \_\_\_\_\_, Serial No. \_\_\_\_\_, are subject to a general license and the regulations of a Licensing State. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL

THIS SOURCE CONTAINS RADIUM-226.

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DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

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Name of Manufacturer or Importer

- (c) shall not transfer, abandon, or dispose of such source except by transfer to a person authorized by a license from the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to receive the source;
  - (d) shall store such source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241, plutonium, or radium-226 which might otherwise escape during storage; and,
  - (e) shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.
- (6) These general licenses do not authorize the manufacture of calibration or reference sources containing americium-241, plutonium, or radium-226.

(I) General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing.<sup>4</sup>

- (1) A general license is hereby issued to any physician, veterinarian, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of 105 CMR 120.122(I)(2), (3), (4), (5), and (6), the following radioactive materials in prepackaged units for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:
- (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 reference or calibration sources, in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each.

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<sup>3</sup> Showing only the name of the appropriate material.

<sup>4</sup> The New Drug provisions of the Federal Food, Drug, and Cosmetic Act also govern the availability and use of any specific diagnostic drugs in interstate commerce.

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- (f) Iodine-131, in units not exceeding ten microcuries (370 kBq) each.
  - (g) Iron-59, in units not exceeding 20 microcuries (740 kBq) each.
  - (h) Selenium-75, in units not exceeding ten microcuries (370 kBq) each.
- (2) No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by 105 CMR 120.122(I)(1) until he has filed form MRCP 120.100-2, "Certificate - *In Vitro* Testing with Radioactive Material Under General License", with the Agency and received from the Agency a validated copy of form MRCP 120.100-2 with certification number assigned, or, has a license that authorizes the medical use of radioactive material that was issued under 105 CMR 120.500. The physician, veterinarian, clinical laboratory or hospital shall furnish on form MRCP 120.100-2 the following information and such other information as may be required by that form:
- (a) Name and address of the physician, veterinarian, clinical laboratory or hospital;
  - (b) The location of use; and,
  - (c) A statement that the physician, veterinarian, clinical laboratory or hospital has appropriate radiation measuring instruments to carry out *in vitro* clinical or laboratory tests with radioactive material as authorized under the general license in 105 CMR 120.122(I)(1) and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.
- (3) A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by 105 CMR 120.122(I)(1) shall comply with the following:
- (a) The general licensee shall not possess at any one time, pursuant to the general license in 105 CMR 120.122(I)(1), at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, iron-59, and/or cobalt-57 in excess of 200 microcuries (7.4 MBq).
  - (b) The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.
  - (c) The general licensee shall use the radioactive material only for the uses authorized by 105 CMR 120.122(I)(1)
  - (d) The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the Agency, the U.S. Nuclear Regulatory Commission, any Agreement State or Licensing State, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.
  - (e) The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in 105 CMR 120.122(I)(1)(e) as required by 105 CMR 120.251.
- (4) The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to 105 CMR 120.122(I)(1):
- (a) Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to 105 CMR 120.128(H) or in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission, any Agreement State or Licensing State which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), iron-59, selenium-75, cobalt-57, or Mock Iodine-125 to persons generally licensed under 105 CMR 120.122(I) or its equivalent; and
  - (b) unless 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

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appears in a leaflet or brochure which accompanies the package:

1. This radioactive material shall 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 Commission has entered into an agreement for the exercise of regulatory authority.

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Name of Manufacturer

2. This radioactive material shall 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.

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Name of Manufacturer

(5) The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general license of 105 CMR 120.122(I)(1) shall report in writing to the Agency, any changes in the information furnished by him in the "Certificate - *In Vitro* Testing with Radioactive Material Under General License", form MRCP 120.100-2. The report shall be furnished within 30 days after the effective date of such change.

(6) Any person using radioactive material pursuant to the general license of 105 CMR 120.122(I)(1) is exempt from the requirements of 105 CMR 120.200 and 120.750 with respect to radioactive material covered by that general license, except that such persons using the Mock Iodine-125 described in 105 CMR 120.122(I)(1)(e) shall comply with the provisions of 105 CMR 120.251, 120.281 and 120.282.

(J) Ice Detection Devices.

(1) A general license is hereby issued to own, receive, acquire, possess, use, and transfer strontium-90 contained in ice detection devices, provided each device contains not more than 50 microcuries (1.85 MBq) of strontium-90 and each device has been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission or each device has been manufactured in accordance with the specifications contained in a specific license issued by the Agency or an Agreement State to the manufacturer of such device pursuant to licensing requirements equivalent to those in 10 CFR Part 32, § 32.61.

(2) Persons who own, receive, acquire, possess, use, or transfer strontium-90 contained in ice detection devices pursuant to the general license in 105 CMR 120.122(J)(1),

(a) shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person

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- holding a specific license from the U.S. Nuclear Regulatory Commission or an Agreement State to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of 105 CMR 120.251;
- (b) shall assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon; and,
- (c) are exempt from the requirements of 105 CMR 120.200 and 120.750 except that such persons shall comply with the provisions of 105 CMR 120.251, 120.281 and 120.282.
- (3) This general license does not authorize the manufacture, assembly, disassembly or repair of strontium-90 in ice detection devices.
- (4) This general license is subject to the provisions of 105 CMR 120.001 through 120.019, 120.131, 120.140, 120.150, and 120.770.

### 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.
- (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 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"; or

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

### 120.125: General Requirements for the Issuance of Specific Licenses

- (A) A license application will be approved only if the Agency determines that:
  - (1) the applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with 105 CMR 120.000 in such a manner as to minimize danger to public health and safety or property;
  - (2) the applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety or property;
  - (3) the issuance of the license will not be inimical to the health and safety of the public; and,
  - (4) the applicant satisfies any applicable special requirements in 105 CMR 120.126, 120.127, 120.128, 120.300, 120.500, 120.620 120.800, 120.890 or 120.900.
  
- (B) Environmental Report, Commencement of Construction.
  - (1) In the case of an application for a license to receive and possess radioactive material for commercial waste disposal, or for the conduct of any other activity which the Agency determines will significantly affect the quality of the environment, a license application shall be reviewed and approved by the Agency before commencement of construction of the plant or facility in which the activity will be conducted. Issuance of the license shall be based upon a consideration by the Agency of the environmental, economic, technical and other benefits in comparison with the environmental costs and available alternatives and a determination that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values;
  - (2) Commencement of construction prior to such conclusion shall be grounds for denial of a license to receive and possess radioactive material in such plant or facility. As used in 105 CMR 120.125(B) the term "commencement of construction" means any clearing of land, excavation, or other substantial action that would adversely affect the environment of a site. The term does not mean site exploration, necessary roads for site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values.
  
- (C) Financial Surety Arrangements and Recordkeeping for Decommissioning.
  - (1) Unless exempted by 105 CMR 120.125(C)(3), issuance, renewal or amendment of a license shall be dependent upon satisfactory financial surety arrangements to ensure the protection of the public health and safety in the event of abandonment, default or other inability of the licensee to meet the requirements of M.G.L. c. 111H, § 9 and 105 CMR 120.000.

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- (2) Each applicant for a specific license authorizing the possession and use of unsealed radioactive material with a half-life greater than 120 days and in quantities exceeding  $10^5$  times the applicable quantities set forth in 105 CMR 120.196: *Appendix B*, Table II shall submit a decommissioning funding plan as described in 105 CMR 120.125(C)(6) ~~(4)(e)~~. The decommissioning funding plan must also be submitted when a combination of isotopes is involved if R divided by  $10^5$  is greater than 1 (unity rule), where R is defined as the sum of the ratios of the quantity of each isotope to the applicable value in 105 CMR 120.196: *Appendix B*, Table II.
- (3) Each applicant for a specific license authorizing possession and use of radioactive material of half-life greater than 120 days and in quantities specified in 105 CMR 120.125(C)(5) shall either:
- (a) submit a decommissioning funding plan as described in 105 CMR 120.125(C)(6); or
  - (b) submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by 105 CMR 120.125(C)(5) using one of the methods described in 105 120.125(C)(7). For an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued, but prior to the receipt of licensed material. As part of the certification, a copy of the financial instrument obtained to satisfy the requirements of 105 CMR 120.125(C)(7) is to be submitted to the Agency.
- (4) (a) Each holder of a specific license issued on or after March 11, 1994, which is of a type described in 105 CMR 120.125(C)(2) or (3), shall provide financial assurance for decommissioning in accordance with the criteria set forth in 105 CMR 120.125(C)(1) through 120.125(C)(8).
- (b) Each holder of a specific license issued before March 11, 1994, and of a type described in 105 CMR 120.125(C)(2) shall submit, on or before March 11, 1995, a decommissioning funding plan or a certification of financial assurance for decommissioning in an amount at least equal to \$1,125,000, in accordance with the criteria set forth in this part. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan at this time, the licensee shall include a decommissioning funding plan in any application for license renewal.
- (c) Each holder of a specific license issued before March 11, 1994, and of a type described in 105 CMR 120.125(C)(3) shall submit, on or before March 11, 1995, a certification of financial assurance for decommissioning or a decommissioning funding plan in accordance with the criteria set forth in 105 CMR 120.125(C)(1) through 120.125(C)(8).
- (d) Waste collectors and waste processors, as defined in 10 CFR part 20, Appendix G must establish an Agency-approved decommissioning funding plan to assure the availability of funds for decommissioning activities conducted over the life of the licensed facility. The decommissioning funding plan must include the cost of disposal of the maximum radioactivity (curies) of radioactive material permitted by the license, and the cost of disposal of the maximum quantity, by volume, of radioactive material that could be present at the licensee's facility at any time, in addition to the cost to remediate the licensee's site to meet the license termination criteria of 105 CMR 120.200. The decommissioning funding plan must be submitted by April 6, 2007.

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(5) Table of Required Amounts of Financial Assurance for Decommissioning by Quantity of Material:

-1	Greater than $10^4$ but less than or equal to $10^5$ times the applicable quantities in 105 CMR 120.196: <i>Appendix B</i> , Table II in unsealed form. (For a combination of isotopes, if R, as defined in 105 CMR 120.125(C)(2), divided by $10^4$ is greater than 1 but R divided by $10^5$ is less than or equal to 1.)	\$1,125,000
-2a	Greater than $10^3$ but less than or equal to $10^4$ times the applicable quantities in 105 CMR 120.196: <i>Appendix B</i> , Table II in unsealed form. (For a combination of isotopes, if R, as defined in 105 CMR 120.125(C)(2), divided by $10^3$ is greater than 1 but R divided by $10^4$ is less than or equal to 1.)	\$225,000
-2b	<u>Greater than 10 mCi but less than 100 mCi of source material</u>	<u>\$225,000</u>
-3	Greater than $10^{10}$ times the applicable quantities in 105 CMR 120.196: <i>Appendix B</i> , Table II in sealed sources or plated foils. (For a combination of isotopes, if R, as defined in 105 CMR 120.125(C)(2), divided by $10^{10}$ is greater than 1.)	\$113,000

(a) Licensees required to submit the \$1,125,000 amount must do so by October 6, 2006.

(b) Licensees required to submit the \$113,000 or \$225,000 amount must do so by April 6, 2007.

(6) Each decommissioning funding plan must contain a cost estimate for decommissioning and a description of the method of assuring funds for decommissioning from 105 CMR 120.125(C)(7), including means of adjusting cost estimates and associated funding levels periodically over the life of the facility. Cost estimates must be adjusted at intervals not to exceed three years. The decommissioning funding plan must also contain a certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning and a signed original of the financial instrument obtained to satisfy the requirements of 105 CMR 120.125(7).

(7) Financial assurance for decommissioning must be provided by one or more of the following methods:

(a) Prepayment. Prepayment is the deposit prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

(b) A Surety Method. A surety method, insurance or other guarantee method. These methods guarantee that decommissioning costs will be paid should the licensee default.

1. A surety method may be in the form of a surety bond, issued by a corporate surety company authorized to transact business in the commonwealth; or

2. An irrevocable letter of credit, or line of credit; or

3. A parent company guarantee of funds for decommissioning costs may be used if the guarantee and test are as contained in 105 CMR 120.198: *Appendix D*. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of 105 CMR 120.125(C).

a. For commercial corporations that issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in

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105 CMR 120.198: *Appendix E.*

b. For commercial companies that do not issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and test are as contained in 105 CMR 120.198: *Appendix F.*

c. For nonprofit entities, such as colleges, universities, and nonprofit hospitals, a guarantee of funds by the applicant or licensee may be used if the guarantee and test are as contained in 105 CMR 120.198: *Appendix G.*

4. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

a. The surety method or insurance must be open-ended or, if written for a specified term, such as five years, must be renewed automatically unless 90 days or more prior to the renewal date, the issuer notifies the Agency, the beneficiary, and the licensee of its intention not to renew. The surety method or insurance must also provide that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the Agency within 30 days after receipt of notification of cancellation.

b. The surety method or insurance must be payable to a trust established for decommissioning costs. The trustee and trust must be acceptable to the Agency. An acceptable trustee includes an appropriate state or federal government agency or an entity that has the authority to act as a trustee and whose trust operations are regulated and examined by a federal or state agency.

c. The surety method or insurance must remain in effect until the Agency has terminated the license.

(c) An External Sinking Fund. An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities. The surety or insurance provisions must be as stated in 105 CMR 120.125(C)(7)(b).

(d) Statement of Intent. In the case of federal, state, or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount pursuant to 105 CMR 120.125(C)(5), and indicating that funds for decommissioning will be obtained when necessary.

(8) Each person licensed under 105 CMR 120.100 shall keep records of information important to the safe and effective decommissioning of the facility in an identified location until the license is terminated by the Agency. If records of relevant information are kept for other purposes, reference to these records and their locations may be used. Information the Agency considers important to decommissioning consists of:

(a) Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas, as in the case of possible seepage into porous materials such as concrete. These records must include any known information on identification of involved nuclides, quantities, forms, and concentrations.

(b) As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and of locations of possible inaccessible contamination such as buried pipes that may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed

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individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.

(c) Except for areas containing only sealed sources (provided the sources have not leaked or no contamination remains after any leak) or radioactive materials having only half-lives of less than 65 days, a list contained in a single document and updated every two years, of the following:

1. all areas designated and formerly designated restricted areas as defined in 105 CMR 120.005;
2. all areas outside of restricted areas that require documentation under 105 CMR 120.125(C)(8)(a);
3. all areas outside of restricted areas where current and previous wastes have been buried as documented under 105 CMR 120.269; and,

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4. all areas outside of restricted areas which contain material such that, if the license expired, the licensee would be required to either decontaminate the area to unrestricted release levels or apply for approval for disposal under 105 CMR 120.252.
- (d) Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.
- (9) The following specific licensees are required to make financial surety arrangements:
  - (a) major processors;
  - (b) waste handling licensees;
  - (c) former U.S. Atomic Energy Commission or NRC licensed facilities; and,
  - (d) all others except persons exempt pursuant to 105 CMR 120.125(C)(10).
- (10) The following persons are exempt from the requirements of 105 CMR 120.125(C)(1):
  - (a) persons authorized to possess no more than 1,000 times the quantity specified in 105 CMR 120.196: *Appendix B, Table 1* or combination of radioactive material listed therein as given in 105 CMR 120.196: *Appendix B, Table 1, Note 1*;
  - (b) persons authorized to possess radioactive noble gases in sealed sources with no radioactive daughter product with half-life greater than 30 days.

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(D)(1)(b).

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~~(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.~~

~~(A) Licensing the Introduction of Radioactive Material into Products in Exempt Concentrations:~~

~~(1) In addition to the requirements set forth in 105 CMR 120.125, a specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of the licensee or another to be transferred to persons exempt under 105 CMR 120.104(A)(1) will be issued if:~~

~~(a) the applicant submits a description of the product or material into which the radioactive material will be introduced, intended use of the radioactive material and the product or material into which it is introduced, method of introduction, initial concentration of the radioactive material in the product or material, control methods to assure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and transfer of the product or material, and estimated concentration of the radioactive material in the product or material at the time of transfer; and,~~

~~(b) the applicant provides reasonable assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in 105 CMR 120.195: Appendix A, that reconcentration of the radioactive material in concentrations exceeding those in 105 CMR 120.195: Appendix A is not likely, that use of lower concentrations is not feasible, and that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by, or application to, a human being.~~

~~(2) Each person licensed under 105 CMR 120.128(A) shall file an annual report with the Agency which shall identify the type and quantity of each product or material into which radioactive material has been introduced during the reporting period; name and address of the person who owned or possessed the product or material, into which radioactive material has been introduced, at the time of introduction; the type and quantity of radionuclide introduced into each such product or material; and the initial concentrations of the radionuclide in the product or material at time of transfer of the radioactive material by the licensee. If no transfers of radioactive material have been made pursuant to 105 CMR 120.128(A) during the reporting period, the report shall so indicate. The report shall cover the year ending June 30<sup>th</sup>, and shall be filed within 30 days thereafter.~~

~~(B) Licensing the Distribution of Radioactive Material in Exempt Quantities:~~

~~(1) An application for a specific license to distribute NARM to persons exempted from 105 CMR 120.000 pursuant to 105 CMR 120.104(B) will be approved if:~~

~~(a) the radioactive material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being;~~

~~(b) the radioactive material is in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and,~~

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- ~~(c) the applicant submits copies of prototype labels and brochures and the Agency approves such labels and brochures.~~
- ~~(2) The license issued under 105 CMR 120.128(B)(1) is subject to the following conditions:~~
- ~~(a) No more than ten exempt quantities shall be sold or transferred in any single transaction. However, an exempt quantity may be composed of fractional parts of one or more of the exempt quantity provided the sum of the fractions shall not exceed unity.~~
- ~~(b) Each exempt quantity shall be separately and individually packaged. No more than ten such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to 105 CMR 120.104(B). The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem (5  $\mu$ Sv) per hour.~~
- ~~(c) The immediate container of each quantity or separately packaged fractional quantity of radioactive material shall bear a durable, legible label which:~~
- ~~1. identifies the radionuclide and the quantity of radioactivity, and~~
  - ~~2. bears the words "Radioactive Material".~~
- ~~(d) In addition to the labeling information required by 105 CMR 120.128(B)(2)(c), the label affixed to the immediate container, or an accompanying brochure, shall:~~
- ~~1. state that the contents are exempt from Licensing State requirements;~~
  - ~~2. bear the words "Radioactive Material - Not for Human Use - Introduction into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or into Products Manufactured for Commercial Distribution is Prohibited - Exempt Quantities Should Not Be Combined"; and~~
  - ~~3. set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material.~~
- ~~(3) Each person licensed under 105 CMR 120.128(B) shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under 105 CMR 120.104(B) or the equivalent regulations of a Licensing State, and stating the kinds and quantities of radioactive material transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the Agency. Each report shall cover the year ending June 30<sup>th</sup>, and shall be filed within 30 days thereafter. If no transfers of radioactive material have been made pursuant to 105 CMR 120.128(B) during the reporting period, the report shall so indicate.~~
- ~~(C) Licensing the Incorporation of Naturally Occurring and Accelerator Produced Radioactive Material into Gas and Aerosol Detectors. An application for a specific license authorizing the incorporation of NARM into gas and aerosol detectors to be distributed to persons exempt under 105 CMR 120.104(C)(3) will be approved if the application satisfies requirements equivalent to those contained in 10 CFR Part 32, § 32.26. The maximum quantity of radium-226 in each device shall not exceed 0.1 microcurie (3.7 kBq).~~
- ~~(D) Licensing Requirements to Manufacture or Initially Transfer Devices Containing Radioactive Material to Persons Generally Licensed Under 105 CMR 120.122(D).~~
- ~~(1) An application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under 105 CMR 120.122(D) or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State will be approved if:~~

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- (a) the applicant satisfies the general requirements of 105 CMR 120.125;
- (b) the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

- 1. the device can be safely operated by persons not having training in radiological protection,
- 2. under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in one year a dose in excess of 10% of the annual limits specified in 105 CMR 120.211(A), and
- 3. under accident conditions such as fire and explosion associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:

- a. Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye 15 rems (150 mSv)
- b. Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than one square centimeter..... 200 rems (2 Sv)
- c. Other organs ..... 50 rems (500 mSv); and,

- (c) each device bears a durable, legible, clearly visible label or labels approved by the Agency, which contain in a clearly identified and separate statement:

- 1. instructions and precautions necessary to assure safe installation, operation, and servicing of the device; documents such as operating and service manuals may be identified in the label and used to provide this information;
- 2. the requirement, or lack of requirement, for leak testing, or for testing any "on-off" mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity; and,
- 3. the information called for in one of the following statements, as appropriate, in the same or substantially similar form:

The receipt, possession, use, and transfer of this device, 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. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited. [The model, serial number, and name of the manufacturer or distributor may be omitted from the label provided the information is elsewhere specified in labeling affixed to the device.]

CAUTION - RADIOACTIVE MATERIAL

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Name of Manufacturer or Distributor

[Note: Devices licensed under 10 CFR 32.53 prior to January 19, 1975 may bear labels authorized by the regulations in effect on January 1, 1975.]

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- (d) each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the isotope and quantity, the words, "Caution-Radioactive Material," the radiation symbol described in 105 CMR 120 237, and the name of the manufacturer or initial distributor.
- (e) each device meeting the criteria of 105 CMR 120 122(D)(3)(m)1., bears a permanent (*e.g.*, embossed, etched, stamped, or engraved) label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, "Caution-Radioactive Material," and, if practicable, the radiation symbol described in 105 CMR 120 237.
- (2) In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the "on-off" mechanism and indicator, if any, or for leakage of radioactive material or for both, the applicant shall include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the "on-off" mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the Agency will consider information which includes, but is not limited to:
- (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 devices or similarly designed and constructed devices.
- (3) In the event the applicant desires that the general licensee under 105 CMR 120.122(D), or under equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the "on-off" mechanism and indicator, or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and basis for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a dose in excess of 10% of the annual limits specified in 105 CMR 120.211(A).
- (4) Each person licensed under 105 CMR 120.128(D) to initially transfer devices to generally licensed persons shall:
- (a) if a device containing radioactive material is to be transferred for use under the general license contained in 105 CMR 120.122(D), each person that is licensed under 105 CMR 120.128(D) shall provide the information specified in 120.128(D)(4) to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:
    - 1. a copy of the general license contained in 105 CMR 120.122(D); if 105 CMR 120.122(D)(3)(b) through (d)

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do not apply to the particular device, those paragraphs may be omitted;

2. a copy of 105 CMR 120.122, 120.009(A), 120.281, and 120.282;
3. a list of the services that can only be performed by a specific licensee; and,
4. information on acceptable disposal options including estimated costs of disposal;

(b) if radioactive material is to be transferred in a device for use under an equivalent general license of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State each person that is licensed under 105 CMR 120.128(D) shall provide the information specified in 105 CMR 120.128(D)(4)(b) to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

1. a copy of NRC or Agreement State regulations equivalent to 105 CMR 120.122(D), 120.009(A), 120.281, and 120.282. If a copy of the 105 CMR 120.000 is provided to a prospective general licensee in lieu of the U.S. Nuclear Regulatory Commission's, Agreement State's, or Licensing State's regulations, it shall be accompanied by a note explaining that use of the device is regulated by the U.S. Nuclear Regulatory Commission, the Agreement State; or Licensing State; if certain paragraphs of the regulations do not apply to the particular device, those paragraphs may be omitted;
2. a list of the services that can only be performed by a specific licensee;
3. information on acceptable disposal options including estimated costs of disposal; and,
4. the name or title, address, and phone number of the contact at the U.S. Nuclear Regulatory Commission, the Agreement State, or Licensing State from which additional information may be obtained;

(c) an alternative approach to informing customers may be proposed by the licensee for approval by the Agency;

(d) each device that is transferred after February 19, 2002 must meet the labeling requirements in 105 CMR 120.128(D)(1)(c) through (e);

(e) if a notification of bankruptcy has been made under 105 CMR 120.131(E) or the license is to be terminated, each person licensed under 105 CMR 120.128(D) shall provide, upon request, to the Agency and to any appropriate Agreement State or NRC, records of final disposition required under 105 CMR 120.128(D)(5)(c).

(5) Each person licensed under 105 CMR 120.128(D) to initially transfer devices to generally licensed persons shall comply with the requirements of 105 CMR 120.128(D)(5).

(a) The person shall report to the Agency all transfers of devices to persons for use under the general license in 105 CMR 120.122(D) and all receipts of devices from persons licensed under 105 CMR 120.122(D). The report must be submitted on a quarterly basis on NRC Form 653 - "Transfers of Industrial Devices Report" or in a clear and legible report containing all of the data required by the form.

1. The required information for transfers to general licensees includes:

- a. the identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use;
- b. the name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

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- c. the date of transfer;
    - d. the type, model number, and serial number of the device transferred; and,
    - e. the quantity and type of byproduct material contained in the device.
  2. If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).
  3. For devices received from a 105 CMR 120.122(D) general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.
  4. If the licensee makes changes to a device possessed by a 105 CMR 120.122(D) general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.
  5. The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.
  6. The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.
  7. If no transfers have been made to U.S. Nuclear Regulatory Commission Licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission.
  8. If no transfers have been made to general licensees within a particular State during the reporting period, this information shall be reported to the responsible State agency upon request of that agency.
- (b) The person shall report all transfers of devices to persons for use under a general license in the U.S. Nuclear Regulatory Commission's, an Agreement State's, or a Licensing State's regulations that are equivalent to 105 CMR 120.122(D) and all receipts of devices from general licensees in the U.S. Nuclear Regulatory Commissions, an Agreement State's, or a Licensing State's jurisdiction to the responsible agency. The report must be submitted on Form 653 - "Transfers of Industrial Devices Report" or in a clear and legible report containing all of the data required by the form.
1. The required information for transfers to general licensees includes:
    - a. the identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use;
    - b. the name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;
    - c. the date of transfer;
    - d. the type, model number, and serial number of the device transferred; and,
    - e. the quantity and type of byproduct material contained in the device.
  2. If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

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3. For devices received from a general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.
  4. If the licensee makes changes to a device possessed by a general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.
  5. The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.
  6. The report must clearly identify the specific licensee submitting the report and must include the license number of the specific licensee.
  7. If no transfers have been made to U.S. Nuclear Regulatory Commission Licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission.
  8. If no transfers have been made to general licensees within a particular State during the reporting period, this information shall be reported to the responsible State agency upon request of that agency.
- (c) The person shall maintain all information concerning transfers and receipts of devices that supports the reports required by 105 CMR 120.128(D)(5). Records required by 105 CMR 120.128(D)(5)(c) must be maintained for a period of three years following the date of the recorded event.

(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.

(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

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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

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CAUTION - RADIOACTIVE MATERIAL

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Name of manufacturer or initial transferor

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(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.
  - (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

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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) ~~241(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.

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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.

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

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### (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:
  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,

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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, 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.

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(K) Manufacture and Distribution of Generators or Reagent Kits for Preparation of Radiopharmaceuticals Containing Radioactive Material.<sup>5</sup> 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 ~~33~~ will be approved if:

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

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<sup>5</sup> 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 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;

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(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 120.4 000 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 120.4 000 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.

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(C) Each person licensed by the Agency pursuant to 105 CMR 120.4000 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.

(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(D)(d) for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.

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

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(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.

(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)(c).

### 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;

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(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,

(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.

### ~~(B) Licenses of Naturally Occurring and Accelerator Produced Radioactive Material.~~

~~(1) Subject to 105 CMR 120.000, any person who holds a specific license from a Licensing 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(B)(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(B)(1) except by transfer to a person:~~

~~1. specifically licensed by the Agency or by another Licensing State to receive such material; or,~~

~~2. exempt from the requirements for a license for such material under 105 CMR 120.104.~~

~~(2) Notwithstanding the provisions of 105 CMR 120.190(B)(1), any person who holds a specific license issued by a Licensing 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~~

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~~of the specific license issued to such person by a Licensing 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,~~

~~(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.~~

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~~(3) The Agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by a Licensing 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) ~~and 120.190(B)~~ 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.

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120.195: Appendix A -- Exempt Concentrations

Element (Atomic Number)	Isotope	Column I Gas Concentration $\mu\text{Ci/ml}$ <u>1/</u>	Column II Liquid and solid concentration $\mu\text{Ci/ml}$ <u>2/</u>
Antimony (51)	Sb-122		$3 \times 10^{-4}$
	Sb-124		$2 \times 10^{-4}$
	Sb-125		$1 \times 10^{-3}$
Argon (18)	Ar-37	$1 \times 10^{-3}$	
	Ar-41	$4 \times 10^{-7}$	
Arsenic (33)	As-73		$5 \times 10^{-3}$
	As-74		$5 \times 10^{-4}$
	As-76		$2 \times 10^{-4}$
	As-77		$8 \times 10^{-4}$
Barium (56)	Ba-131		$2 \times 10^{-3}$
	Ba-140		$3 \times 10^{-4}$
Beryllium (4)	Be-7		$2 \times 10^{-2}$
Bismuth (83)	Bi-206		$4 \times 10^{-4}$
Bromine (35)	Br-82	$4 \times 10^{-7}$	$3 \times 10^{-3}$
Cadmium (48)	Cd-109		$2 \times 10^{-3}$
	Cd-115m		$3 \times 10^{-4}$
	Cd-115		$3 \times 10^{-4}$
Calcium (20)	Ca-45		$9 \times 10^{-5}$
	Ca-47		$5 \times 10^{-4}$
Carbon (6)	C-14	$1 \times 10^{-6}$	$8 \times 10^{-3}$
Cerium (58)	Ce-141		$9 \times 10^{-4}$
	Ce-143		$4 \times 10^{-4}$
	Ce-144		$1 \times 10^{-4}$
Cesium (55)	Cs-131		$2 \times 10^{-2}$
	Cs-134m		$6 \times 10^{-2}$
	Cs-134		$9 \times 10^{-5}$

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Element (Atomic Number)	Isotope	Column I Gas Concentration $\mu\text{Ci/ml}$ <u>1</u> /	Column II Liquid and solid concentration $\mu\text{Ci/ml}$ <u>2</u> /
Chlorine (17)	Cl-38	$9 \times 10^{-7}$	$4 \times 10^{-3}$
Chromium (24)	Cr-51		$2 \times 10^{-2}$
Cobalt (27)	Co-57		$5 \times 10^{-3}$
	Co-58		$1 \times 10^{-3}$
	Co-60		$5 \times 10^{-4}$
Copper (29)	Cu-64		$3 \times 10^{-3}$
Dysprosium (66)	Dy-165		$4 \times 10^{-3}$
	Dy-166		$4 \times 10^{-4}$
Erbium (68)	Er-169		$9 \times 10^{-4}$
	Er-171		$1 \times 10^{-3}$
Europium (63)	Eu-152/ (9.2h)		$6 \times 10^{-4}$
	Eu-155		$2 \times 10^{-3}$
Fluorine (9)	F-18	$2 \times 10^{-6}$	$8 \times 10^{-3}$
Gadolinium (64)	Gd-153		$2 \times 10^{-3}$
	Gd-159		$8 \times 10^{-4}$
Gallium (31)	Ga-72		$4 \times 10^{-4}$
Germanium (32)	Ge-71		$2 \times 10^{-2}$
Gold (79)	Au-196		$2 \times 10^{-3}$
	Au-198		$5 \times 10^{-4}$
	Au-199		$2 \times 10^{-3}$
Hafnium (72)	Hf-181		$7 \times 10^{-4}$
Hydrogen (1)	H-3	$5 \times 10^{-6}$	$3 \times 10^{-2}$
Indium (49)	In-113m		$1 \times 10^{-2}$
	In-114m		$2 \times 10^{-4}$
Iodine (53)	I-126	$3 \times 10^{-9}$	$2 \times 10^{-5}$

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Element (Atomic Number)	Isotope	Column I Gas Concentration $\mu\text{Ci/ml}$ <u>1</u> /	Column II Liquid and solid concentration $\mu\text{Ci/ml}$ <u>2</u> /
	I-131	$3 \times 10^{-9}$	$2 \times 10^{-5}$
	I-132	$8 \times 10^{-8}$	$6 \times 10^{-4}$
	I-133	$1 \times 10^{-8}$	$7 \times 10^{-5}$
	I-134	$2 \times 10^{-7}$	$1 \times 10^{-3}$
Iridium (77)	Ir-190		$2 \times 10^{-3}$
	Ir-192		$4 \times 10^{-4}$
	Ir-194		$3 \times 10^{-4}$
Iron (26)	Fe-55		$8 \times 10^{-3}$
	Fe-59		$6 \times 10^{-4}$
Krypton (36)	Kr-85m	$1 \times 10^{-6}$	
	Kr-85	$3 \times 10^{-6}$	
Lanthanum (57)	La-140		$2 \times 10^{-4}$
Lead (82)	Pb-203		$4 \times 10^{-3}$
Lutetium (71)	Lu-177		$1 \times 10^{-3}$
Manganese (25)	Mn-52		$3 \times 10^{-4}$
	Mn-54		$1 \times 10^{-3}$
	Mn-56		$1 \times 10^{-3}$
Mercury (80)	Hg-197m		$2 \times 10^{-3}$
	Hg-197		$3 \times 10^{-3}$
	Hg-203		$2 \times 10^{-4}$
Molybdenum (42)	Mo-99		$2 \times 10^{-3}$
Neodymium (60)	Nd-147		$6 \times 10^{-4}$
	Nd-149		$3 \times 10^{-3}$
Nickel (28)	Ni-65		$1 \times 10^{-3}$
Niobium (Columbium) (41)	Nb-95		$1 \times 10^{-3}$
	Nb-97		$9 \times 10^{-3}$
Osmium (76)	Os-185		$7 \times 10^{-4}$
	Os-191m		$3 \times 10^{-2}$

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Element (Atomic Number)	Isotope	Column I Gas Concentration $\mu\text{Ci/ml}$ <u>1</u> /	Column II Liquid and solid concentration $\mu\text{Ci/ml}$ <u>2</u> /
	Os-191 Os-193		$2 \times 10^{-3}$ $6 \times 10^{-4}$
Palladium (46)	Pd-103 Pd-109		$3 \times 10^{-3}$ $9 \times 10^{-4}$
Phosphorus (15)	P-32 P-33		$2 \times 10^{-4}$ $1 \times 10^{-3}$
Platinum (78)	Pt-191 Pt-193m Pt-197m Pt-197		$1 \times 10^{-3}$ $1 \times 10^{-2}$ $1 \times 10^{-2}$ $1 \times 10^{-3}$
Potassium (19)	K-42		$3 \times 10^{-3}$
Praseodymium (59)	Pr-142 Pr-143		$3 \times 10^{-4}$ $5 \times 10^{-4}$
Promethium (61)	Pm-147 Pm-149		$2 \times 10^{-3}$ $4 \times 10^{-4}$
Rhenium (75)	Re-183 Re-186 Re-188		$6 \times 10^{-3}$ $9 \times 10^{-4}$ $6 \times 10^{-4}$
Rhodium (45)	Rh-103m Rh-105		$1 \times 10^{-1}$ $1 \times 10^{-3}$
Rubidium (37)	Rb-86		$7 \times 10^{-4}$
Ruthenium (44)	Ru-97 Ru-103 Ru-105 Ru-106		$4 \times 10^{-3}$ $8 \times 10^{-4}$ $1 \times 10^{-3}$ $1 \times 10^{-4}$
Samarium (62)	Sm-153		$8 \times 10^{-4}$
Scandium (21)	Sc-46 Sc-47		$4 \times 10^{-4}$ $9 \times 10^{-4}$

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Element (Atomic Number)	Isotope	Column I Gas Concentration $\mu\text{Ci/ml}$ <u>1</u> /	Column II Liquid and solid concentration $\mu\text{Ci/ml}$ <u>2</u> /
	Sc-48		$3 \times 10^{-4}$
Selenium (34)	Se-75		$3 \times 10^{-3}$
Silicon (14)	Si-31		$9 \times 10^{-3}$
Silver (47)	Ag-105		$1 \times 10^{-3}$
	Ag-110m		$3 \times 10^{-4}$
	Ag-111		$4 \times 10^{-4}$
Sodium (11)	Na-24		$2 \times 10^{-3}$
Strontium (38)	Sr-85		$1 \times 10^{-3}$
	Sr-89		$1 \times 10^{-4}$
	Sr-91		$7 \times 10^{-4}$
	Sr-92		$7 \times 10^{-4}$
Sulfur (16)	S-35	$9 \times 10^{-8}$	$6 \times 10^{-4}$
Tantalum (73)	Ta-182		$4 \times 10^{-4}$
Technetium (43)	Tc-96m		$1 \times 10^{-1}$
	Tc-96		$1 \times 10^{-3}$
Tellurium (52)	Te-125m		$2 \times 10^{-3}$
	Te-127m		$6 \times 10^{-4}$
	Te-127		$3 \times 10^{-3}$
	Te-129m		$3 \times 10^{-4}$
	Te-131m		$6 \times 10^{-4}$
	Te-132		$3 \times 10^{-4}$
Terbium (65)	Tb-160		$4 \times 10^{-4}$
Thallium (81)	Tl-200		$4 \times 10^{-3}$
	Tl-201		$3 \times 10^{-3}$
	Tl-202		$1 \times 10^{-3}$
	Tl-204		$1 \times 10^{-3}$
Thulium (69)	Tm-170		$5 \times 10^{-4}$
	Tm-171		$5 \times 10^{-3}$

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Element (Atomic Number)	Isotope	Column I Gas Concentration $\mu\text{Ci/ml}$ <u>1</u> /	Column II Liquid and solid concentration $\mu\text{Ci/ml}$ <u>2</u> /
Tin (50)	Sn-113		$9 \times 10^{-4}$
	Sn-125		$2 \times 10^{-4}$
Tungsten (Wolfram) (74)	W-181		$4 \times 10^{-3}$
	W-187		$7 \times 10^{-4}$
Vanadium (23)	V-48		$3 \times 10^{-4}$
Xenon (54)	Xe-131m	$4 \times 10^{-6}$	
	Xe-133	$3 \times 10^{-6}$	
	Xe-135	$1 \times 10^{-6}$	
Ytterbium (70)	Yb-175		$1 \times 10^{-3}$
Yttrium (39)	Y-90		$2 \times 10^{-4}$
	Y-91m		$3 \times 10^{-2}$
	Y-91		$3 \times 10^{-4}$
	Y-92		$6 \times 10^{-4}$
	Y-93		$3 \times 10^{-4}$
Zinc (30)	Zn-65		$1 \times 10^{-3}$
	Zn-69m		$7 \times 10^{-4}$
	Zn-69		$2 \times 10^{-2}$
Zirconium (40)	Zr-95		$6 \times 10^{-4}$
	Zr-97		$2 \times 10^{-4}$
Beta and/or gamma emitting radioactive material not listed above with half-life of less than three years.		$1 \times 10^{-10}$	$1 \times 10^{-6}$

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120.195: continued

Note 1: Many radioisotopes transform into isotopes which are also radioactive. In expressing the concentrations in 105 CMR 120.195: *Appendix A*, the activity stated is that of the parent isotope and takes into account the daughters.

Note 2: For purposes of 105 CMR 120.104(A) where there is involved a combination of isotopes, the limit for the combination should be derived as follows: Determine for each isotope in the product the ratio between the radioactivity concentration present in the product and the exempt radioactivity concentration established in 120.195: *Appendix A* for the specific isotope when not in combination. The sum of such ratios may not exceed "1".

Example: 
$$\frac{\text{Concentration of Isotope A in Product}}{\text{Exempt concentration of Isotope A}}$$

$$\frac{\text{Concentration of Isotope B in Product}}{\text{Exempt concentration of Isotope B}} \leq 1$$

Note 3: To convert  $\mu\text{Ci/ml}$  to SI units of megabecquerels per liter multiply the above values by 37.

Example: Zirconium (40) Zr-97 ( $2 \times 10^{-4} \mu\text{Ci/ml}$  multiplied by 37 is equivalent to  $74 \times 10^{-4} \text{MBq/l}$ )

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120.196: Appendix B -- Table I Exempt Quantities

<u>Radioactive</u> <u>Material</u>	<u>Micro-</u> <u>curies</u>
Antimony-122 (Sb 122)	100
Antimony-124 (Sb 124)	10
Antimony-125 (Sb 125)	10
Arsenic-73 (As 73)	100
Arsenic-74 (As 74)	10
Arsenic-76 (As 76)	10
Arsenic-77 (As 77)	100
Barium-131 (Ba 131)	10
Barium-133 (Ba 133)	10
Barium-140 (Ba 140)	10
Bismuth-210 (Bi 210)	1
Bromine-82 (Br 82)	10
Cadmium-109 (Cd 109)	10
Cadmium-115m (Cd 115m)	10
Cadmium-115 (Cd 115)	100
Calcium-45 (Ca 45)	10
Calcium-47 (Ca 47)	10
Carbon-14 (C 14)	100
Cerium-141 (Ce 141)	100
Cerium-143 (Ce 143)	100
Cerium-144 (Ce 144)	1
Cesium-129 (Cs 129)	100
Cesium-131 (Cs 131)	1,000
Cesium-134m (Cs 134m)	100
Cesium-134 (Cs 134)	1
Cesium-135 (Cs 135)	10
Cesium-136 (Cs 136)	10
Cesium-137 (Cs 137)	10
Chlorine-36 (Cl 36)	10

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Chlorine-38 (Cl 38)	10
Chromium-51 (Cr 51)	1,000
Cobalt-57 (Co 57)	100
Cobalt-58m (Co 58m)	10
Cobalt-58 (Co 58)	10
Cobalt-60 (Co 60)	1
Copper-64 (Cu 64)	100
Dysprosium-165 (Dy 165)	10
Dysprosium-166 (Dy 166)	100
Erbium-169 (Er 169)	100
Erbium-171 (Er 171)	100
Europium-152 (Eu 152)9.2h	100
Europium-152 (Eu 152)13 yr	1
Europium-154 (Eu 154)	1
Europium-155 (Eu 155)	10
Fluorine-18 (F 18)	1,000
Gadolinium-153 (Gd 153)	10
Gadolinium-159 (Gd 159)	100
Gallium-67 (Ga 67)	100
Gallium-72 (Ga 72)	10
Germanium-68 (Ge 68)	10
Germanium-71 (Ge 71)	100
Gold-195 (Au 195)	10
Gold-198 (Au 198)	100
Gold-199 (Au 199)	100
Hafnium-181 (Hf 181)	10
Holmium-166 (Ho 166)	100

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120.196 Table 1: continued

Radioactive <u>Material</u>	Micro- <u>curies</u>
Hydrogen-3 (H 3)	1,000
Indium-111 (In 111)	100
Indium-113m (In 113m)	100
Indium-114m (In 114m)	10
Indium-115m (In 115m)	100
Indium-115 (In 115)	10
Iodine-123 (I 123)	100
Iodine-125 (I 125)	1
Iodine-126 (I 126)	1
Iodine-129 (I 129)	0.1
Iodine-131 (I 131)	1
Iodine-132 (I 132)	10
Iodine-133 (I 133)	1
Iodine-134 (I 134)	10
Iodine-135 (I 135)	10
Iridium-192 (Ir 192)	10
Iridium-194 (Ir 194)	100
Iron-52 (Fe 52)	10
Iron-55 (Fe 55)	100
Iron-59 (Fe 59)	10
Krypton-85 (Kr 85)	100
Krypton-87 (Kr 87)	10
Lanthanum-140 (La 140)	10
Lutetium-177 (Lu 177)	100
Manganese-52 (Mn 52)	10
Manganese-54 (Mn 54)	10
Manganese-56 (Mn 56)	10
Mercury-197m (Hg 197m)	100
Mercury-197 (Hg 197)	100

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Mercury-203 (Hg 203)	10
Molybdenum-99 (Mo 99)	100
Neodymium-147 (Nd 147)	100
Neodymium-149 (Nd 149)	100
Nickel-59 (Ni 59)	100
Nickel-63 (Ni 63)	10
Nickel-65 (Ni 65)	100
Niobium-93m (Nb 93m)	10
Niobium-95 (Nb 95)	10
Niobium-97 (Nb 97)	10
Osmium-185 (Os 185)	10
Osmium-191m (Os 191m)	100
Osmium-191 (Os 191)	100
Osmium-193 (Os 193)	100
Palladium-103 (Pd 103)	100
Palladium-109 (Pd 109)	100
Phosphorus-32 (P 32)	10
Phosphorus-33 (P 33)	100
Platinum-191 (Pt 191)	100
Platinum-193m (Pt 193m)	100
Platinum-193 (Pt 193)	100
Platinum-197m (Pt 197m)	100
Platinum-197 (Pt 197)	100
Polonium-210 (Po 210)	0.1
Potassium-42 (K 42)	10
Potassium-43 (K 43)	10
Praseodymium-142 (Pr 142)	100
Praseodymium-143 (Pr 143)	100

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120.196 Table 1: continued

Radioactive <u>Material</u>	Micro- <u>curies</u>
Promethium-147 (Pm 147)	10
Promethium-149 (Pm 149)	10
Rhenium-186 (Re 186)	100
Rhenium-188 (Re 188)	100
Rhodium-103m (Rh 103m)	100
Rhodium-105 (Rh 105)	100
Rubidium-81 (Rb 81)	10
Rubidium-86 (Rb 86)	10
Rubidium-87 (Rb 87)	10
Ruthenium-97 (Ru 97)	100
Ruthenium-103 (Ru 103)	10
Ruthenium-105 (Ru 105)	10
Ruthenium-106 (Ru 106)	1
Samarium-151 (Sm 151)	10
Samarium-153 (Sm 153)	100
Scandium-46 (Sc 46)	10
Scandium-47 (Sc 47)	100
Scandium-48 (Sc 48)	10
Selenium-75 (Se 75)	10
Silicon-31 (Si 31)	100
Silver-105 (Ag 105)	10
Silver-110m (Ag 110m)	1
Silver-111 (Ag 111)	100
Sodium-22 (Na 22)	10
Sodium-24 (Na 24)	10
Strontium-85 (Sr 85)	10
Strontium-89 (Sr 89)	1
Strontium-90 (Sr 90)	0.1
Strontium-91 (Sr 91)	10

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Strontium-92 (Sr 92)	10
Sulphur-35 (S 35)	100
Tantalum-182 (Ta 182)	10
Technetium-96 (Tc 96)	10
Technetium-97m (Tc 97m)	100
Technetium-97 (Tc 97)	100
Technetium-99m (Tc 99m)	100
Technetium-99 (Tc 99)	10
Tellurium-125m (Te 125m)	10
Tellurium-127m (Te 127m)	10
Tellurium-127 (Te 127)	100
Tellurium-129m (Te 129m)	10
Tellurium-129 (Te 129)	100
Tellurium-131m (Te 131m)	10
Tellurium-132 (Te 132)	10
Terbium-160 (Tb 160)	10
Thallium-200 (Tl 200)	100
Thallium-201 (Tl 201)	100
Thallium-202 (Tl 202)	100
Thallium-204 (Tl 204)	10
Thulium-170 (Tm 170)	10
Thulium-171 (Tm 171)	10
Tin-113 (Sn 113)	10
Tin-125 (Sn 125)	10
Tungsten-181 (W 181)	10
Tungsten-185 (W 185)	10
Tungsten-187 (W 187)	100
Vanadium-48 (V 48)	10

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120.196 Table 1: continued

Radioactive <u>Material</u>	Micro- <u>curies</u>
Xenon-131m (Xe 131m)	1,000
Xenon-133 (Xe 133)	100
Xenon-135 (Xe 135)	100
Ytterbium-175 (Yb 175)	100
Yttrium-87 (Y 87)	10
Yttrium-88 (Y 88)	10
Yttrium-90 (Y 90)	10
Yttrium-91 (Y 91)	10
Yttrium-92 (Y 92)	100
Yttrium-93 (Y 93)	100
Zinc-65 (Zn 65)	10
Zinc-69m (Zn 69m)	100
Zinc-69 (Zn 69)	1,000
Zirconium-93 (Zr 93)	10
Zirconium-95 (Zr 95)	10
Zirconium-97 (Zr 97)	10
Any radioactive material not listed above other than alpha-emitting radioactive material	0.1

Note 1: For purposes of 105 CMR 100.125(C)(3) where there is involved a combination of isotopes, the limit for the combination should be derived as follows:

Determine the amount of each isotope possessed and 1,000 times the amount in 105 CMR 120.196: *Appendix B, Table 1* for each of those isotopes when not in combination. The sum of the ratios of those quantities may not exceed 1.

Example:

**Error!**

*for Isotope A*

*for Isotope B*

Note 2: To convert microcuries ( $\mu\text{Ci}$ ) to SI units of kilobecquerels (kBq), multiply the above values by 37.

Example: Zirconium-97 (10  $\mu\text{Ci}$  multiplied by 37 is equivalent to 370 kBq).

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120.196: Table II -- Quantities For Use With 105 CMR 120.125(C)(1)

<u>Material</u>	<u>Microcuries</u>
Americium-241	0.01
Antimony-122	100.00
Antimony-124	10.00
Antimony-125	10.00
Arsenic-73	100.00
Arsenic-74	10.00
Arsenic-76	10.00
Arsenic-77	100.00
Barium-131	10.00
Barium-133	10.00
Barium-140	10.00
Bismuth-210	1.00
Bromine-82	10.00
Cadmium-109	10.00
Cadmium-115m	10.00
Cadmium-115	100.00
Calcium-45	10.00
Calcium-47	10.00
Carbon-14	100.00
Cerium-141	100.00
Cerium-143	100.00
Cerium-144	1.00
Cesium-131	1,000.00
Cesium-134m	100.00
Cesium-134	1.0
Cesium-135	10.00
Cesium-136	10.00
Cesium-137	10.00
Chlorine-36	10.00
Chlorine-38	10.00
Cobalt-57	10.00
Chromium-51	1,000.00
Cobalt-58m	10.00
Cobalt-58	10.00
Cobalt-60	1.00
Copper-64	100.00
Dysprosium-165	10.00
Dysprosium-166	100.00
Erbium-169	100.00
Erbium-171	100.00
Europium-152 (9.2 h)	100.00
Europium-152 (13 yr)	1.00
Europium-154	1.00

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Europium-155	10.00
Fluorine-18	1,000.00
Gadolinium-153	10.00
Gadolinium-159	100.00
Gallium-72	10.00
Germanium-71	100.00
Gold-198	100.00
Gold-199	100.00
Hafnium-181	10.00
Holmium-166	100.00
Hydrogen-3	1,000.00
Indium-113m	100.00
Indium-114m	10.00
Indium-115m	100.00
Indium-115	10.00
Iodine-125	1.00

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120.196 Table II: continued

<u>Material</u>	<u>Microcuries</u>
Iodine-126	1.00
Iodine-129	0.1
Iodine-131	1.0
Iodine-132	10.00
Iodine-133	1.00
Iodine-134	10.00
Iodine-135	10.00
Iridium-192	10.00
Iridium-194	100.00
Iron-55	100.00
Iron-59	10.00
Krypton-85	100.00
Krypton-87	10.00
Lanthanum-140	10.00
Lutetium-177	100.00
Manganese-52	10.00
Manganese-54	10.00
Manganese-56	10.00
Mercury-197m	100.00
Mercury-197	100.00
Mercury-203	10.00
Molybdenum-99	100.00
Neodymium-147	100.00
Neodymium-149	100.00
Nickel-59	100.00
Nickel-63	10.00
Nickel-65	100.00
Niobium-93m	10.00
Niobium-95	10.00
Niobium-97	10.00
Osmium-185	10.00
Osmium-191m	100.00
Osmium-191	100.00
Osmium-193	100.00
Palladium-103	100.00
Palladium-109	100.00
Phosphorus-32	10.00
Phosphorus-33	100.00
Platinum-191	100.00
Platinum-193m	100.00
Platinum-193	100.00
Platinum-197m	100.00

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Platinum-197	100.00
Plutonium-239	0.01
Polonium-210	0.1
Potassium-42	10.00
Praseodymium-142	100.00
Praseodymium-143	100.00
Promethium-147	10.00
Promethium-149	10.00
Radium-226	0.01
Rhenium-186	100.00
Rhenium-188	100.00
Rhodium-103m	100.00
Rhodium-105	100.00
Rubidium-86	10.00
Rubidium-87	10.00
Ruthenium-97	100.00

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120.196 Table II: continued

<u>Material</u>	<u>Microcuries</u>
Ruthenium-103	10.00
Ruthenium-105	10.00
Ruthenium-106	1.00
Samarium-151	10.00
Samarium-153	100.00
Scandium-46	10.00
Scandium-47	100.00
Scandium-48	10.00
Selenium-75	10.00
Silicon-31	100.00
Silver-105	10.00
Silver-110m	1.00
Silver-111	100.00
Sodium-22	1.0
Sodium-24	10.00
Strontium-85	10.00
Strontium-89	1.00
Strontium-90	0.1
Strontium-91	10.00
Strontium-92	10.00
Sulphur-35	100.00
Tantalum-182	10.00
Technetium-96	10.00
Technetium-97m	100.00
Technetium-97	100.00
Technetium-99m	100.00
Technetium-99	10.00
Tellurium-125m	10.00
Tellurium-127m	10.00
Tellurium-127	100.00
Tellurium-129m	10.00
Tellurium-129	100.00
Tellurium-131m	10.00
Tellurium-132	10.00
Terbium-160	10.00
Thallium-200	100.00
Thallium-201	100.00
Thallium-202	100.00
Thallium-204	10.00
Thorium (natural)	100.00
Thulium-170	10.00
Thulium-171	10.00

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Tin-113	10.00
Tin-125	10.00
Tungsten-181	10.00
Tungsten-185	10.00
Tungsten-187	100.00
Uranium (natural)	100.00
Uranium-233	0.01
Uranium-234/235	0.01
Vanadium-48	10.00
Xenon-131m	1,000.00
Xenon-133	100.00
Xenon-135	100.00
Ytterbium-175	100.00
Yttrium-90	10.00
Yttrium-91	10.00
Yttrium-92	100.00

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120.196 Table II: continued

<u>Material</u>	<u>Microcuries</u>
Yttrium-93	100.00
Zinc-65	10.00
Zinc-69m	100.00
Zinc-69	1,000.00
Zirconium-93	10.00
Zirconium-95	10.00
Zirconium-97	10.00
Any alpha-emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition	0.01
Any radionuclide other than alpha-emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition	0.1

Note: For purposes of 105 CMR 120.125(C)(1), where there is involved a combination of radionuclides in known amounts, the limit for the combination should be derived as follows: Determine, for each radionuclide in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific radionuclide when not in combination. The sum of such ratios for all the radionuclides in the combination is R.

Note: To convert microcuries ( $\mu\text{Ci}$ ) to SI units of kilobecquerels (kBq), multiply the above values by 37.

Example: Zirconium-97 ( $10 \mu\text{Ci}$ ) ( $37$ ) = 370 kBq.  
 ( $10 \mu\text{Ci}$  multiplied by 37 is equivalent to 370 kBq)

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120.196: Table III Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release

	<u>Radioactive Material</u> <sup>1</sup>	<u>Release fraction</u>	<u>Quantity(Ci)</u>
	Actinium-228	0.001	4,000
	Americium-241	0.001	2
	Americium-242	0.001	2
	Americium-243	0.001	2
	Antimony-124	0.01	4,000
	Antimony-126	0.01	6,000
	Barium-133	0.01	10,000
	Barium-140	0.01	30,000
	Bismuth-207	0.01	5,000
	Bismuth-210	0.01	600
	Cadmium-109	0.01	1,000
	Cadmium-113	0.01	80
	Calcium-45	0.01	20,000
	Californium-252	0.001	9 (20mg)
	Carbon-14	0.01	50,000
		Non CO	
	Cerium-141	0.01	10,000
	Cerium-144	0.01	300
	Cesium-134	0.01	2,000
	Cesium-137	0.01	3,000
	Chlorine-36	0.5	100
	Chromium-51	0.01	300,000
	Cobalt-60	0.001	5,000

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	Copper-64	0.01	200,000
	Curium-242	0.001	60
	Curium-243	0.001	3
	Curium-244	0.001	4
	Curium-245	0.001	2
	Europium-152	0.01	500
	Europium-154	0.01	400
	Europium-155	0.01	3,000
	Germanium-68	0.01	2,000
	Gadolinium-153	0.01	5,000
	Gold-198	0.01	30,000
	Hafnium-172	0.01	400
	Hafnium-181	0.01	7,000
	Holmium-166m	0.01	100
	Hydrogen-3	0.5	20,000
	Indium-114m	0.01	1,000
	Iodine-125	0.5	10
	Iodine-131	0.5	10
	Iridium-192	0.001	40,000
	Iron-55	0.01	40,000
	Iron-59	0.01	7,000
	Krypton-85	1.0	6000000
	Lead-210	0.01	8
	Manganese-56	0.01	60,000
	Mercury-203	0.01	10,000
	Molybdenum-99	0.01	30,000
	Neptunium-237	0.001	2

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	Nickel-63	0.01	20,000
	Niobium-94	0.01	300
	Phosphorus-32	0.5	100
_____			
<sup>1</sup> For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material in Table III exceeds one.			

120.196 Table III: continued

	<u>Radioactive Material</u> <sup>1</sup>	<u>Release fraction</u>	<u>Quantity(Ci)</u>
	Phosphorus-33	0.5	1,000
	Polonium-210	0.01	10
	Potassium-42	0.01	9,000
	Promethium-145	0.01	4,000
	Promethium-147	0.01	4,000
	<u>Radium-226</u>	<u>0.001</u>	<u>100</u>
	Ruthenium-106	0.01	200
	Samarium-151	0.01	4,000
	Scandium-46	0.01	3,000
	Selenium-75	0.01	10,000
	Silver-110m	0.01	1,000
	Sodium-22	0.01	9,000
	Sodium-24	0.01	10,000
	Strontium-89	0.01	3,000
	Strontium-90	0.01	90
	Sulphur-35	0.5	900
	Technetium-99	0.01	10,000

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	Technetium-99m	0.01	400,000
	Tellurium-127m	0.01	5,000
	Tellurium-129m	0.01	5,000
	Terbium-160	0.01	4,000
	Thulium-170	0.01	4,000
	Tin-113	0.01	10,000
	Tin-123	0.01	3,000
	Tin-126	0.01	1,000
	Titanium-44	0.01	100
	Vanadium-48	0.01	7,000
	Xenon-133	1.0	900,000
	Yttrium-91	0.01	2,000
	Zinc-65	0.01	5,000
	Zirconium-93	0.01	400
	Zirconium-95	0.01	5,000
	Any other beta-gamma emitter	0.01	10,000
	Mixed fission products	0.01	1,000
	Mixed corrosion products	0.01	10,000
	Contaminated equipment $\beta$ - $\gamma$	0.001	10,000
	Irradiated material, any form		
	other than solid noncombustible	0.01	1,000
	Irradiated material, solid		
	noncombustible	0.001	10,000
	Mixed radioactive waste, $\beta$ - $\gamma$	0.01	1,000
	Packaged mixed waste <sup>3</sup>	0.001	10,000
	Contaminated equipment, alpha	0.0001	20
	Any other alph emitter	0.001	2

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	Packaged waste alpha <sup>2</sup>	0.0001	20
	Combinations of radioactive		
	materials listed <sup>1</sup>	-----	----

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- <sup>1</sup> For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material in Table III exceeds one.
  - <sup>2</sup> For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for the material in Table III exceeds one.
  - <sup>3</sup> Waste packaged in Type B containers does not require an emergency plan.

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120.197: Appendix C -- Limits for Broad Licenses

RADIOACTIVE MATERIAL	COLUMN I CURIES	COLUMN II CURIES
Antimony-122	1.0	0.01
Antimony-124	1.0	0.01
Antimony-125	1.0	0.01
Arsenic-73	10.0	0.1
Arsenic-74	1.0	0.01
Arsenic-76	1.0	0.01
Arsenic-77	10.0	0.1
Barium-131	10.0	0.1
Barium-140	1.0	0.01
Beryllium-7	10.0	0.1
Bismuth-210	0.1	0.001
Bromine-82	10.0	0.1
Cadmium-109	1.0	0.01
Cadmium-115m	1.0	0.01
Cadmium-115	10.0	0.1
Calcium-45	1.0	0.01
Calcium-47	10.0	0.1
Carbon-14	100.0	1.0
Cerium-141	10.0	0.1
Cerium-143	10.0	0.1
Cerium-144	0.1	0.001
Cesium-131	100.0	1.0
Cesium-134m	100.0	1.0
Cesium-134	0.1	0.001
Cesium-135	1.0	0.01

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RADIOACTIVE MATERIAL	COLUMN I CURIES	COLUMN II CURIES
Cesium-136	10.0	0.1
Cesium-137	0.1	0.001
Chlorine-36	1.0	0.01
Chlorine-38	100.0	1.0
Chromium-51	100.0	1.0
Cobalt-57	10.0	0.1
Cobalt-58m	100.0	1.0
Cobalt-58	1.0	0.01
Cobalt-60	0.1	0.001
Copper-64	10.0	0.1
Dysprosium-165	100.0	1.0
Dysprosium-166	10.0	0.1
Erbium-169	10.0	0.1
Erbium-171	10.0	0.1
Europium-152 (9.2 h)	10.0	0.1
Europium-152 (13 y)	0.1	0.001
Europium-154	0.1	0.001
Europium-155	1.0	0.01
Fluorine-18	100.0	1.0
Gadolinium-153	1.0	0.01
Gadolinium-159	10.0	0.1
Gallium-72	10.0	0.1
Germanium-71	100.0	1.0
Gold-198	10.0	0.1
Gold-199	10.0	0.1

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RADIOACTIVE MATERIAL	COLUMN I CURIES	COLUMN II CURIES
Hafnium-181	1.0	0.01
Holmium-166	10.0	0.1
Hydrogen-3	100.0	1.0
Indium-113m	100.0	1.0
Indium-114m	1.0	0.01
Indium-115m	100.0	1.0
Indium-115	1.0	0.01
Iodine-125	0.1	0.001
Iodine-126	0.1	0.001
Iodine-129	0.1	0.001
Iodine-131	0.1	0.001
Iodine-132	10.0	0.1
Iodine-133	1.0	0.01
Iodine-134	10.0	0.1
Iodine-135	1.0	0.01
Iridium-192	1.0	0.01
Iridium-194	10.0	0.1
Iron-55	10.0	0.1
Iron-59	1.0	0.01
Krypton-85	100.0	1.0
Krypton-87	10.0	0.1
Lanthanum-140	1.0	0.01
Lutetium-177	10.0	0.1
Manganese-52	1.0	0.01
Manganese-54	1.0	0.01
Manganese-56	10.0	0.1

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RADIOACTIVE MATERIAL	COLUMN I CURIES	COLUMN II CURIES
Mercury-197m	10.0	0.1
Mercury-197	10.0	0.1
Mercury-203	1.0	0.01
Molybdenum-99	10.0	0.1
Neodymium-147	10.0	0.1
Neodymium-149	10.0	0.1
Nickel-59	10.0	0.1
Nickel-63	1.0	0.01
Nickel-65	10.0	0.1
Niobium-93m	1.0	0.01
Niobium-95	1.0	0.01
Niobium-97	100.0	1.0
Osmium-185	1.0	0.01
Osmium-191m	100.0	1.0
Osmium-191	10.0	0.1
Osmium-193	10.0	0.1
Palladium-103	10.0	0.1
Palladium-109	10.0	0.1
Phosphorus-32	1.0	0.01
Phosphorus-33	10.0	0.1
Platinum-191	10.0	0.1
Platinum-193m	100.0	1.0
Platinum-193	10.0	0.1
Platinum-197m	100.0	1.0
Platinum-197	10.0	0.1
Polonium-210	0.01	0.0001

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RADIOACTIVE MATERIAL	COLUMN I CURIES	COLUMN II CURIES
Potassium-42	1.0	0.01
Praseodymium-142	10.0	0.1
Praseodymium-143	10.0	0.1
Promethium-147	1.0	0.01
Promethium-149	10.0	0.1
Radium-226	0.01	0.0001
Rhenium-186	10.0	0.1
Rhenium-188	10.0	0.1
Rhodium-103m	1,000.0	10.0
Rhodium-105	10.0	0.1
Rubidium-86	1.0	0.01
Rubidium-87	1.0	0.01
Ruthenium-97	100.0	1.0
Ruthenium-103	1.0	0.01
Ruthenium-105	10.0	0.1
Ruthenium-106	0.1	0.001
Samarium-151	1.0	0.01
Samarium-153	10.0	0.1
Scandium-46	1.0	0.01
Scandium-47	10.0	0.1
Scandium-48	1.0	0.01
Selenium-75	1.0	0.01
Silicon-31	10.0	0.1
Silver-105	1.0	0.01
Silver-110m	0.1	0.001
Silver-111	10.0	0.1

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RADIOACTIVE MATERIAL	COLUMN I CURIES	COLUMN II CURIES
Sodium-22	0.1	0.001
Sodium-24	1.0	0.01
Strontium-85m	1,000.0	10.0
Strontium-85	1.0	0.01
Strontium-89	1.0	0.01
Strontium-90	0.01	0.0001
Strontium-91	10.0	0.1
Strontium-92	10.0	0.1
Sulphur-35	10.0	0.1
Tantalum-182	1.0	0.01
Technetium-96	10.0	0.1
Technetium-97m	10.0	0.1
Technetium-97	10.0	0.1
Technetium-99m	100.0	1.0
Technetium-99	1.0	0.01
Tellurium-125m	1.0	0.01
Tellurium-127m	1.0	0.01
Tellurium-127	10.0	0.1
Tellurium-129m	1.0	0.01
Tellurium-129	100.0	1.0
Tellurium-131m	10.0	0.1
Tellurium-132	1.0	0.01
Terbium-160	1.0	0.01
Thallium-200	10.0	0.1
Thallium-201	10.0	0.1
Thallium-202	10.0	0.1

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RADIOACTIVE MATERIAL	COLUMN I CURIES	COLUMN II CURIES
Thallium-204	1.0	0.01
Thulium-170	1.0	0.01
Thulium-171	1.0	0.01
Tin-113	1.0	0.01
Tin-125	1.0	0.01
Tungsten-181	1.0	0.01
Tungsten-185	1.0	0.01
Tungsten-187	10.0	0.1
Vanadium-48	1.0	0.01
Xenon-131m	1,000.0	10.0
Xenon-133	100.0	1.0
Xenon-135	100.0	1.0
Ytterbium-175	10.0	0.1
Yttrium-90	1.0	0.01
Yttrium-91	1.0	0.01
Yttrium-92	10.0	0.1
Yttrium-93	1.0	0.01
Zinc-65	1.0	0.01
Zinc-69m	10.0	0.1
Zinc-69	100.0	1.0
Zirconium-93	1.0	0.01
Zirconium-95	1.0	0.01
Zirconium-97	1.0	0.01
Any Radioactive material other than source material, special nuclear material, or alpha emitting radioactive material not listed above.	0.1	0.001

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Note 1: To convert curies (Ci) to SI units of gigabecquerels (GBq), multiply the above values by 37.

Example: Zirconium-97 (Col. II) (0.01 Ci multiplied by 37 is equivalent to 0.37 GBq)

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## 120.200: STANDARDS FOR PROTECTION AGAINST RADIATION

### 120.203: Definitions

Nationally tracked source means a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in 105 CMR 120.298: Appendix D. In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

### 120.210: Radiation Protection Programs

- (A) Each licensee or registrant shall develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of 105 CMR 120.200 ~~240~~. See 105 CMR 120.262 for recordkeeping requirements relating to these programs.
- (B) The licensee or registrant shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).
- (C) The licensee or registrant shall, at intervals not to exceed 12 months, review the radiation protection program content and implementation.
- (D) To implement the ALARA requirements of 105 CMR 120.210(B), and notwithstanding the requirements in 105 CMR 120.221, a constraint on air emissions of radioactive material to the environment, excluding Radon-222 and its daughters, shall be established by licensees, such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 0.1 mSv (10 mrem) per year from these emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee shall report the exceedance as provided in 105 CMR 120.283 and promptly take appropriate corrective action to ensure against recurrence.

### 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.

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

(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~~ 4), 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.

### 120.218: Dose Equivalent to an Embryo/Fetus

(A) The licensee or registrant shall ensure that the dose equivalent to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed five millisieverts (0.5 rems). See 105 CMR 120.267 for recordkeeping requirements.

(B) The licensee or registrant shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in 105 CMR 120.218(A).

(C) The dose equivalent to the embryo/fetus is the sum of:

- (1) the deep dose equivalent to the declared pregnant woman; and
- (2) the dose equivalent resulting from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

(D) If the dose equivalent to the embryo/fetus is found to have exceeded ~~5.0 mSv~~ ~~5 millisieverts~~ (0.5 rem), or is within ~~0.5 mSv~~ ~~0.05 rem~~ (0.05 rem) of this dose, by the time the woman declares the pregnancy to the licensee or registrant, the licensee or registrant shall be deemed to be in compliance with 105 CMR 120.218(A), if the additional dose to the embryo/fetus does not exceed 0.5 millisievert (0.05 rem) during the remainder of the pregnancy.

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### 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.
- (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.

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120.282: Notification of Incidents

(A) Immediate Notification. Notwithstanding any other requirements for notification, each licensee or registrant shall immediately report each event involving a source of radiation possessed by the licensee or registrant that may have caused or threatens to cause any of the following conditions:

- (1) An individual to receive:
  - (a) a total effective dose equivalent of 0.25 sievert (25 rems) or more;
  - (b) ~~a lens~~ ~~an eye~~ dose equivalent of 0.75 sievert (75 rems) or more;
  - (c) a shallow dose equivalent to the skin or extremities or a total organ dose equivalent of 2.5 grays (250 rads) or more; or
- (2) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

120.286: Reports of Individual Monitoring

- (A) The requirements of 105 CMR 120.286 apply to each person licensed or registered by the Agency:
- (1) Possess or use sources of radiation for purposes of industrial radiography pursuant to 105 CMR 120.100 and 120.300; or
  - (2) Possess or use at any time, for processing or manufacturing for distribution pursuant to 105 CMR 120.100 or 105 CMR 120.500, radioactive material in quantities exceeding any one of the following quantities:

Radionuclide, Activity

Radionuclide	Activity	
	Ci	<del>Ci</del> GBq
Cesium-137	1	37
Cobalt-60	1	37
Gold-198	100	3,700
Iodine-131	1	37
Iridium-192	10	370
Krypton-85	1,000	37,000
Promethium-147	10	370
Technetium-99m	1,000	37,000

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[*Note*: The Agency may require as a license condition, or by rule, regulation, or order pursuant to 105 CMR 120.012, reports from licensees or registrants who are licensed or registered to use radionuclides not on this list, in quantities sufficient to cause comparable radiation levels.]

(B) Each licensee or registrant in a category listed in 105 CMR 120.286(A) shall submit an annual report of the results of individual monitoring carried out by the licensee or registrant for each individual for whom monitoring was required by 105 CMR 120.226 during that year. The licensee or registrant may include additional data for individuals for whom monitoring was provided but not required. The licensee or registrant shall use Agency Form MRCP 120.200-2 or equivalent or electronic media containing all the information required by Agency Form MRCP 120.200-2.

(C) The licensee or registrant shall file the report required by 105 CMR 120.286(A), covering the preceding year, on or before April 30<sup>th</sup> each year. The licensee or registrant shall submit the report to the Agency.

### 120.290: Reports of Transactions Involving Nationally Tracked Sources

Each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report as specified in 105 CMR 120.290(A) through 120.290(E) for each type of transaction.

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

- (1) The name, address, and license number of the reporting licensee;
- (2) The name of the individual preparing the report;
- (3) The manufacturer, model, and serial number of the source;
- (4) The radioactive material in the source;
- (5) The initial source strength in becquerels (curies) at the time of manufacture; and,
- (6) The manufacture date of the source.

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

- (1) The name, address, and license number of the reporting licensee;
- (2) The name of the individual preparing the report;
- (3) The name and license number of the recipient facility and the shipping address;
- (4) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely

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identify the source:

(5) The radioactive material in the source;

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

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

(8) The shipping date;

(9) The estimated arrival date; and

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

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

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

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

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

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

(5) The radioactive material in the source;

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

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

(8) The date of receipt; and

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

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

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

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

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

(4) The radioactive material in the source;

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

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

(7) The disassemble date of the source.

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

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

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

(3) The waste manifest number;

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

(5) The date of disposal; and

(6) The method of disposal.

(F) The reports discussed in 105 CMR 120.290(A) through 120.290(E) must be submitted by the close of the next business day after the transaction. A single report may be submitted for multiple sources and transactions. The reports must be submitted to the National Source Tracking System by using:

(1) The on-line National Source Tracking System;

(2) Electronically using a computerreadable format;

(3) By facsimile;

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

(5) By telephone with followup by facsimile or mail.

(G) Each licensee shall correct any error in previously filed reports or file a new report for any missed transaction within 5 business days of the discovery of the error or missed transaction. Such errors may be detected by a variety of methods such as administrative reviews or by physical inventories required by regulation. In addition, each licensee shall reconcile the inventory of nationally tracked sources possessed by the licensee against that licensee's data in the National Source Tracking System. The reconciliation must be conducted during the month of January in each year. The reconciliation process must include resolving any discrepancies between the National Source Tracking System and the actual inventory by filing the reports identified by 105 CMR 120.290(A) through 120.290(E). By January 31 of each year, each licensee must submit to the National Source Tracking System confirmation that the data in the National Source Tracking System is correct.

(H) Each licensee that possesses Category 1 nationally tracked sources shall report its initial inventory of Category 1 nationally tracked sources to the National Source Tracking System by January 31, 2009. Each licensee that possesses Category 2 nationally tracked sources shall report its initial inventory of Category 2 nationally tracked sources to the National Source Tracking System by January 31, 2009. The information may be submitted by using any of the methods identified by 105 CMR 120.290(F)(1) through 120.290(F)(4). The initial inventory report must include the following information:

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

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

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

(4) The radioactive material in the sealed source;

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

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

120.296: Appendix B -- Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of

Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release  
to Sanitary Sewerage

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Introduction. For each radionuclide, Table I indicates the chemical form which is to be used for selecting the appropriate ALI or DAC value. The ALIs and DACs for inhalation are given for an aerosol with an activity median aerodynamic diameter (AMAD) of 1  $\mu\text{m}$ , micron, and for three classes (D,W,Y) of radioactive material, which refer to their retention (approximately days, weeks or years) in the pulmonary region of the lung. This classification applies to a range of clearance half-times for D if less than 10 days, for W from 10 to 100 days, and for Y greater than 100 days. The class (D, W, or Y) given in the column headed "Class" applies only to the inhalation ALIs and DACs given in Table I, column 2 and 3. Table II provides concentration limits for airborne and liquid effluents released to the general environment. Table III provides concentration limits for discharges to sanitary sewerage.

Note: The values in Tables I, II, and III are presented in the computer "E" notation. In this notation a value of 6E-02 represents a value of  $6 \times 10^{-2}$  or 0.06, 6E+2 represents  $6 \times 10^2$  or 600, and 6E+0 represents  $6 \times 10^0$  or 6.

## Table I "Occupational Values"

Note that the columns in 105 CMR 120.296: *Appendix B*, Table I captioned "Oral Ingestion ALI," "Inhalation ALI," and "DAC," are applicable to occupational exposure to radioactive material.

The ALIs in 105 CMR 120.296: *Appendix B* are the annual intakes of given radionuclide by "Reference Man" which would result in either (1) a committed effective dose equivalent of 5 rems (0.05 sievert), stochastic ALI, or (2) a committed dose equivalent of 50 rems (0.5 sievert) to an organ or tissue, non-stochastic ALI. The stochastic ALIs were derived to result in a risk, due to irradiation of organs and tissues, comparable to the risk associated with deep dose equivalent to the whole body of five rems (0.05 sievert). The derivation includes multiplying the committed dose equivalent to an organ or tissue by a weighting factor,  $w_T$ . This weighting factor is the proportion of the risk of stochastic effects resulting from irradiation of the organ or tissue, T, to the total risk of stochastic effects when the whole body is irradiated uniformly. The values of  $w_T$  are listed under the definition of "weighting factor" in 105 CMR 120.203. The non-stochastic ALIs were derived to avoid non-stochastic effects, such as prompt damage to tissue or reduction in organ function.

A value of  $w_T = 0.06$  is applicable to each of the five organs or tissues in the "remainder" category receiving the highest dose equivalents, and the dose equivalents of all other remaining tissues may be disregarded. The following portions of the GI tract -- stomach, small intestine, upper large intestine, and lower large intestine -- are to be treated as four separate organs.

Note that the dose equivalents for an extremity, skin and lens of the eye are not considered in computing the committed effective dose equivalent, but are subject to limits that must be met separately.

When an ALI is defined by the stochastic dose limit, this value alone is given. When an ALI is determined by the non-stochastic dose limit to an organ, the organ or tissue to which the limit applies is shown, and the ALI for the stochastic limit is shown in parentheses. Abbreviated organ or tissue designations are used:

LLI wall	=	lower large intestine wall;
St wall	=	stomach wall;
Blad wall	=	bladder wall; and,
Bone surf	=	bone surface.

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The use of the ALIs listed first, the more limiting of the stochastic and non-stochastic ALIs, will ensure that non-stochastic effects are avoided and that the risk of stochastic effects is limited to an acceptably low value. If, in a particular situation involving a radionuclide for which the non-stochastic ALI is limiting, use of that non-stochastic ALI is considered unduly conservative, the licensee may use the stochastic ALI to determine the committed effective dose equivalent. However, the licensee shall also ensure that the 50 rems (0.5 sievert) dose equivalent limit for any organ or tissue is not exceeded by the sum of the external deep dose equivalent plus the internal committed dose equivalent to that organ, not the effective dose. For the case where there is no external dose contribution, this would be demonstrated if the sum of the fractions of the nonstochastic ALIs ( $ALI_{ns}$ ) that contribute to the committed dose equivalent to the organ receiving the highest dose does not exceed unity, that is,  $\sum (\text{intake (in } \mu\text{Ci) of each radionuclide}/ALI_{ns}) \leq 1.0$ . If there is an external deep dose equivalent contribution of  $H_d$ , then this sum must be less than  $1 - (H_d/50)$ , instead of  $\leq 1.0$ .

Note that the dose equivalents for an extremity, skin, and lens of the eye are not considered in computing the committed effective dose equivalent, but are subject to limits that must be met separately.

The derived air concentration (DAC) values are derived limits intended to control chronic occupational exposures. The relationship between the DAC and the ALI is given by:

$$DAC = ALI(\text{in } \mu\text{Ci}) / (2000 \text{ hours per working year} \times 60 \text{ minutes/hour} \times 2 \times 10^4 \text{ ml per minute}) = [ALI/2.4 \times 10^9] \mu\text{Ci/ml},$$

where  $2 \times 10^4$  ml is the volume of air breathed per minute at work by Reference Man under working conditions of light work.

The DAC values relate to one of two modes of exposure: either external submersion or the internal committed dose equivalents resulting from inhalation of radioactive materials. DACs based upon submersion are for immersion in a semi-infinite cloud of uniform concentration and apply to each radionuclide separately.

The ALI and DAC values include contributions to exposure by the single radionuclide named and any in-growth of daughter radionuclides produced in the body by decay of the parent. However, intakes that include both the parent and daughter radionuclides should be treated by the general method appropriate for mixtures.

The values of ALI and DAC do not apply directly when the individual both ingests and inhales a radionuclide, when the individual is exposed to a mixture of radionuclides by either inhalation or ingestion or both, or when the individual is exposed to both internal and external irradiation. See 105 CMR 120.212. When an individual is exposed to radioactive materials which fall under several of the translocation classifications of the same radionuclide, such as, Class D, Class W, or Class Y, the exposure may be evaluated as if it were a mixture of different radionuclides.

It should be noted that the classification of a compound as Class D, W, or Y is based on the chemical form of the compound and does not take into account the radiological half-life of different radionuclides. For this reason, values are given for Class D, W, and Y compounds, even for very short-lived radionuclides.

Table II "Effluent Concentrations". The columns in 105 CMR 120.296: *Appendix B*, Table II captioned "Effluents," "Air" and "Water" are applicable to the assessment and control of dose to the public, particularly in the implementation of the provisions of 105 CMR 120.222. The concentration values given in 105 CMR 120.296: *Appendix B*, Table II, Columns 1 and 2 are equivalent to the radionuclide concentrations which, if inhaled or ingested continuously over the course of a year, would produce a total effective dose equivalent of 0.05 rem (0.5 millisievert).

Consideration of non-stochastic limits has not been included in deriving the air and water effluent concentration limits because non-stochastic effects are presumed not to occur at or below the dose levels established for individual members of the public. For radionuclides, where the non-stochastic limit was governing in deriving the occupational DAC, the stochastic ALI

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was used in deriving the corresponding airborne effluent limit in Table II. For this reason, the DAC and airborne effluent limits are not always proportional as was the case in the previous Appendix 105 CMR 120.295: *Appendix A*.

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The air concentration values listed in Table II, Column 1 were derived by one of two methods. For those radionuclides for which the stochastic limit is governing, the occupational stochastic inhalation ALI was divided by  $2.4 \times 10^9$  ml, relating the inhalation ALI to the DAC, as explained above, and then divided by a factor of 300. The factor of 300 includes the following components: a factor of 50 to relate the 5 rems (0.05 sievert) annual occupational dose limit to the one mSv (0.1 rem) limit for members of the public, a factor of three to adjust for the difference in exposure time and the inhalation rate for a worker and that for members of the public; and a factor of two to adjust the occupational values, derived for adults, so that they are applicable to other age groups.

For those radionuclides for which submersion, that is external dose, is limiting, the occupational DAC in 105 CMR 120.296: *Appendix B*, Table I, Column 3 was divided by 219. The factor of 219 is composed of a factor of 50, as described above, and a factor of 4.38 relating occupational exposure for 2,000 hours per year to full-time exposure (8,760 hours per year). Note that an additional factor of 2 for age considerations is not warranted in the submersion case.

The water concentrations were derived by taking the most restrictive occupational stochastic oral ingestion ALI and dividing by  $7.3 \times 10^7$ . The factor of  $7.3 \times 10^7$  (ml) includes the following components: the factors of 50 and 2 described above and a factor of  $7.3 \times 10^5$  (ml) which is the annual water intake of "Reference Man".

Note 2 of 105 CMR 120.296: *Appendix B* provides groupings of radionuclides which are applicable to unknown mixtures of radionuclides. These groupings, including occupational inhalation ALIs and DACs, air and water effluent concentrations and releases to sewer, require demonstrating that the most limiting radionuclides in successive classes are absent. The limit for the unknown mixture is defined when the presence of one of the listed radionuclides cannot be definitely excluded as being present either from knowledge of the radionuclide composition of the source or from actual measurements.

Table III "Releases to Sewers". The monthly average concentrations for release to sanitary sewerage are applicable to the provisions in 105 CMR 120.253. The concentration values were derived by taking the most restrictive occupational stochastic oral ingestion ALI and dividing by  $7.3 \times 10^6$  (ml). The factor of  $7.3 \times 10^6$  (ml) is composed of a factor of  $7.3 \times 10^5$  (ml), the annual water intake by "Reference Man", and a factor of ten, such that the concentrations, if the sewage released by the licensee were the only source of water ingested by a "Reference Man" during a year, would result in a committed effective dose equivalent of five mSv (0.5 rem).

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LIST OF ELEMENTS

List of Elements

<u>Name</u>	<u>Atomic</u>	
	<u>Symbol</u>	<u>No.</u>
<u>Actinium</u>	<u>Ac</u>	<u>89</u>
<u>Aluminium</u>	<u>Al</u>	<u>13</u>
<u>Americium</u>	<u>Am</u>	<u>95</u>
<u>Antimony</u>	<u>Sb</u>	<u>51</u>
<u>Argon</u>	<u>Ar</u>	<u>18</u>
<u>Arsenic</u>	<u>As</u>	<u>33</u>
<u>Astatine</u>	<u>At</u>	<u>85</u>
<u>Barium</u>	<u>Ba</u>	<u>56</u>
<u>Berkelium</u>	<u>Bk</u>	<u>97</u>
<u>Beryllium</u>	<u>Be</u>	<u>4</u>
<u>Bismuth</u>	<u>Bi</u>	<u>83</u>
<u>Bromine</u>	<u>Br</u>	<u>35</u>
<u>Cadmium</u>	<u>Cd</u>	<u>48</u>
<u>Calcium</u>	<u>Ca</u>	<u>20</u>

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<u>Californium</u>	<u>Cf</u>	<u>98</u>
<u>Carbon</u>	<u>C</u>	<u>6</u>
<u>Cerium</u>	<u>Ce</u>	<u>58</u>
<u>Cesium</u>	<u>Cs</u>	<u>55</u>
<u>Chlorine</u>	<u>Cl</u>	<u>17</u>
<u>Chromium</u>	<u>Cr</u>	<u>24</u>
<u>Cobalt</u>	<u>Co</u>	<u>27</u>
<u>Copper</u>	<u>Cu</u>	<u>29</u>
<u>Curium</u>	<u>Cm</u>	<u>96</u>
<u>Dysprosium</u>	<u>Dy</u>	<u>66</u>
<u>Einsteinium</u>	<u>Es</u>	<u>99</u>
<u>Erbium</u>	<u>Er</u>	<u>68</u>
<u>Europium</u>	<u>Eu</u>	<u>63</u>
<u>Fermium</u>	<u>Fm</u>	<u>100</u>
<u>Fluorine</u>	<u>F</u>	<u>9</u>
<u>Francium</u>	<u>Fr</u>	<u>87</u>
<u>Gadolinium</u>	<u>Gd</u>	<u>64</u>
<u>Gallium</u>	<u>Ga</u>	<u>31</u>
<u>Germanium</u>	<u>Ge</u>	<u>32</u>

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<u>Gold</u>	<u>Au</u>	<u>79</u>
<u>Hafnium</u>	<u>Hf</u>	<u>72</u>
<u>Holmium</u>	<u>Ho</u>	<u>67</u>
<u>Hydrogen</u>	<u>H</u>	<u>1</u>
<u>Indium</u>	<u>In</u>	<u>49</u>
<u>Iodine</u>	<u>I</u>	<u>53</u>
<u>Iridium</u>	<u>Ir</u>	<u>77</u>
<u>Iron</u>	<u>Fe</u>	<u>26</u>
<u>Krypton</u>	<u>Kr</u>	<u>36</u>
<u>Lanthanum</u>	<u>La</u>	<u>57</u>
<u>Lead</u>	<u>Pb</u>	<u>82</u>
<u>Lutetium</u>	<u>Lu</u>	<u>71</u>
<u>Magnesium</u>	<u>Mg</u>	<u>12</u>
<u>Manganese</u>	<u>Mn</u>	<u>25</u>
<u>Mendelevium</u>	<u>Md</u>	<u>101</u>
<u>Mercury</u>	<u>Hg</u>	<u>80</u>
<u>Molybdenum</u>	<u>Mo</u>	<u>42</u>
<u>Neodymium</u>	<u>Nd</u>	<u>60</u>
<u>Neptunium</u>	<u>Np</u>	<u>93</u>

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<u>Nickel</u>	<u>Ni</u>	<u>28</u>
<u>Niobium</u>	<u>Nb</u>	<u>41</u>
<u>Nitrogen</u>	<u>N</u>	<u>7</u>
<u>Osmium</u>	<u>Os</u>	<u>76</u>
<u>Oxygen</u>	<u>O</u>	<u>8</u>
<u>Palladium</u>	<u>Pd</u>	<u>46</u>
<u>Phosphorus</u>	<u>P</u>	<u>15</u>
<u>Platinum</u>	<u>Pt</u>	<u>78</u>
<u>Plutonium</u>	<u>Pu</u>	<u>94</u>
<u>Polonium</u>	<u>Po</u>	<u>84</u>
<u>Potassium</u>	<u>K</u>	<u>19</u>
<u>Praseodymium</u>	<u>Pr</u>	<u>59</u>
<u>Promethium</u>	<u>Pm</u>	<u>61</u>
<u>Protactinium</u>	<u>Pa</u>	<u>91</u>
<u>Radium</u>	<u>Ra</u>	<u>88</u>
<u>Radon</u>	<u>Rn</u>	<u>86</u>
<u>Rhenium</u>	<u>Re</u>	<u>75</u>
<u>Rhodium</u>	<u>Rh</u>	<u>45</u>
<u>Rubidium</u>	<u>Rb</u>	<u>37</u>

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<u>Ruthenium</u>	<u>Ru</u>	<u>44</u>
<u>Samarium</u>	<u>Sm</u>	<u>62</u>
<u>Scandium</u>	<u>Sc</u>	<u>21</u>
<u>Selenium</u>	<u>Se</u>	<u>34</u>
<u>Silicon</u>	<u>Si</u>	<u>14</u>
<u>Silver</u>	<u>Ag</u>	<u>47</u>
<u>Sodium</u>	<u>Na</u>	<u>11</u>
<u>Strontium</u>	<u>Sr</u>	<u>38</u>
<u>Sulfur</u>	<u>S</u>	<u>16</u>
<u>Tantalum</u>	<u>Ta</u>	<u>73</u>
<u>Technetium</u>	<u>Tc</u>	<u>43</u>
<u>Tellurium</u>	<u>Te</u>	<u>52</u>
<u>Terbium</u>	<u>Tb</u>	<u>65</u>
<u>Thallium</u>	<u>Tl</u>	<u>81</u>
<u>Thorium</u>	<u>Th</u>	<u>90</u>
<u>Thulium</u>	<u>Tm</u>	<u>69</u>
<u>Tin</u>	<u>Sn</u>	<u>50</u>
<u>Titanium</u>	<u>Ti</u>	<u>22</u>
<u>Tungsten</u>	<u>W</u>	<u>74</u>

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<u>Uranium</u>	<u>U</u>	<u>92</u>
<u>Vanadium</u>	<u>V</u>	<u>23</u>
<u>Xenon</u>	<u>Xe</u>	<u>54</u>
<u>Yterbium</u>	<u>Yb</u>	<u>70</u>
<u>Yttrium</u>	<u>Y</u>	<u>39</u>
<u>Zinc</u>	<u>Zn</u>	<u>30</u>
<u>Zirconium</u>	<u>Zr</u>	<u>40</u>

			Atomic			Atomic
	Name	Symbol	Number	Name	Symbol	Number
	Actinium	Ae	89	Barium	Ba	56
	Aluminum	Al	13	Berkelium	Bk	97
	Americium	Am	95	Beryllium	Be	4
	Antimony	Sb	51	Bismuth	Bi	83
	Argon	Ar	18	Bromine	Br	35
	Arsenic	As	33	Cadmium	Cd	48
	Astatine	At	85	Calcium	Ca	20

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	Californium	Cf	98
	Carbon	C	6
	Cerium	Ce	58
	Cesium	Cs	55
	Chlorine	Cl	17
	Chromium	Cr	24
	Cobalt	Co	27
	Copper	Cu	29
	Curium	Cm	96
	Dysprosium	Dy	66
	Einsteinium	Es	99
	Erbium	Er	68
	Europium	Eu	63
	Fermium	Fm	100
	Fluorine	F	9
	Francium	Fr	87
	Gadolinium	Gd	64
	Gallium	Ga	31
	Germanium	Ge	32
	Gold	Au	79
	Hafnium	Hf	72
	Holmium	Ho	67
	Hydrogen	H	1
	Indium	In	49
	Iodine		153
	Iridium	Ir	77
	Iron	Fe	26

	Krypton	Kr	36
	Lanthanum	La	57
	Lead	Pb	82
	Lutetium	Lu	71
	Magnesium	Mg	12
	Manganese	Mn	25
	Mendelevium	Md	101
	Mercury	Hg	80
	Molybdenum	Mo	42
	Neodymium	Nd	60
	Neptunium	Np	93
	Nickel	Ni	28
	Niobium	Nb	41
	Osmium	Os	76
	Palladium	Pd	46
	Phosphorus	P	15
	Platinum	Pt	78
	Plutonium	Pu	94
	Polonium	Po	84
	Potassium	K	19
	Praseodymium	Pr	59
	Promethium	Pm	61
	Protactinium	Pa	91
	Radium	Ra	88
	Radon	Rn	86
	Rhenium	Re	75
	Rhodium	Rh	45

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	Rubidium	Rb	37
	Ruthenium	Ru	44
	Samarium	Sm	62
	Scandium	Sc	21
	Selenium	Se	34
	Silicon	Si	14
	Silver	Ag	47
	Sodium	Na	11
	Strontium	Sr	38
	Sulfur	S	16
	Tantalum	Ta	73
	Technetium	Tc	43
	Tellurium	Te	52
	Terbium	Tb	65
	Thallium	Tl	81

	Thorium	Th	90
	Thulium	Tm	69
	Tin	Sn	50
	Titanium	Ti	22
	Tungsten	W	74
	Uranium	U	92
	Vanadium	V	23
	Xenon	Xe	54
	Ytterbium	Yb	70
	Yttrium	Y	39
	Zinc	Zn	30
	Zirconium		Zr40

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Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration
			oral Ingestion	Inhalation	DAC	Air	Water	( $\mu\text{Ci/ml}$ )
			ALI ( $\mu\text{Ci}$ )	ALI ( $\mu\text{Ci}$ )	( $\mu\text{Ci/ml}$ )	( $\mu\text{Ci/ml}$ )	( $\mu\text{Ci/ml}$ )	( $\mu\text{Ci/ml}$ )
1	Hydrogen-3	Water, DAC includes skin absorption	8E+4	8E+4	2E-5	1E-7	1E-3	1E-2
Gas (HT or T <sub>2</sub> ) Submersion <sup>1</sup> : Use above values as HT and T <sub>2</sub> oxidize in air and in the body to HTO.								
4	Beryllium-7	W, all compounds except those given for Y	4E+4	2E+4	9E-6	3E-8	6E-4	6E-3
		Y, oxides, halides, and nitrates	-	2E+4	8E-6	3E-8	-	-
4	Beryllium-10	W, see <sup>7</sup> Be	1E+3	2E+2	6E-8	2E-10	-	-
		LLI wall (1E+3)	-	-	-	-	2E-5	2E-4
		Y, see <sup>7</sup> Be	-	1E+1	6E-9	2E-11	-	-
6	Carbon-11 <sup>2</sup>	Monoxide	-	1E+6	5E-4	2E-6	-	-
		Dioxide	-	6E+5	3E-4	9E-7	-	-
		Compounds	4E+5	4E+5	2E-4	6E-7	6E-3	6E-2
6	Carbon-14	Monoxide	-	2E+6	7E-4	2E-6	-	-
7	Nitrogen-13 <sup>2</sup>	Submersion <sup>1</sup>	-	-	4E-6	2E-8	-	-
8	Oxygen-15 <sup>2</sup>	Submersion <sup>1</sup>	-	-	4E-6	2E-8	-	-
		Dioxide	-	2E+5	9E-5	3E-7	-	-
		Compounds	2E+3	2E+3	1E-6	3E-9	3E-5	3E-4
9	Fluorine-18 <sup>2</sup>	D, fluorides of H, Li, Na, K, Rb, Cs, and Fr	5E+4	7E+4	3E-5	1E-7	-	-
		St wall (5E+4)	-	-	-	-	7E-4	7E-3
		W, fluorides of Be, Mg, Ca, Sr, Ba, Ra, Al, Ga, In, Tl, As, Sb, Bi, Fe, Ru, Os,	-	9E+4	4E-5	1E-7	-	-

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Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1 oral Ingestion ALI ( $\mu$ Ci)	Col. 2 Inhalation ALI ( $\mu$ Ci)	Col. 3 DAC ( $\mu$ Ci/ml)	Col. 1 Air ( $\mu$ Ci/ml)	Col. 2 Water ( $\mu$ Ci/ml)	Monthly Average Concentration ( $\mu$ Ci/ml)
		<u>Co, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Sc, Y, Ti, Zr, V, Nb, Ta, Mn, Tc, and Re</u>						
		<u>Y, lanthanum fluoride</u>	=	<u>8E+4</u>	<u>3E-5</u>	<u>1E-7</u>	=	=
<u>11</u>	<u>Sodium-22</u>	<u>D, all compounds</u>	<u>4E+2</u>	<u>6E+2</u>	<u>3E-7</u>	<u>9E-10</u>	<u>6E-6</u>	<u>6E-5</u>
<u>11</u>	<u>Sodium-24</u>	<u>D, all compounds</u>	<u>4E+3</u>	<u>5E+3</u>	<u>2E-6</u>	<u>7E-9</u>	<u>5E-5</u>	<u>5E-4</u>
<u>12</u>	<u>Magnesium-28</u>	<u>D, all compounds except those given for W</u>	<u>7E+2</u>	<u>2E+3</u>	<u>7E-7</u>	<u>2E-9</u>	<u>9E-6</u>	<u>9E-5</u>
		<u>W, oxides, hydroxides, carbides, halides, and nitrates</u>	=	<u>1E+3</u>	<u>5E-7</u>	<u>2E-9</u>	=	=
<u>13</u>	<u>Aluminum-26</u>	<u>D, all compounds except those given for W</u>	<u>4E+2</u>	<u>6E+1</u>	<u>3E-8</u>	<u>9E-11</u>	<u>6E-6</u>	<u>6E-5</u>
		<u>W, oxides, hydroxides, carbides, halides, and nitrates</u>	=	<u>9E+1</u>	<u>4E-8</u>	<u>1E-10</u>	=	=

~~120.298: Appendix D — Requirements for Transfer of Low-level Radioactive Waste for Disposal at Land Disposal Facilities and Manifests~~

~~(A) Manifest. The shipment manifest shall contain the name, address, and telephone number of the person generating the waste. The manifest shall also include the name, address, and telephone number or the name and U.S. Environmental Protection Agency hazardous waste identification number of the person transporting the waste to the land disposal facility. The manifest shall also indicate: a physical description of the waste, the volume, radionuclide identity and quantity, the total radioactivity, and the principal chemical form. The solidification agent shall be specified. Waste containing more than 0.1% chelating agents by weight shall be identified and the weight percentage of the chelating agent estimated. Wastes classified as Class A, Class B, or Class C in 105 CMR 120.299(A) shall be clearly identified as such in the manifest. The total quantity of the radionuclides hydrogen 3, carbon 14, technetium 99, and iodine 129 shall be shown. The manifest required by 105 CMR 120.298(A) may be shipping papers used to~~

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~~meet U.S. Department of Transportation or U.S. Environmental Protection Agency regulations or requirements of the receiver, provided all the required information is included. Copies of manifests required by 105 CMR 120.298(A) may be legible carbon copies or legible photocopies.~~

~~(B) Certification. The waste generator shall include in the shipment manifest a certification that the transported materials are properly classified, described, packaged, marked, and labeled and are in proper condition for transportation according to the applicable regulations of the U.S. Department of Transportation and the Agency. An authorized representative of the waste generator shall sign and date the manifest.~~

~~(C) Control and Tracking.~~

~~(1) Any radioactive waste generator who transfers radioactive waste to a land disposal facility or a licensed waste collector shall comply with the requirements in 105 CMR 120.298(C)(1)(a) through (h). Any radioactive waste generator who transfers waste to a licensed waste processor who treats or repackages waste shall comply with the requirements of 105 CMR 120.298(C)(1)(d) through (h). A licensee shall:~~

- ~~(a) Prepare all wastes so that the waste is classified according to 105 CMR 120.299(A) and meets the waste characteristics requirements in 105 CMR 120.299(B);~~
- ~~(b) Label each package of waste to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with 105 CMR 120.299(A);~~
- ~~(c) Conduct a quality control program to ensure compliance with 105 CMR 120.299(A) and (B); the program shall include management evaluation of audits;~~
- ~~(d) Prepare shipping manifests to meet the requirements of 105 CMR 120.298(A) and (B);~~
- ~~(e) Forward a copy of the manifest to the intended recipient, at the time of shipment, or deliver to a collector at the time the waste is collected, obtaining acknowledgment of receipt in the form of a signed copy of the manifest or equivalent documentation from the collector;~~
- ~~(f) Include one copy of the manifest with the shipment;~~
- ~~(g) Retain a copy of the manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by 105 CMR 120.140; and,~~
- ~~(h) For any shipments or any portion of a shipment for which acknowledgment of receipt has not been received within the times set forth in 105 CMR 120.200, conduct an investigation in accordance with 105 CMR 120.298(C)(5).~~
- ~~(i) Forward a copy of the manifest to the Agency at the time of transfer or shipment.~~

~~(2) Any waste collector licensee who handles only prepackaged waste shall:~~

- ~~(a) Acknowledge receipt of the waste from the generator within one week of receipt by returning a signed copy of the manifest or equivalent documentation;~~

~~(b) Prepare a new manifest to reflect consolidated shipments; the new manifest shall serve as a listing or index for the detailed generator manifests. Copies of the generator manifests shall be a part of the new manifest. The waste collector may prepare a new manifest without attaching the generator manifests, provided the new manifest contains for each package the information specified in 105 CMR 120.298(A). The collector licensee shall certify that nothing has been done to the waste that would invalidate the generator's certification;~~

~~120.298: continued~~

- ~~(c) Forward a copy of the new manifest to the land disposal facility operator at the time of shipment;~~
  - ~~(d) Include the new manifest with the shipment to the disposal site;~~
  - ~~(e) Retain a copy of the manifest and documentation of acknowledgement of receipt as the record of transfer of licensed material as required by 105 CMR 120.140, and retain information from generator manifest until the license is terminated and disposition is authorized by the Agency; and;~~
  - ~~(f) For any shipments or any portion of a shipment for which acknowledgement of receipt is not received within the times set forth in 105 CMR 120.298(C), conduct an investigation in accordance with 105 CMR 120.298(C)(5).~~
- ~~(3) Any licensed waste processor who treats or repackages wastes shall:~~
- ~~(a) Acknowledge receipt of the waste from the generator within one week of receipt by returning a signed copy of the manifest or equivalent documentation;~~
  - ~~(b) Prepare a new manifest that meets the requirements of 105 CMR 120.298(A) and (B). Preparation of the new manifest reflects that the processor is responsible for the waste;~~
  - ~~(c) Prepare all wastes so that the waste is classified according to 105 CMR 120.299(A) and meets the waste characteristics requirements in 105 CMR 120.299(B);~~
  - ~~(d) Label each package of waste to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with 105 CMR 120.299(A) and (C);~~
  - ~~(e) Conduct a quality control program to ensure compliance with 105 CMR 120.299(A) and (B). The program shall include management evaluation of audits;~~
  - ~~(f) Forward a copy of the new manifest to the disposal site operator or waste collector at the time of shipment, or deliver to a collector at the time the waste is collected, obtaining acknowledgement of receipt in the form of a signed copy of the manifest or equivalent documentation by the collector;~~
  - ~~(g) Include the new manifest with the shipment;~~
  - ~~(h) Retain copies of original manifests and new manifests and documentation of acknowledgement of receipt as the record of transfer of licensed material required by 105 CMR 120.140; and;~~
  - ~~(i) For any shipment or portion of a shipment for which acknowledgement is not received within the times set~~

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forth in 105 CMR 120.298(C), conduct an investigation in accordance with 105 CMR 120.298(C)(5).

~~(5) The land disposal facility operator shall:~~

~~(a) Acknowledge receipt of the waste within one week of receipt by returning a signed copy of the manifest or equivalent documentation to the shipper. The shipper to be notified is the licensee who last possessed the waste and transferred the waste to the operator. The returned copy of the manifest or equivalent documentation shall indicate any discrepancies between materials listed on the manifest and materials received;~~

~~(b) Maintain copies of all completed manifests or equivalent documentation until the Agency authorizes their disposition; and,~~

~~(c) Notify the shipper, that is, the generator, the collector, or processor, and the Agency when any shipment or portion of a shipment has not arrived within 60 days after the advance manifest was received.~~

~~(5) Any shipment or portion of a shipment for which acknowledgement is not received within the times set forth in 105 CMR 120.298 shall:~~

~~(a) be investigated by the shipper if the shipper has not received notification or receipt within 20 days after transfer; and,~~

~~(b) be traced and reported to whom. The investigation shall include tracing the shipment and filing a report with the Agency. Each licensee who conducts a trace investigation shall file a written report with the Agency within two weeks of completion of the investigation.~~

120.298: Appendix D --Nationally Tracked Source Thresholds

The Terabecquerel (TBq) values are the regulatory standard. The curie (Ci) values specified are obtained by converting from the TBq value. The curie values are provided for practical usefulness only and are rounded after conversion.

Radioactive material	Category 1(TBq)	Category 1(Ci)	Category 2(TBq)	Category 2(Ci)
<u>Actinium 227</u>	<u>20</u>	<u>540</u>	<u>0.2</u>	<u>5.4</u>
<u>Americium 241</u>	<u>60</u>	<u>1,600</u>	<u>0.6</u>	<u>16</u>
<u>Americium 241/Ba</u>	<u>60</u>	<u>1,600</u>	<u>0.6</u>	<u>16</u>
<u>Californium 252</u>	<u>20</u>	<u>540</u>	<u>0.2</u>	<u>5.4</u>
<u>Cesium 60</u>	<u>30</u>	<u>810</u>	<u>0.3</u>	<u>8.1</u>
<u>Cesium 244</u>	<u>50</u>	<u>1,400</u>	<u>0.5</u>	<u>14</u>
<u>Cesium 137</u>	<u>100</u>	<u>2,700</u>	<u>1</u>	<u>27</u>
<u>Cadmium 153</u>	<u>1,000</u>	<u>27,000</u>	<u>10</u>	<u>270</u>
<u>Iridium 192</u>	<u>80</u>	<u>2,200</u>	<u>0.8</u>	<u>22</u>
<u>Plutonium 238</u>	<u>60</u>	<u>1,600</u>	<u>0.6</u>	<u>16</u>

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<u>Plutonium-239/Po</u>	<u>60</u>	<u>1600</u>	<u>0.6</u>	<u>16</u>
<u>Polonium-210</u>	<u>60</u>	<u>1600</u>	<u>0.6</u>	<u>16</u>
<u>Promethium-147</u>	<u>40,000</u>	<u>1100,000</u>	<u>400</u>	<u>11,000</u>
<u>Radium-226</u>	<u>40</u>	<u>1100</u>	<u>0.4</u>	<u>11</u>
<u>Selenium-75</u>	<u>200</u>	<u>5,400</u>	<u>2</u>	<u>54</u>
<u>Strontium-90</u>	<u>1,000</u>	<u>27,000</u>	<u>10</u>	<u>270</u>
<u>Thesium-228</u>	<u>20</u>	<u>540</u>	<u>0.2</u>	<u>5.4</u>
<u>Thesium-220</u>	<u>20</u>	<u>540</u>	<u>0.2</u>	<u>5.4</u>
<u>Thalium-170</u>	<u>20,000</u>	<u>540,000</u>	<u>200</u>	<u>5,400</u>
<u>Ytterbium-169</u>	<u>300</u>	<u>8,100</u>	<u>3</u>	<u>81</u>



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105 CMR 120.000: MASSACHUSETTS REGULATIONS FOR THE CONTROL OF RADIATION (MRCR)

120.001: GENERAL PROVISIONS

120.005: Definitions

Alert means events may occur, are in progress, or have occurred that could lead to a release of radioactive material but that the release is not expected to require a response by offsite response organizations to protect persons offsite.

Positron Emission Tomography (PET) radionuclide production facility means a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

Byproduct material means:

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

(2)(a) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or

(b) Any material that:

(i) Has been made radioactive by use of a particle accelerator; and

(ii) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

(3) Any discrete source of naturally occurring radioactive material, other than source material, that:

(a) The Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

(b) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

~~(4) Any radioactive material, except special nuclear material, yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material; and~~

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

Consortium means an association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within

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the consortium must be located at an educational institution or a Federal facility or a medical facility.

Cyclotron means a particle accelerator in which the charged particles travel in an outward spiral or circular path. A cyclotron accelerates charged particles at energies usually in excess of 10 megaelectron volts and is commonly used for production of short half-life radionuclides for medical use. (See Accelerator).

Discrete Source means a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, industrial, or research activities.

Healing Arts Radiologic Screening means the completion of a procedure that irradiates an individual, with no symptoms or other potential indicators of disease, to ionizing radiation for the purpose of diagnosing the presence or absence of disease within the individual.

Nationally tracked source means a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in 105 CMR 120.298: Appendix D. In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

Site area emergency means events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a response by offsite response organizations to protect persons offsite.

Waste means those low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in paragraphs (2), (3), and (4) of the definition of Byproduct material set forth in this section.

### 120.013: Communications

All correspondence in compliance with 105 CMR 120.000 shall be sent to the Department of Public Health, Radiation Control Program, at the program's current mailing address, as stated in the website <http://mass.gov/dph/rcp> <http://mass.gov/dph/rcp>.

### 120.016: Enforcement Policy and Procedures

#### (C) Grounds for Denial, Modification, Limitation, Revocation or Refusal to Renew a License or Certificate of Registration.

(1) Specific Grounds. The Department may issue an order denying, revoking, modifying, limiting, or refusing to renew a license or certificate of registration sought or issued under 105 CMR 120.000, or issue an order to cease an activity, for any

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one of the following reasons:

- (a) The applicant, licensee or registrant has failed to submit the information required for licensure or registration under 105 CMR 120.000.
- (b) The applicant failed to meet the requirements for licensure or registration as specified in 105 CMR 120.000.
- (c) The applicant, licensee or registrant is not suitable and responsible to operate a facility as required or provide the service as licensed or registered.
- (d) The applicant, licensee or registrant has obtained or attempted to obtain or maintain a certificate of registration or license by fraud, misrepresentation, or by the submission of incorrect, false or misleading information.
- (e) The applicant, licensee or registrant has failed to pay licensure and/or registration fees.
- (f) The applicant, licensee or registrant has failed to pay civil penalties or criminal fines levied in accordance with of M.G.L. c. 111, § 5O or 5P and/or 105 CMR 120.000.
- (g) The applicant, licensee or registrant has:
  - 1. failed to allow duly authorized agents of the Agency to conduct inspections; or
  - 2. attempted to impede the work of duly authorized representatives of the Agency or the enforcement of any provisions of M.G.L. c. 111 §§ 5N through 5P or 105 CMR 120.000.
- (h) The applicant, licensee or registrant has been convicted of, pleaded guilty to, or has, in a judicial proceeding, admitted facts sufficient for a finding that he/she is guilty of, any criminal violation relating directly or indirectly to his/her fitness to be licensed or registered under 105 CMR 120.000.
- (i) The applicant, licensee or registrant has been the subject of proceedings which resulted in the suspension, denial, modification, limitation, or revocation of a similar license or certificate of registration or refusal of renewal of a similar license.
- (j) The applicant, licensee or registrant has violated Department regulations or a license condition and has a history of non-compliance with the same or similar violation or has received a warning letter from the Department within the last five years for the same or similar violation. ~~The applicant, licensee or registrant has been the subject of proceedings which were ultimately resolved by Settlement Agreement but which were initiated to suspend, deny, modify, limit, or revoke or refuse renewal of a license, unless the Settlement Agreement contained provisions which either:~~
  - ~~a. stated that the licensee, applicant or registrant was not guilty of the violations the person was charged with; or~~
  - ~~b. provided that the charges or violations that were the subject of the Settlement Agreement or the Settlement Agreement itself cannot be used in whole or in part as the basis for any future licensing, registration or enforcement action by the Department.~~

(G ~~F~~) Civil Penalties.

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- (1) If the Department determines, after a notice has been issued and an opportunity for a hearing has been provided, that a licensee, registrant or vendor has not complied with an order issued pursuant to M.G.L. c. 111, § 5O or with any provision of M.G.L. c. 111, §§ 5N through 5P or with any applicable rule, regulation, license or certificate of registration adopted or issued thereunder, the Department, in *lieu* of, or in addition to suspending, denying, modifying, limiting, revoking, or refusing renewal of a license or certificate of registration, may assess civil penalties in an amount not exceeding \$100,000 per violation. Such civil penalty may be assessed whether or not the violation was willful.
- (2) The decision whether to issue a civil penalty and the amount of any civil penalty depends on the facts of each case. Generally, civil penalties are most likely to be imposed for Severity Level I violations and if mitigating circumstances are absent, for Severity Level II violations. Civil penalties are considered for Severity Level III violations, and may be imposed for Severity Level IV violations that are similar to previous violations that occurred after the date of the last inspection or within two years, whichever period is greater for which the licensee did not take effective corrective action.
- (3) Civil penalties may be assessed for known and conscious violations of the reporting requirements of 105 CMR 120.000 and for any willful violation of any Agency requirement including those at any severity level.
- (4) Payment of civil penalties imposed under M.G.L. c. 111, § 5O shall be made by check, draft, or money order payable to the Commonwealth of Massachusetts, and mailed to the Radiation Control Program.
- (5) Factors in Determining the Amount of Penalty. In determining the amount of the civil penalty, the Department shall consider the following:
  - (a) The willfulness of the violation;
  - (b) The actual and potential danger to the public health or the environment;
  - (c) The actual or potential costs of such danger to the public health or the environment;
  - (d) The actual or potential damage or injury to the public health or environment;
  - (e) The actual and potential cost of such damage or injury;
  - (f) The actual or potential cost to the Commonwealth of enforcing provisions of 105 CMR 120.000;
  - (g) Whether the person being assessed the civil penalty did everything reasonable to prevent failure to, to come into compliance promptly, and to remedy and mitigate whatever harm might have been done as a result of the failure to comply;
  - (h) Whether the person being assessed the civil penalty has previously failed to comply with any order issued pursuant to M.G.L. c. 111, §§ 5N through 5P or any rule or regulation adopted hereunder;
  - (i) Whether imposition of a civil penalty is likely to deter future non-compliance;
  - (j) The financial condition of the person being assessed the civil penalty; and,
  - (k) The public interest.

### (H G) Escalation of Enforcement Sanctions.

- (1) The Department considers violations of Severity Levels I, II or III to be of significant regulatory concern. When Severity Level I, II or III violations occur, the Department will, where necessary, issue orders in conjunction with civil penalties to achieve immediate corrective actions and to deter further recurrence of serious violations. The Department

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carefully considers the circumstances of each case in selecting and applying the sanction(s) appropriate to the case in accordance with the criteria described in 105 CMR 120.016(D).

(2) The progression of enforcement actions for similar violations will usually be based on similar violations at an individual facility and not on similar violations under the same license. However, under some circumstances, *e.g.*, where there is common control over some facet of facility operations, similar violations may be charged even though the second violation occurred at a different facility or under a different license. For example, a health physics violation at one division of a dual unit hospital that repeats an earlier violation of the other division might be considered similar.

(~~I H~~) Criminal Enforcement. The Department may elect to enforce any section of 105 CMR 120.000 or provision of M.G.L. c. 111, § 5P by seeking to have criminal sanctions imposed. Any person who violates M.G.L. c. 111, § 5N or § 5O or any rule, regulation, license, registration, or order adopted or issued under said M.G.L. c. 111, § 5N or § 5O shall be fined not less than \$100 nor more than \$2,000, or be imprisoned for a period of not more than two years, or both. Any person who continues to violate the provisions of the aforementioned laws after due notice by the Department shall be fined not less than \$1,000 nor more than \$20,000 or be imprisoned for a period of not more than 20 years, or both. After due notice has been issued by the Department, each day of such violation shall constitute a separate offense.

(~~J I~~) Judicial Enforcement. The Department may apply directly to the Supreme Judicial Court or Superior Court to enforce any provision of M.G.L. c. 111, §§ 5N through 5P and/or any rule or regulation, license, registration, or order adopted and issued thereunder by the Department. When a person is engaged in or about to engage in any act or practice which constitutes or will constitute a violation of such provision, rule, regulation, license, registration, or order, the Department may seek to restrain such act or practice or the use or occupation of premises or parts thereof or such other equitable relief as public health and safety requires.

(~~K J~~) Nonexclusivity of Enforcement Procedures. None of the enforcement procedures contained in 105 CMR 120.000 are mutually exclusive. Any enforcement procedures may be invoked simultaneously if the situation so requires.

(~~L K~~) Deliberate Misconduct.

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

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

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

(2) A person who violates 105 CMR 120.016(~~L~~ ~~K~~)(1)(a) or (1)(b) may be subject to enforcement action in accordance with the procedures in 105 CMR 120.016.

(3) For the purposes of 105 CMR 120.016(~~L~~ ~~K~~)(1)(a), deliberate misconduct by a person means an intentional act or omission that the person knows:

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

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

# 105 CMR: DEPARTMENT OF PUBLIC HEALTH

## 120.500: USE OF RADIONUCLIDES IN THE HEALING ARTS

### GENERAL INFORMATION

#### 120.501: Purpose and Scope

105 CMR 120.500 establishes requirements and provisions for the production, preparation, compounding and use of radionuclides in the healing arts and for issuance of licenses authorizing these activities. These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects. The requirements and provisions of 105 CMR 120.500 are in addition to, and not in substitution for, others in 105 CMR 120.000. The requirements and provisions of 105 CMR 120.000 apply to applicants and licensees subject to 105 CMR 120.500 unless specifically exempted. (*See* exemption in 105 CMR 120.104(C)(5)).

#### 120.502: Definitions

As used in 105 CMR 120.500, the following definitions apply:

Address of Use means the building or buildings that are identified on the license and where radioactive material may be produced, prepared, received, used, or stored.

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

Authorized Medical Physicist means an individual who:

- (1) Meets the requirements in 105 CMR 120.525 or 120.528; or
- (2) Is identified as a medical physicist on a specific medical use license or equivalent permit issued by the Agency, Nuclear Regulatory Commission, Agreement State or Licensing State; or
- (3) Is identified as a medical physicist on a permit issued by an Agency, Nuclear Regulatory Commission, Agreement State or Licensing State specific medical use license of broad scope that is authorized to permit the use of radioactive material.

Authorized Nuclear Pharmacist means a pharmacist as defined in 105 CMR 120 005 who:

- (1) Meets the requirements in 105 CMR 120.526 or 120.528; or
- (2) Is identified as an authorized nuclear pharmacist on a specific license or equivalent permit that authorizes medical use, the practice of nuclear pharmacy, commercial nuclear pharmacy or the manufacture and distribution of radiopharmaceuticals issued by the Agency, Nuclear Regulatory Commission, Agreement State or Licensing State; or

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- (3) Is identified as an authorized nuclear pharmacist on a permit issued by an Agency, NRC or Agreement State or Licensing State specific licensee of broad scope that is authorized to permit the use of radioactive material; or
- (4) Is a qualified nuclear pharmacist under 247 CMR 13.00

Authorized User means a physician, dentist, or podiatrist who:

- (1) Meets the requirements in 105 CMR 120.529, 120.546(A), 120.551(A), 120.556(A), 120.557(A), 120.558(A), 120.566(A), 120.567, 120.569(A), or 120.587(A);
- (2) Identified as an authorized user on a NRC or Agreement State or Licensing State license that authorizes the medical use of radioactive material; or
- (3) Identified as an authorized user on a permit issued by an Agency, NRC or Agreement State or Licensing State specific licensee of broad scope that is authorized to permit the medical use of radioactive material.

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

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

Client's Address means the address of use or a temporary jobsite for the purpose of providing mobile medical service in accordance with 105 CMR 120.541.

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

Dentist means an individual licensed by the Commonwealth to practice dentistry.

Diagnostic Clinical Procedures Manual means a collection of written procedures that describes each method (and other instructions and precautions) by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration.

High Dose-rate Remote Afterloader means a device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the treatment site.

Low Dose-rate Remote Afterloader means a device that remotely delivers a dose rate of less than or equal to two gray (200 rads) per hour at the treatment site.

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

Manual Brachytherapy means a type of therapy in which brachytherapy sources are manually applied or inserted.

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

Medical Use means the intentional internal or external administration of radioactive material, or the radiation from radioactive

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material to patients or human research subjects under the supervision of an authorized user.

Medium Dose-rate Remote Afterloader (MDR) means a device that remotely delivers a dose rate of greater than two gray (200 rads), but less than, or equal to, 12 gray (1200 rads) per hour at the treatment site.

Mobile Medical Service means the transportation of radioactive material and its medical use at the client's address.

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Output means the Exposure rate, dose rate, or a quantity related in a known manner to these rates from a brachytherapy source or a teletherapy, remote afterloader, or gamma stereotactic radio-surgery unit for a specified set of exposure conditions.

Patient Intervention means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

*Positron Emission Tomography (PET) radionuclide production facility means a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.*

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

Prescribed Dosage means the quantity of a radiopharmaceutical activity as documented:

- (1) In a written directive as specified in 105 CMR 120.521; or
- (2) In accordance with the directions of the authorized user for procedures performed pursuant to 105 CMR 120.544, 120.547 and 120.552.

Prescribed Dose means:

- (1) For gamma stereotactic radiosurgery, the total dose as documented in the written directive; or
- (2) For teletherapy, the total dose and dose per fraction as documented in the written directive; or
- (3) For manual brachytherapy, either the total source strength and exposure time, or the total dose, as documented in the written directive; or
- (4) For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

Pulsed Dose-rate Remote Afterloader means a special type of remote afterloading device that uses a single source capable of delivering dose rates in the "high dose-rate" range, but:

- (1) Is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and
- (2) Is used to simulate the radiobiology of a low dose rate treatment by inserting the source for a given fraction of each hour.

Radiation Safety Officer means an individual who:

- (1) Meets the requirements in 105 CMR 120.524(A) or(C)(1) and ~~or~~ 120.528; or
- (2) Is identified as a Radiation Safety Officer on a Nuclear Regulatory Commission or Agreement State license or other equivalent permit or license recognized by the Agency for similar types and uses of radioactive material.

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

Sealed Source and Device Registry means the national registry that contains all the registration certificates, generated by both Nuclear Regulatory Commission and the Agreement States, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

Stereotactic Radiosurgery means the use of external radiation in conjunction with a stereotactic guidance device to precisely

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deliver a dose to a tissue volume.

Structured Educational Program means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

Teletherapy as used in 105 CMR 120.500, means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.

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Temporary Jobsite means a location where mobile medical services are conducted other than those location(s) of use authorized on the license.

Therapeutic Dosage means a dosage of unsealed radioactive material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

Therapeutic Dose means a radiation dose delivered from a sealed source containing radioactive material to a patient or human research subject for palliative or curative treatment.

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

Type of Use means use of radioactive material as specified under 105 CMR 120.544, 120.547, 120.552, 120.559, 120.569, 120.570 or 120.589.

Unit Dosage means a dosage that:

- (1) Is obtained or prepared in accordance with 105 CMR 120.544, 120.547, 120.552; and,
- (2) Is to be administered as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

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

Written Directive means an authorized user's written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in 105 CMR 120.521.

### 120.503: Maintenance of Records

Each record required by 105 CMR 120.500 must be legible throughout the retention period specified by each Agency regulation. The record may be the original, a reproduced copy, or a microform provided that the copy or microform is authenticated by authorized personnel and the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

### 120.504: Provisions for Research Involving Human Subjects

A licensee may conduct research involving human subjects using radioactive material provided:

(A) That the research is conducted, funded, supported, or regulated by a Federal agency which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a licensee shall apply for and receive approval of a specific amendment to its Agency license before conducting such research. Both types of licensees shall, at a minimum, obtain prior informed consent from the human subjects and obtain prior review and approval of the research activities by an "Institutional Review Board" in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of

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### Human Subjects;

(B) The research involving human subjects authorized in 105 CMR 120.504(A) shall be conducted using radioactive material authorized for medical use in the license; and

(C) Nothing in 105 CMR 120.504 relieves licensees from complying with the other requirements in 105 CMR 120.500.

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(D) Nothing in 105 CMR 120.500 relieves the licensee from complying with applicable U.S. Food and Drug Administration, other Federal, and State requirements governing radioactive drugs or devices.

### 120.505: Implementation

(A) A licensee shall implement the provisions in 105 CMR 120.500 on October 6, 2006.

(B) When a requirement in 105 CMR 120.500 differs from the requirement in an existing license condition, the requirement in 105 CMR 120.500 shall govern.

(C) Any existing license condition that is not affected by a requirement in 105 CMR 120.500 remains in effect until there is a license amendment or license renewal.

(D) If a license condition exempted a licensee from a provision of 105 CMR 120.500 on October 6, 2006, it will continue to exempt a licensee from the corresponding provision in 105 CMR 120.500.

(E) If a license condition cites provisions in 105 CMR 120.500 that will be deleted on October 6, 2006, then the license condition remains in effect until there is a license amendment or license renewal that modifies or removes this condition.

(F) Licensees shall continue to comply with any license condition that requires it to implement procedures required by 105 CMR 120.573, 120.579, 120.580 and 120.581 until there is a license amendment or renewal that modifies the license condition.

### 120.506: License Required

(A) A person shall only manufacture, produce, prepare, compound, acquire, receive, possess, use, or transfer radioactive material for medical use in accordance with a specific license issued by the Agency, the Nuclear Regulatory Commission or an Agreement State, or as allowed in 105 CMR 120.506(B)(1) or (B)(2)

(B)(1) Unless prohibited by license condition, an individual may receive, possess, use, or transfer radioactive material in accordance with 105 CMR 120.500 under the supervision of an authorized user as provided in 105 CMR 120.510.

(2) Unless prohibited by license condition, an individual may prepare unsealed radioactive material for medical use in accordance with 105 CMR 120.500 under the supervision of an authorized nuclear pharmacist or an authorized user as provided in 105 CMR 120.510.

### 120.507: Application for License, Amendments, or Renewal

(A) An application must be signed by the applicant's or licensee's management.

(B) An application for a license for medical use of radioactive material as described in 105 CMR 120.544, 120.547, 120.552, 120.559, 120.568, 120.570 or 120.589 must be made by:

(1) Filing an original and one copy of Agency application form MRCP 120.100- 4 that includes the facility diagram, equipment, and training, experience and qualifications of the Radiation safety Officer, authorized user(s), authorized medical physicist(s), and authorized nuclear pharmacist(s), and

(2) Submitting procedures required by 105 CMR 120.522, 120.531, 120.573, 120.579, 120.580 and 120.581, as applicable.

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- (C) A request for a license amendment or renewal must be made by:
  - (1) Submitting an original and one copy of either:
    - (a) Agency form MRCP 120.100- 4; or
    - (b) a letter requesting the amendment or renewal; and

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(2) Submitting procedures required by 105 CMR 120.522, 120.531, 120.573, 120.579, 120.580 and 120.581, as applicable.

(D) In addition to the requirements in 105 CMR 120.507(A) and 120.507(C), an application for a license or amendment for medical use of radioactive material as described in 105 CMR 120.589 must also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in 105 CMR 120.501 through 120.543, as well as any specific information on:

- (1) Radiation safety precautions and instructions;
- (2) Training and experience of proposed users;
- (3) Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and
- (4) Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.

(E) The applicant or licensee shall also provide any other information requested by the Agency in its review of the application.

(F) An applicant that satisfies the requirements specified in 105 CMR 120.127(B) may apply for a Type A specific license of broad scope.

### 120.508: License Amendments

A licensee shall apply for and must receive a license amendment:

(A) Before it receives, prepares or uses radioactive material for a type of use that is permitted under 105 CMR 120.500, but that is not authorized on the licensee's current license issued pursuant to 105 CMR 120.500;

(B) Before permitting anyone, except a visiting authorized user, a visiting authorized medical physicist or visiting authorized nuclear pharmacist described in 105 CMR 120.511, to work as an authorized user, authorized medical physicist or an authorized nuclear pharmacist, respectively, under the license except an individual who is:

- (1) for an authorized user, an individual who meets the requirements in 105 CMR 120.529, 120.546(A), 120.551(A), 120.556(A), 120.557(A), 120.558(A), 120.566(A), 120.567, 120.569(A), or 120.587(A);
- (2) for an authorized nuclear pharmacist, an individual who meets the requirements in 105 CMR 120.526(A) and 120.529;
- (3) for an authorized medical physicist, an individual who meets the requirements in 105 CMR 120.525(A) and 120.529;
- (4) identified as an authorized user or an authorized nuclear pharmacist or authorized medical physicist on an Agency, or the U.S. Nuclear Regulatory Commission or Agreement State or Licensing State license that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy, respectively; or,
- (5) identified as an authorized user or an authorized nuclear pharmacist or authorized medical physicist on a permit issued by the Agency, or the U.S. Nuclear Regulatory Commission or Agreement State or Licensing State specific licensee of broad scope that is authorized to permit the use of radioactive material in medical use or the practice of nuclear pharmacy, respectively;

(C) Before changing a Radiation Safety Officer, except as provided in 105 CMR 120.515(C).

(D) Before receiving radioactive material in excess of the amount, or in a different physical or chemical form than is authorized on the license;

(E) Before adding to or changing the areas of use identified in the application or on the license, except as specified in 105 CMR 120.509; and

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(F) Before changing the address(es) of use identified in the application or on the license;

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- (G) Before changing statements, representations, and procedures which are incorporated into the license; and
- (H) Before releasing licensed facilities for unrestricted use.

### 120.509: Notifications

- (A) A licensee shall provide to the Agency a copy of the board certification, the Agency, NRC, Agreement State or Licensing State license, or the permit issued by a licensee of broad scope for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user or an authorized nuclear pharmacist pursuant to 105 CMR 120.508(B).
- (B) A licensee shall notify the Agency by letter no later than 30 days after:
  - (1) An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer or an authorized medical physicist permanently discontinues performance of duties under the license or has a name change;
  - (2) The licensee's mailing address changes;
  - (3) The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in 105 CMR 120.131(B); or,
  - (4) The licensee has added to or changed the areas where radioactive material is used in accordance with 105 CMR 120.544 and 120.547.

### 120.510: Exemptions Regarding Type A Specific Licenses of Broad Scope

A licensee possessing a Type A specific license of broad scope for medical use is exempt from:

- (A) The provisions of 105 CMR 120.507(D) regarding the need to file an amendment to the license for medical use of radioactive material as described in 105 CMR 120.589;
- (B) The provisions of 105 CMR 120.508(B) regarding the need to file an amendment before permitting anyone to work as an authorized user, an authorized nuclear pharmacist or authorized medical physicist under the license;
- (C) The provisions of 105 CMR 120.508(E) regarding additions to or changes in the areas of use at the addresses specified in the license;
- (D) The provisions of 105 CMR 120.509(A) regarding notification to the Agency for new authorized users, new authorized nuclear pharmacists and new authorized medical physicists; and,
- (E) The provisions of 105 CMR 120.523(A) regarding suppliers for sealed sources.

### 120.511: License Issuance

- (A) The Agency shall issue a license for the medical use of radioactive material if:
  - (1) The applicant has filed Agency application form MRCP 120.100- 4 in accordance with the instructions in 105 CMR 120.507;
  - (2) The applicant has paid any applicable fee;
  - (3) The applicant meets the requirements of 105 CMR 120.100; and,

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(4) The Agency finds the applicant equipped and committed to observe the safety standards established by the Agency in these regulations for the protection of the public health and safety.

(B) The Agency shall issue a license for mobile services if the applicant:

- (1) Meets the requirements in 105 CMR 120.511(A); and,
- (2) Assures that individuals to whom radioactive drugs or radiation from implants containing radioactive material will be administered, may be released following treatment in accordance with 105 CMR 120.527.

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### 120.513: Specific Exemptions

The Agency may, upon application of any interested person or upon its own initiative, grant such exemptions from the regulations in 105 CMR 120.500 as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

### GENERAL ADMINISTRATIVE REQUIREMENTS

### 120.515: Authority and Responsibilities for the Radiation Protection Program

(A) In addition to the radiation protection program requirements of 105 CMR 120.210, a licensee's management must approve in writing:

- (1) Requests for license application, renewal, or amendments before submittal to the Agency;
- (2) Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist or authorized medical physicist; and
- (3) Radiation protection program changes that do not require a license amendment and are permitted under 105 CMR 120.517.

(B) A licensee's management shall appoint a Radiation Safety Officer, who agrees in writing to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.

(C) For up to 60 days each year, a licensee may permit an authorized user or an individual qualified to be a radiation safety officer to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in 105 CMR 120.515(E), provided the licensee takes the actions required in 105 CMR 120.515(B), (D), (E) and (H). A licensee may simultaneously appoint more than one temporary RSO, if needed, to ensure that the licensee has a temporary RSO that satisfies the requirements to be an RSO for each of the different uses of radioactive material permitted by the license.

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

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

- (1) Identify radiation safety problems;
- (2) Initiate, recommend, or provide corrective actions;
- (3) Stop unsafe operations; and,
- (4) Verify implementation of corrective actions.

(F) Licensees that are authorized for two or more different types of radioactive material use under 105 CMR 120.552, 120.559, 120.570, and 120.589, or two or more types of units under 105 CMR 120.571 shall establish a Radiation Safety Committee to oversee all uses of radioactive material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer, and may include other members as the licensee deems appropriate.

(G) A licensee's Radiation Safety Committee shall meet as necessary, but at a minimum shall meet at intervals not to exceed six months. The licensee shall maintain minutes of each meeting in accordance with 105 CMR 120.590(A).

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(H) A licensee shall retain a record of actions taken pursuant to 105 CMR 120.515(A), 120.515(B) and 120.515(D) in accordance with 105 CMR 120.590(A).

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### 120.517: Radiation Protection Program Changes

- (A) A licensee may revise its radiation protection program without Agency approval if:
- (1) The revision does not require an amendment under 105 CMR 120.508;
  - (2) The revision is in compliance with the regulations and the license;
  - (3) The revision has been reviewed and approved by the Radiation Safety Officer, licensee management and licensee's Radiation Safety Committee (if applicable); and,
  - (4) The affected individuals are instructed on the revised program before the changes are implemented.
- (B) A licensee shall retain a record of each change in accordance with 105 CMR 120.590(B).

### 120.518: Duties of Authorized User and Authorized Medical Physicist

#### 120.519: Supervision

- (A) A licensee that permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by 105 CMR 120.506(B)(1) shall:
- (1) In addition to the requirements in 105 CMR 120.753, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures in 105 CMR 120.500, and license conditions with respect to the use of radioactive material;
  - (2) Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures, written directive procedures, regulations of 105 CMR 120.500, and license conditions with respect to the medical use of radioactive material; and
  - (3) Require that only those individuals permitted under state and local regulations and specifically trained, and designated by the authorized user, be permitted to administer radionuclides or radiation to patients or human research subjects.
- (B) A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by 105 CMR 120.506(B)(2) ~~(C)~~, shall:
- (1) Instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and
  - (2) Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, the written radiation protection procedures in 105 CMR 120.500, and license conditions.
- (C) Unless physical presence as described in other sections of 105 CMR 120.500 is required, a licensee that permits supervised activities under 105 CMR 120.519(A) and 120.519(B) shall require an authorized user to be immediately available (by telephone within ten minutes) to communicate with the supervised individual, and able to be physically present within one hour of notification; and
- (D) A licensee that permits supervised activities under 105 CMR 120.519(A) and 120.519(B) is responsible for the acts and omissions of the supervised individual.

### 120.520: Visiting Authorized User, Visiting Authorized Nuclear Pharmacist or Visiting Medical Physicist

- (A) A licensee may permit any visiting authorized user, visiting authorized nuclear pharmacist or visiting authorized medical physicist to work as an authorized user, authorized nuclear pharmacist or medical physicist, respectively, under the terms of the licensee's license for 60 days each year if:

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(1) The visiting authorized user, the visiting authorized nuclear pharmacist or the visiting authorized medical physicist has the prior written permission of the licensee's management and, if the work is performed on behalf of an institution, the institution's Radiation Safety Committee;

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- (2) The licensee has a copy of an Agency, Agreement State, Licensing State or U.S. Nuclear Regulatory Commission license that identifies the visiting authorized user, the visiting authorized nuclear pharmacist or the visiting authorized medical physicist by name as an authorized user for medical use, as an authorized nuclear pharmacist, or as an authorized medical physicist respectively; and
- (3) Only those procedures for which the visiting authorized user is specifically authorized by an Agency, Agreement State, Licensing State or U.S. Nuclear Regulatory Commission license are performed by that individual.

(B) A licensee need not apply for a license amendment in order to permit a visiting authorized user, a visiting authorized nuclear pharmacist or a visiting authorized medical physicist to use licensed material as described in 105 CMR 120.520(A).

(C) A licensee shall retain copies of the records specified in 105 CMR 120.520(A), as specified in 105 CMR 120.590(A).

### 120.521: Written Directives

(A) A written directive must be dated and signed by an authorized user prior to administration of I-131 sodium iodide greater than 1.11 megabecquerel (30  $\mu$ Ci), any therapeutic dosage of radioactive material or any therapeutic dose of radiation from radioactive material.

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

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

- (1) For an administration of a dosage of radioactive drug containing radioactive material, the radioactive drug containing radioactive material, dosage, and route of administration;
- (2) For gamma stereotactic radiosurgery, the total dose, treatment site, and number of target coordinate settings per treatment for each anatomically distinct treatment site;
- (3) For teletherapy, the total dose, dose per fraction, number of fractions, and treatment site;
- (4) For high dose rate remote afterloading brachytherapy, the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or
- (5) For all other brachytherapy including LDR, MDR, and PDR:
  - (a) Prior to implantation: treatment site, the radionuclide, and dose; and,
  - (b) After implantation but prior to completion of the procedure: the radioisotope, treatment site, number of sources, and total source strength and exposure time (or, the total dose).

(C) A written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to the administration of the dosage of radioactive drug containing radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

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

(D) The licensee shall retain the written directive in accordance with 105 CMR 120.590(C).

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### 120.522: Procedures for Administrations Requiring a Written Directive

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

- (1) The patient's or human research subject's identity is verified before each administration; and

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

(B) The procedures required by 105 CMR 120.522(A) must, at a minimum, address the following items that are applicable for the licensee's use of radioactive material:

- (1) Verifying the identity of the patient or human research subject;
- (2) Verifying that the specific details of the administration are in accordance with the treatment plan, if applicable, and the written directive;
- (3) Checking both manual and computer-generated dose calculations; and
- (4) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by 105 CMR 120.570.

### 120.523: Suppliers for Sealed Sources or Devices Containing Sealed Sources for Medical Use

For medical use, a licensee may only use:

(A) Sealed sources or devices initially manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to 105 CMR 120.100 or the equivalent requirements of the Nuclear Regulatory Commission, an Agreement State or a Licensing State; or

(B) Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to 105 CMR 120.100 or the equivalent requirements of the Nuclear Regulatory Commission, an Agreement State or a Licensing State.

### 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) 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 speciality board shall require all candidates for certification to: ~~or~~

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

(c) Pass an examination administered by diplomates of the speciality 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 2 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 speciality board recognized by the Commission or an Agreement State; or

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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 120.551 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

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

(a) 200 hours of didactic 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; 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 paragraph 105 CMR 120.524(E) and in paragraphs (a)(1)(i) and (a)(1)(ii) or (a)(2)(i) and (a)(2)(ii) or (b)(1) or (c)(1) or (c)(2) of this section, and has achieved a level of radiation safety knowledge sufficient to

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function independently as a Radiation Safety Officer for a medical use licensee; and

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

~~(2) Has obtained written certification, signed by a preceptor RSO, that the individual has satisfactorily completed the requirements in 105 CMR 120.524(B)(1) and has achieved a level of radiation safety knowledge sufficient to independently function as an RSO for medical uses of radioactive material; or~~

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120.524: continued

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

## 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 includes all of the training and experience requirements in 105 CMR 120.525(B) and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State; or has been recognized by the Commission or an Agreement State and who meets the requirements in 105 CMR 120.525(B)(2) and 120.525(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 2 years of full-time practical training and/or supervised experience in medical physics—~~

~~(a) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the 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 120.566 or 120.587, or, before October 24, 2005, authorized users who meet the requirements in 10 CFR 35.940 or 10 CFR 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 1 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 1 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~~

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(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 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, or, before October 24, 2005, 10 CFR 35.961, 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.

~~(B) (1) Holds a master's or doctor's degree in physics, biophysics, radiological physics, medical~~

~~physics, or health physics, or an equivalent training program approved by the Agency, another Agreement State or the Nuclear Regulatory Commission and has completed one year of full-time training in therapeutic radiological physics and an additional year of full-time practical experience under the supervision of a medical physicist at a medical institution that includes the tasks listed in 105 CMR 120.536, 120.564(E), 120.576, 120.577, 120.578, 120.579, 120.580, 120.581 and 120.583, as applicable; and~~

~~(2) Has obtained written certification, signed by a preceptor authorized medical physicist, that the individual has satisfactorily completed the requirements in 105 CMR 120.525(B)(1) and has achieved a level of competency sufficient to independently function as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.~~

### 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 as a nuclear pharmacist by a specialty board whose certification process includes all of the requirements in 105 CMR 120.526(B) and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State; or 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

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

(a) 200 hours of classroom and laboratory ~~Didactic~~ 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;
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 certification, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in 105 CMR 120.526(A)(1), 120.526(A)(2), and 120.526(A)(3) or 120.526(B)(1) ~~(B)(1)~~ and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

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### 120.528: Training Provisions for Experienced Radiation Safety Officer, Medical Physicist, Authorized User, and

#### 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, that authorizes medical use or the practice of nuclear pharmacy, before October 6, 2006 need not comply with the training requirements of 105 CMR 120.524, 120.525 and 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, 120.525 and 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, 120.525, 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, dental, or podiatric 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, that authorizes medical use or the practice of nuclear pharmacy, issued before October 6, 2006 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, 120.557, 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, 120.557, 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, 120.557, 120.558, 120.566, 120.567,

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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 this paragraph, qualifies as an authorized user for those materials and uses performed before these dates, for purposes of 105 CMR 120.500.

### 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).

### 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:

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- (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  $\frac{1}{3}$  and  $\frac{2}{3}$  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:
- (1) Direct measurement of radioactivity; or
  - (2) A decay correction, based on the activity or activity concentration determined by:
    - (a) A manufacturer or preparer licensed pursuant to 105 CMR 120.128(J) or equivalent provisions of the Nuclear Regulatory Commission or Agreement State; or
    - (b) An Agreement State or NRC 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
    - (c) A PET radioactive drug producer licensed under 105 CMR 120.128(A) or equivalent NRC or Agreement State requirements. ~~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:
- (1) Direct measurement of radioactivity;
  - (2) Combination of radioactivity and mathematical calculations; or
  - (3) Combination of volumetric measurements and mathematical calculations, based on the measurement made by:
    - (a) A manufacturer or preparer licensed pursuant to 105 CMR 120.128(J) or equivalent NRC or Agreement State

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requirements; or

(b) A PET radioactive drug producer licensed pursuant to 105 CMR 120.128(A) or equivalent NRC or Agreement State requirements. ~~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).

## 120.535: Authorization for Calibration, Transmission and Reference Sources

Any person authorized by 105 CMR 120.50~~6~~ <sup>3</sup> 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  $\mu$ 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.

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(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  $\mu$ Ci) of radioactive material in the sample. If the leak test reveals the presence of 185 becquerels (0.005  $\mu$ 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 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*

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*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).

(E) The licensee shall immediately notify the Agency in accordance with 105 CMR 120.594 ~~θ~~(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.

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(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.

(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) 7; and,
- (2) Retain a record of each survey required by 105 CMR 120.541(A)(4) in accordance with 105 CMR 120.590(L) 7.

(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.

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## 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).

### 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 120.128(A) or equivalent regulations of the Nuclear Regulatory Commission or equivalent Agreement State requirements; or

(B) Excluding production PET radionuclides, ~~or~~ prepared by:

(1) an authorized nuclear pharmacist;

(2) A ~~a~~ physician who is an authorized user and who meets the requirements specified in 105 CMR 120.551 ~~46~~, or 105 CMR 120.556 and 105 CMR 120.551(C)(1)(b)7.; or

(3) a ~~An~~ individual under the supervision ~~of either~~ as specified in 105 CMR 120.519, of the authorized nuclear pharmacist

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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:

(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) of this section. (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: includes all of the requirements in 105 CMR 120.546(C) and whose certification has been recognized by the Nuclear Regulatory Commission, or an Agreement State; or~~

~~(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 120.546 (C)(1)(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 105 CMR 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 8 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. ~~The training and experience must include: that includes:~~

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

1. Radiation physics and instrumentation;

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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 120.546, 120.551 or 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~~ ~~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 ~~medical event misadministration~~ involving the use of unsealed radioactive material;
5. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and,
6. Administering dosages to patients or human research subjects; and,

(2) Has obtained written ~~attestation, certification,~~ 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 120.546(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~~ ~~Radioactive~~ Material

Written Directive Not Required

### 120.547: Use of Unsealed Radioactive 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~~ 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;

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(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) 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 and 120.551(C)(1)(b)7.; or

(3) An individual under the supervision of either 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

(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  $\mu$ 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  $\mu$ 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  $\mu$ 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

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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 Commission or an Agreement State and who meets the requirements in paragraph 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: includes all of the requirements in 105 CMR 120.551(C) and whose certification has been recognized by the Nuclear Regulatory Commission, or an Agreement State; or

(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 120.551(C)(1)(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

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120.551: continued

(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 5 528, 120.551 or 120.551(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. 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; and
6. Administering dosages of radioactive drugs to patients or human research subjects; ~~and~~  
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 certification, 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 120.551(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 and 120.547.

SPECIFIC REQUIREMENTS FOR THE USE OF UNSEALED RADIOACTIVE MATERIAL

WRITTEN DIRECTIVE REQUIRED

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### 120.552: Use of Unsealed Radioactive 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:

(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 120.128(A) 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, or

(3) An individual under the supervision, as specified in 105 CMR 120.519, of the authorized nuclear pharmacist in 120.552(B)(2) of this section or the physician who is an authorized user in 120.552(B)(2) of this section; 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 105 CMR 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

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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 120.221(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.

(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 Radioactive 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 120.556(B)(2). (Specialty boards whose

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~~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: includes all of the requirements in 105 CMR 120.556(B) and whose certification has been recognized by the Nuclear Regulatory Commission, or an Agreement State; or~~

~~(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 120.556(B)(1)(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~~

(B)(1) Has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed ~~radioactive~~ byproduct material requiring a written directive, ~~that includes~~ 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~~ 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 120.556 or ~~or~~ equivalent Agreement State, or Nuclear Regulatory Commission requirements, ~~involving~~, 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. 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. [Reserved]

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~~7. Administering dosages to patients or human research subjects; and~~

~~7. Eluting generator systems, measuring and testing the eluate for radiochemical purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs containing radioactive material; and~~

~~7(2) 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. This experience may be obtained concurrently with the supervised work experience required by 105 CMR 120.556(B)(1)(b):~~

~~a. (a) Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131;~~

~~b. (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. (c) Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV; and/or~~

~~d. (d) Parenteral administration of any other radionuclide; and~~

~~(2) Has obtained written attestation that the individual has satisfactorily completed the requirements—certification, signed by a preceptor authorized user, who meets the requirements in 105 CMR 120.556(A)(1) and 120.556(B)(1)(b)7. or 120.556(B)(1) or equivalent Agreement State, or Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements 105 CMR 120.556(B)(1) and 105 CMR 120.556(B)(2) and has achieved a level of competency sufficient to independently function as an authorized user for the medical uses authorized under 105 CMR 120.552-6. The written attestation must be signed by a preceptor authorized user, who meets the requirements of 105 CMR 120.528, 120.556 (B) 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 (i.e., 105 CMR 120.556(B)(1 2)(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 120.557C(2) and whose certification has been recognized by an Agreement State or the Nuclear Regulatory Commission and who meets the requirements in 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 (A), 120.556(B), for uses listed in 120.556(B)(1 2)(b)7.b. (a) or (b), 120.558 or equivalent Agreement State or Nuclear Regulatory Commission requirements; or

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(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(A), ~~120.556(B)~~, 120.557 ~~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)(~~2~~)(a) (1)(b)7.a or 7.b. ~~or 120.556(B)(2)(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 ~~Calibrating~~ 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 ~~radioactive~~ 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

(3) Has obtained written attestation certification ~~certification~~ that the individual has satisfactorily completed the requirements in 105 CMR 120.557(C)(1) and 120.557(C)(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. ~~of unsealed radioactive material using sodium iodide I-131.~~ The written attestation certification must be signed by a preceptor authorized user, who meets the requirements of 105 CMR 120.528, 120.556 (A), ~~120.556(B)~~, 120.557 ~~or~~ 120.558, or equivalent Agreement State or Nuclear Regulatory Commission requirements. A ~~The~~ preceptor authorized user who meets the requirements of 105 CMR 120.556(B) must have experience in administering dosages as specified in 120.556(B)(~~2~~)(b) 7.a. or 7.b. ~~(a) and/or (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 ~~7~~(C)(1)

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and 120.558(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(A), ~~120.556(B)~~, for uses listed in 120.556(B)(1 ~~2~~)(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, ~~56(A)~~, 120.556(B), ~~120.557~~ 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 ~~2~~)(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 ~~Calibrating~~ 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 ~~misadministration~~ involving the use of unsealed radioactive byproduct material;
- (e) Using procedures to contain spilled byproduct ~~radioactive~~ 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 greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

(3) Has obtained written ~~certification~~ attestation that the individual has satisfactorily completed the requirements in 105 CMR 120.558(C)(1) and 120.558(C)(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 ~~of unsealed radioactive material using sodium iodide I-131 in activities greater than 1.22 gigabecquerels (33 millicuries)~~. The written ~~certification~~ 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 preceptor authorized user who meets the requirements of 105 CMR 120.556(B) must have experience in administering dosages as specified in 105 CMR 120.556(B)(1 ~~2~~)(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

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requiring a written directive, to be a physician who:

(A) Is an authorized user under 105 CMR 120.558A for uses listed in 105 CMR 120.556(B)(1)(b)7.c. or 120.556(B)(1)(b)7.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 120.556(B)(1)(b)7.d. 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 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 3 cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and

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(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 105 CMR 120.558A(B) or 120.558A(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 120.556(B)(1)(b)7.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.
- (C) A licensee shall retain a record of the surveys in accordance with 105 CMR 120.592(A).

#### 120.561: Brachytherapy Sources Accountability

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- (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:

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120.562: continued

(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.

(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);

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- (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 105 CMR 120.564(A)(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), 105 CMR 120.564(B), or 105 CMR 120.564(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), 105 CMR 120.564(B), and 105 CMR 120.564(C).

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120.564: continued

(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

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 ~~includes all of~~ the requirements in 105 CMR 120.566(B)(3), and whose certification has been recognized by an Agreement State or the Nuclear Regulatory Commission; or (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 3 years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association;  
and

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(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:

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 ~~misadministration~~ medical event involving the use of ~~radioactive byproduct~~ material;
6. Using emergency procedures to control ~~radioactive 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

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120.566: continued

(3) Has obtained written ~~certification~~ 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 120.566(B)(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;
- (d) Follow-up and review of each individual's case history; and

(3) Has obtained written ~~certification~~ 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)(1) and~~ 120.567(B)(1) and 120.567(B)(2) 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: Use of a Sealed Source in a Teletherapy Unit

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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 120.569(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 ~~had~~ 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~~ training in the use of the device for the uses requested.

### PHOTON EMITTING REMOTE AFTERLOADER UNITS, TELE THERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS

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

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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

(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);

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

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- (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.

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120.574: continued

(F) In addition to the requirements specified in 105 CMR 120.574(A) through 105 CMR 120.574(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

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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).

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### 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.

(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

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- (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 of:

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- (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 105 CMR 120.577(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 obtained

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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;

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- (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:

- (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

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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".

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(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 105 CMR 120.579(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
- (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.

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

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(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 105 CMR 120.581(A)(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 105 CMR 120.581(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).

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(C) A licensee shall retain a record of the radiation surveys required in 105 CMR 120.583(A) in accordance with 105 CMR 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.

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## 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:

(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 120 587(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:~~ ~~includes all of the requirements in 105 CMR 120.587(B) and whose certification has been recognized by an Agreement State or the Nuclear Regulatory Commission; or~~

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

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

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

(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. Chemistry of radioactive material for medical use; and~~
- ~~4~~ 5. 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;

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5. Checking and using survey meters; and.

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~~ ~~oncology~~, 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~~ ~~certification~~, ~~that the individual has satisfactorily completed the requirements in 105 CMR 120.587(A)(1) or 120.587(B)(1) and 120.587(B)(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 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 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~~ ~~that the individual has satisfactorily completed the requirements in 105 CMR 120.587(B)(1) and 105 CMR 120.587(B)(2) and has achieved a level of competency sufficient to independently function as an authorized user of the therapeutic medical unit for which the individual is requesting authorized user status.~~

(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.

### OTHER MEDICAL USES OF RADIOACTIVE MATERIAL OR RADIATION FROM RADIOACTIVE MATERIAL

#### 120.589: Other Medical Uses of Radioactive Material or Radiation from Radioactive Material

A licensee may use radioactive material or a radiation source approved for medical use that is not specifically addressed in 105 CMR 120.500 if:

- (A) The applicant or licensee has submitted the information required by 105 CMR 120.507(B), 120.507(C) and 120.507(D); and
- (B) The applicant or licensee has received written approval from the Agency in a license and uses the material in accordance with 105 CMR 120.000 and specific conditions the agency considers necessary for the medical use of the material.

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## RECORDS

### 120.590: Requirements for Record Keeping

#### (A) Records of Authority and Responsibilities for Radiation Protection Programs.

(1) A licensee shall retain a record of actions taken by the licensee's management in accordance with 105 CMR 120.515(A) for five years. The record must include a summary of the actions taken and a signature of licensee management.

(2) The licensee shall retain a current copy of the authorities, duties and responsibilities of the Radiation Safety Officer as required by 105 CMR 120.515(D), and a signed copy of the Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by 105 CMR 120.515(B) The record must include the signature of the Radiation Safety Officer and licensee management.

(B) Records of Radiation Protection Program Safety Changes. A licensee shall retain a record of each radiation protection program change made in accordance with 105 CMR 120.517(A) for five years. The record must include a copy of the old and new procedures; the effective date of the change; and the signature of the licensee management that reviewed and approved the change.

(C) Records of Written Directives. A licensee shall retain a copy of each written directive as required by 105 CMR 120.521 for three years.

(D) Records of Medical Events. A licensee shall retain a record of medical events reported in accordance with 105 CMR 120.594(A) for three years. The record must contain the licensee's name; names of the individuals involved; the social security number or other identification number if one has been assigned, of the individual who is the subject of the medical event; medical event a brief description of the event; why it occurred; the effect, if any, on the individual; the actions, if any, taken, or planned, to prevent recurrence; and, whether the licensee notified the individual (or the individual's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

(E) Record of a Dose to an Embryo/Fetus or a Nursing Child. A licensee shall retain a record of a dose to an embryo/fetus or a nursing child reported in accordance with 105 CMR 120.594(B) for three years. The record must contain the licensee's name; names of all the individuals involved; social security number or other identification number if one has been assigned of the embryo/fetus or nursing child who is the subject of the event; a brief description of the event; why it occurred; the effect, if any, on the embryo/fetus or nursing child; the actions, if any, taken, or planned, to prevent recurrence; and whether the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.]

(F) Records of Calibrations of Instruments used to Measure the Activity of Unsealed Radioactive Material. A licensee shall maintain a record of instrument calibrations required by 105 CMR 120.536(B) for three years. The records must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

(G) Records of Survey Instrument Calibrations. A licensee shall maintain a record of instrument calibrations required by 105 CMR

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120.533 for three years. The record must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

(H) Records of Dosages of Unsealed Radioactive Material for Medical Use. A licensee shall maintain a record of dosage determinations required by 105 CMR 120.534 for three years. The record must contain the radioactive drug; the patient's or human research subject's name, or identification number if one has been assigned; prescribed dosage; the determined dosage, or a notation that the total activity is less than 1.1 MBq (30  $\mu$ Ci); the date and time of the dosage determination; and the name of the individual who determined the dosage.

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(I) Records of Possession of Sealed Sources and Brachytherapy Sources.

(1) A licensee shall retain a record of the leak test required by 105 CMR 120.536(B) for three years. The record must contain the model number, and serial number if one has been assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the results of the test, the date of the test, and the name of the individual who performed the test.

(2) A licensee shall retain a record of the semi-annual physical inventory of sealed sources and brachytherapy sources required by 105 CMR 120.536(E) for three years. The inventory record must contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

(J) Records of Surveys for Ambient Radiation Exposure Rate. A licensee shall retain a record of each survey required by 105 CMR 120.539 for three years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

(K) Records of the Release of Individuals Containing Radioactive Drugs or Implants Containing Radioactive Material.

(1) A licensee shall retain a record, signed by the authorized user, of the basis for authorizing the release of an individual, for three years after the date of release, if the total effective dose equivalent is calculated by:

- (a) Using the retained activity rather than the activity administered;
- (b) Using an occupancy factor less than 0.25 at one meter;
- (c) Using the biological or effective half-life; or
- (d) Considering the shielding by tissue.

(2) A licensee shall retain a record, for three years after the date of release, that the instructions required by 105 CMR 120.540(B) were provided to a breast-feeding woman [if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding five mSv (0.5 rem)].

(L) Records of Administrative and Technical Requirements that Apply to the Provision of Mobile Services.

(1) A licensee shall retain a copy of the letter(s) that permits the use of radioactive material at a client's address of use, as required by 105 CMR 120.541(A)(1), for three years after the last provision of service.

(2) A licensee shall retain the record of each survey required by 105 CMR 120.541(A)(4) for three years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

(M) Records of Decay-in-storage. A licensee shall maintain records of the disposal of licensed materials, as required by 105 CMR 120.543, for three years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.

(N) Records of Radionuclide Purity. A licensee shall maintain a record of the radionuclide contaminant concentration tests required

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by 105 CMR 120.548 for three years. The record must include, for each measured elution of radionuclide used to prepare a radioactive drug, the ratio of the measures expressed as kilobecquerel of contaminant per megabecquerel of desired radionuclide (microcuries/millicurie), or microgram of contaminant per megabecquerel of desired radionuclide (microgram/millicurie), the time and date of the measurement, and the name of the individual who made the measurement.

(P) Records of Safety Instruction and Training. A licensee shall maintain a record of safety instructions and training required by 105 CMR 120.553, 105 CMR 120.562 and 105 CMR 120.573 for three years. The record must include a list of the topics covered, the date of the instruction or training, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

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(Q) Records of Radiation Surveys of Patients and Human Research Subjects. A licensee shall maintain a record of the surveys required by 105 CMR 120.560 and 105 CMR 120.571 for three years. Each record must include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

### 120.592: Requirements for Record Keeping Pertaining to the Use of Sealed Sources

#### (A) Records of Brachytherapy Source Inventory.

- (1) A licensee shall maintain a record of brachytherapy source accountability required by 105 CMR 120.561 for three years.
- (2) For temporary implants, the record must include:
  - (a) The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use; and
  - (b) The number and activity of sources not implanted, the time and date they were returned to storage, and the name of the individual who returned them from storage.
- (3) For permanent implants, the record must include:
  - (a) The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;
  - (b) The number and activity of sources returned to storage, the date they were returned to storage, and the name of the individual who returned them to storage; and
  - (c) The number and activity of sources permanently implanted in the patient or human research subject.

(B) Records of Calibration Measurements on Brachytherapy Sources. A licensee shall maintain a record of the calibrations on brachytherapy sources required by 105 CMR 120.564 for three years after the last use of the source. The record must include the date of the calibration; the manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source; the source output or activity; source positioning accuracy within applicators; and the signature of the authorized medical physicist.

(C) Records of Decay of Strontium-90 Sources for Ophthalmic Treatments. A licensee shall maintain a record of the activity of a strontium-90 source required by 105 CMR 120.564. The record must include the date and initial activity of the source as determined under 105 CMR 120.564, and for each decay calculation, the date and the source activity.

(D) Records of Installation, Maintenance, Adjustment, and Repair. A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by 105 CMR 120.572 for three years. For each installation, maintenance, adjustment and repair, the record must include the date, description of the service, and name(s) of the individual(s) who performed the work.

(E) Records of Dosimetry Equipment.

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- (1) A licensee shall retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with 105 CMR 120.575 for the duration of the license.
- (2) For each calibration, intercomparison, or comparison, the record must include:
  - (a) The date;
  - (b) The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by 105 CMR 120.575(A) and 105 CMR 120.575(B);
  - (c) The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and
  - (d) The names of the individuals who performed the calibration, intercomparison, or comparison.

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(F) Records of Teletherapy, Remote Afterloader, and Gamma Stereotactic Radiosurgery Full Calibrations.

- (1) A licensee shall maintain a record of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations required by 105 CMR 120.576, 105 CMR 120.577 and 105 CMR 120.578 for three years.
- (2) The record must include:
  - (a) The date of the calibration;
  - (b) The manufacturer's name, model number, and serial number for the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit(s), the source(s), and instruments used to calibrate the unit;
  - (c) The results and assessments of the full calibrations;
  - (d) The results of the autoradiograph required for low dose-rate remote afterloader units; and
  - (e) The signature of the authorized medical physicist who performed the full calibration.

(G) Records of Periodic Spot-checks for Teletherapy Units.

- (1) A licensee shall retain a record of each periodic spot-check for teletherapy units required by 105 CMR 120.579 for three years.
- (2) The record must include:
  - (a) The date of the spot-check;
  - (b) The manufacturer's name, model number, and serial number for the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;
  - (c) An assessment of timer linearity and constancy;
  - (d) The calculated on-off error;
  - (e) A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;
  - (f) The determined accuracy of each distance measuring and localization device;
  - (g) The difference between the anticipated output and the measured output;
  - (h) Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and
  - (i) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(H) Records of Periodic Spot-checks for Remote Afterloader Units.

- (1) A licensee shall retain a record of each spot-check for remote afterloader units required by 105 CMR 120.580 for three years.
- (2) The record must include, as applicable:
  - (a) The date of the spot-check;
  - (b) The manufacturer's name, model number, and serial number for the remote afterloader unit and source;
  - (c) An assessment of timer accuracy;
  - (d) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure

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indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and

(e) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

### (I) Records of Periodic Spot-checks for Gamma Stereotactic Radiosurgery Units.

(1) A licensee shall retain a record of each spot-check for gamma stereotactic radiosurgery units required by 105 CMR 120.581 for three years.

(2) The record must include:

(a) The date of the spot-check;

(b) The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;

(c) An assessment of timer linearity and accuracy;

(d) The calculated on-off error;

(e) A determination of trunnion centricity;

(f) The difference between the anticipated output and the measured output;

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- (g) An assessment of source output against computer calculations;
- (h) Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and
- (i) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

### (J) Records of Additional Technical Requirements for Mobile Remote Afterloader Units.

- (1) A licensee shall retain a record of each check for mobile remote afterloader units required by 105 CMR 120.582 for three years.
- (2) The record must include:
  - (a) The date of the check;
  - (b) The manufacturer's name, model number, and serial number of the remote afterloader unit;
  - (c) Notations accounting for all sources before the licensee departs from a facility;
  - (d) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators and source transfer tubes, and source positioning accuracy; and
  - (e) The signature of the individual who performed the check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

### (K) Records of Surveys of Therapeutic Treatment Units.

- (1) A licensee shall maintain a record of radiation surveys of treatment units made in accordance with 105 CMR 120.583 for the duration of use of the unit.
- (2) The record must include:
  - (a) The date of the measurements;
  - (b) The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;
  - (c) Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and
  - (d) The signature of the individual who performed the test.

### (L) Records of Five-year Inspection for Teletherapy and Gamma Stereotactic Surgery Units.

- (1) A licensee shall maintain a record of the five-year inspections for teletherapy and gamma stereotactic radiosurgery units required by 105 CMR 120.584 for the duration of use of the unit.
- (2) The record must contain:
  - (a) The inspector's radioactive materials license number;
  - (b) The date of inspection;
  - (c) The manufacturer's name and model number and serial number of both the treatment unit and source;

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- (d) A list of components inspected and serviced, and the type of service; and
- (f) The signature of the inspector.

### REPORTS

#### 20.594: Reports and Notifications

##### (A) Reports and Notifications of Medical Events.

- (1) Other than events that result from intervention by a patient or human research subject, a licensee shall report any event in which the administration of radioactive material or radiation from radioactive material results in:
  - (a) A dose that differs from the prescribed dose by more than 0.05 Sv (five rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and either
    - 1. The total dose delivered differs from the prescribed dose by 20% or more;
    - 2. The total dosage delivered differs from the prescribed dosage by 20% or more or falls outside the prescribed dosage range; or

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3. The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50% or more.
- (b) A dose that exceeds 0.05 Sv (five rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following:
1. An administration of a wrong radioactive drug;
  2. An administration of a radioactive drug containing radioactive material by the wrong route of administration;
  3. An administration of a dose or dosage to the wrong individual or human research subject;
  4. An administration of a dose or dosage delivered by the wrong mode of treatment; or
  5. A leaking sealed source.
- (c) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50% of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).
- (2) A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results, or will result in, unintended permanent functional damage to an organ or a physiological system, as determined by a physician.
- (3) The licensee shall notify the Agency by telephone no later than the next calendar day after discovery of the medical event.
- (4) The licensee shall submit a written report to the Agency within 15 days after discovery of the medical event.
- (a) The written report must include:
1. The licensee's name;
  2. The name of the prescribing physician;
  3. A brief description of the event;
  4. Why the event occurred;
  5. The effect, if any, on the individual(s) who received the administration;
  6. Actions, if any, that have been taken, or are planned, to prevent recurrence;
  7. Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.
- (b) The report may not contain the individual's name or any other information that could lead to identification of the individual.
- (5) The licensee shall provide notification of the medical event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

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(6) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event or to that individual's responsible relatives or guardians.

(7) A licensee shall retain a record of a medical event in accordance with 105 CMR 120.590(D). A copy of the record required under 105 CMR 120.590(D) shall be provided to the referring physician if other than the licensee, within 15 days after discovery of the medical event.

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### (B) Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child.

(1) A licensee shall report any dose to an embryo/fetus that is greater than five mSv (500 mrem) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

(2) A licensee shall report any dose to a nursing child, that was not specifically approved, in advance, by the authorized user, that is a result of an administration of radioactive material to a breast feeding individual that:

(a) Is greater than five mSv (500 mrem) total effective dose equivalent; or

(b) Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

(3) The licensee shall notify by telephone the Agency no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in 105 CMR 120.594(B)(1) or 105 CMR 120.594(B)(2).

(4) The licensee shall submit a written report to the Agency within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in 105 CMR 120.594(B)(1) or 105 CMR 120.594(B)(2).

(a) The written report must include:

1. The licensee's name;

2. The name of the prescribing physician;

3. A brief description of the event;

4. Why the event occurred;

5. The effect on the embryo/fetus or the nursing child;

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

7. Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

(b) The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

(5) The licensee shall notify the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after of discovery of an event that would require reporting under 105 CMR 120.594(B)(1) or 105 CMR 120.594(B)(2), unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the misadministration, event because of any delay in notification. To meet the requirements of this paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother, when appropriate. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the misadministration event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(6) A licensee shall retain a record of a dose to an embryo/fetus or a nursing child in accordance with 105 CMR 120.590(E). A copy of the record required under 105 CMR 120.590(E) shall be provided to the referring physician, if other than the licensee, within 15 days after discovery of the event.

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(C) Reports of Leaking Sources. A licensee shall file a report with the Agency within five days if a leakage test required by 105 CMR 120.536 reveals the presence of 185 Becquerel (0.005  $\mu\text{Ci}$ ) or more of removable contamination. The written report must include the model number and serial number if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken.

(D) Reports of Patient Departure Prior to Authorized Release.

(1) The licensee shall notify the Agency by telephone immediately upon discovery that a patient or human research subject has departed from the licensee's facility without authorization under 105 CMR 120.540(A).

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(2) The licensee shall submit a written report to the Agency within 30 days after discovery of the unauthorized departure. The written report must include:

- (a) The licensee's name;
- (b) The date and time of the unauthorized departure;
- (c) The projected date and time when release would have occurred;
- (d) The general location address of the patient's or human research subject's home or anticipated destination following departure;
- (e) The radionuclide, chemical and physical form and calculated activity at time of release;
- (f) The apparent reason(s) for the departure prior to authorized release; and,
- (g) A description of any changes in the licensee's patient release criteria or patient instructions that are designed to avoid a recurrence of such an event.

(E) Notification of Deceased Patients or Human Research Subjects Containing Radioactive Material.

(1) The licensee shall notify the Agency by telephone immediately upon discovery that a patient or human research subject containing radioactive material has died, and it is possible that any individual could receive exposures in excess of 105 CMR 120.221 as a result of the deceased's body.

(2) The licensee shall submit a written report to the Agency within 30 days after discovery that the patient or human research subject referenced in 105 CMR 120.594(E)(1) has died. The written report must include:

- (a) The licensee's name;
- (b) The date of death;
- (c) The radionuclide, chemical and physical form and calculated activity at time of death; and
- (d) The names (or titles) and address(es) of known individuals who might have received exposures exceeding five mSv (500 mrem).