Docket # 1114

THE COMMONWEALTH OF MASSACHUSETTS
William Francis Galvin
Secretary of the Commonwealth

RECEIVED
MAR 8 2012
General Counsel

Regulation Filing *To be completed by filing agency*

CHAPTER NUMBER: 105 CMR 120.000

CHAPTER TITLE: Massachusetts Regulations for the Control of Radiation (MRCR)

AGENCY: Department of Public Health

SUMMARY OF REGULATION: *State the general requirements and purposes of this regulation.*

The amendments clarify existing requirements, implement new requirements imposed by the U.S. Nuclear Regulatory Commission and the U.S. Food and Drug Administration, and authorize physician assistants to perform fluoroscopic procedures based on successful completion of an approved training curriculum and in accordance with a written practice agreement with their supervising physician.

REGULATORY AUTHORITY: M.G.L. c. 111, secs. 3, 5M, 5N, 5O, and 5P

AGENCY CONTACT: Jim Ballin PHONE: 617-624-5220

ADDRESS: 250 Washington Street, Boston, MA 02108

Compliance with M.G.L. c. 30A

EMERGENCY ADOPTION - *If this regulation is adopted as an emergency, state the nature of the emergency.*

PRIOR NOTIFICATION AND/OR APPROVAL - *If prior notification to and/or approval of the Governor, Legislature or others was required, list each notification, and/or approval and date, including notice to the Local Government Advisory Commission.*

Notice to Executive Office of Communities and Development and the Massachusetts Municipal Association on July 26, 2011.

PUBLIC REVIEW - *M.G.L. c. 30A sections 2 and/or 3 requires notice of the hearing or comment period, including a small business impact statement, be filed with the Secretary of the Commonwealth, published in appropriate newspapers, and sent to persons to whom specific notice must be given at least 21 days prior to such hearing or comment period.*

Date of public hearing or comment period: September 6, 2011

FISCAL EFFECT - *Estimate the fiscal effect of the public and private sectors.*

For the first and second year: **Minimal fiscal effect as most changes are clarification of existing requirements**

For the first five years: **Minimal fiscal effect as most changes are clarification of existing requirements**

No fiscal effect:

SMALL BUSINESS IMPACT - *M.G.L. c. 30A section 5 requires each agency to file an amended small business impact statement with the Secretary of the Commonwealth prior to the adoption of a proposed regulation. If the purpose of this regulation is to set rates for the state, this section does not apply.*

Date amended small business impact statement was filed: **February 8, 2012**

CODE OF MASSACHUSETTS REGULATIONS INDEX - *List key subjects that are relevant to this regulation:*
radiation control

PROMULGATION - *State the action taken by this regulation and its effect on existing provisions of the Code of Massachusetts Regulations (CMR) or repeal, replace or amend. List by CMR number:*

Amends 105 CMR 120.000

ATTESTATION - *The regulation described herein and attached hereto is a true copy of the regulation adopted by this agency.* ATTEST:

SIGNATURE: James Ballin DATE: 2-16-12

Publication - *To be completed by the Regulations Division*

MASSACHUSETTS REGISTER NUMBER: 1203 DATE: 3/2/12

EFFECTIVE DATE: 3/2/12

CODE OF MASSACHUSETTS REGULATIONS

Remove these pages:	*Insert these pages:*
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A TRUE COPY ATTEST
WILLIAM FRANCIS GALVIN
SECRETARY OF THE COMMONWEALTH
DATE 2/16/12 CLERK

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120.005: continued

$$\frac{175 \text{ (grams U-235)}}{350} + \frac{50 \text{ (grams U-233)}}{200} + \frac{50 \text{ (grams Pu)}}{200} = 1$$

Supplied Air Respirator (SAR) or Airline Respirator means an atmosphere supplying respirator for which the source of breathing air is not designed to be carried by the user.

Survey means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, and/or presence of sources of radiation. When appropriate, such evaluation includes, but is not limited to, tests, physical examinations, and measurements of levels of radiation or concentrations of radioactive material present.

Test means the process of verifying compliance with an applicable regulation.

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

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

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

Traceable to National Standard (See Instrument Traceability or Source Traceability)

U.S. Department of Energy means the Department of Energy established by Public Law 95-91, August 4, 1977, 91 Stat. 565, 42 U.S.C. 7101 *et seq.*, to the extent that the Department exercises functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the Administrator thereof pursuant to sections 104(b), (c) and (d) of the Energy Reorganization Act of 1974 (Public Law 93-438, October 11, 1974, 88 Stat. 1233 at 1237, effective January 19, 1975) and retransferred to the Secretary of Energy pursuant to section 301(a) of the Department of Energy Organization Act (Public Law 95-91, August 4, 1977, 91 Stat. 565 at 577-578, 42 U.S.C. 7151, effective October 1, 1977.)

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

Unrefined and Unprocessed Ore means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining.

Unrestricted Area (Uncontrolled Area) means area access to which is neither limited nor controlled by the licensee or registrant. For purposes of 105 CMR 120.000, Uncontrolled Area is an equivalent term.

Vendor means a supplier of products or services to be used by a licensee or registrant or a licensed or registered facility or activity.

Very High Radiation Area means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of 5 Gy (500 rad) in one hour at one meter from a source of radiation or one meter from any surface that the radiation penetrates [*Note*: At very high doses rates, units of absorbed dose, gray and rad, are appropriate, rather than units of dose equivalent, sievert and rem].

120.005: continued

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 105 CMR 120.005: Byproduct Material(2) through (4).

Waste Handling Licensees means persons licensed to receive and store radioactive wastes prior to disposal and/or persons licensed to dispose of radioactive waste.

Week means seven consecutive days starting on Sunday.

Whole Body means, for purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.

Worker means an individual engaged in work under a license or registration issued by the Agency and controlled by a licensee or registrant, but does not include the licensee or registrant.

Working Level (WL) means any combination of short-lived radon daughters in one liter of air that will result in the ultimate emission of 1.3E+5 MeV of potential alpha particle energy. The short-lived radon daughters are -- for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212.

Working Level Month (WLM) means an exposure to one working level for 170 hours - 2,000 working hours per year divided by 12 months per year is approximately equal to 170 hours per month.

Year means the period of time beginning in January used to determine compliance with the provisions of 105 CMR 120.000. The licensee or registrant may change the starting date of the year used to determine compliance by the licensee or registrant provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

120.006: Exemptions

(A) General Provision. The Agency may, upon application therefore or upon its own initiative, grant such exemptions or exceptions from the requirements of 105 CMR 120.000 as it determines are authorized by law and will not result in undue hazard to public health and safety or property.

(B) U.S. Department of Energy Contractors and U.S. Nuclear Regulatory Commission Contractors. Any U.S. Department of Energy contractor or subcontractor and any U.S. Nuclear Regulatory Commission contractor or subcontractor of the following categories operating within this Commonwealth is exempt from 105 CMR 120.000 to the extent that such contractor or subcontractor under his contract receives, possesses, uses, transfers or acquires sources of radiation:

(1) Prime contractors performing work for the U.S. Department of Energy at U.S. Government-owned or Government-controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;

(2) Prime contractors of the U.S. Department of Energy performing research in, or development, manufacture, storage, testing, or transportation of, atomic weapons or components thereof;

(3) Prime contractors of the U.S. Department of Energy using or operating nuclear reactors or other nuclear devices in a United States Government-owned vehicle or vessel; and,

(4) Any other prime contractor or subcontractor of the U.S. Department of Energy or of the U.S. Nuclear Regulatory Commission when the State and the U.S. Nuclear Regulatory Commission jointly determine:

120.026: continued

(2) Calibration of radiation machines or radiation measurement instruments or devices;
(3) Radiation protection or health physics consultations or surveys; and,
(4) Personnel dosimetry services.

120.027: Certificate of Registration

(A) No person shall maintain a facility that is required by 105 CMR 120.000 to be registered unless such a person has obtained a valid certificate of registration for such facility.

(B) A person who applies for registration and whose application meets the requirements of 105 CMR 120.000, shall, upon payment of the required fee, be issued a certificate of registration effective on the date stated on such certificate.

(C) A current certificate of registration or a legible copy thereof shall be posted conspicuously at each registered facility.

(D) The Director of the Radiation Control Program may incorporate in the certificate of registration, at the time of issuance or thereafter, any such additional requirements and conditions with respect to the registrant's receipt, possession, use, and transfer of radiation machines as said Director finds appropriate and necessary for the protection of the general public or individuals against radiation hazards.

120.028: Expiration of Notice of Registration

Each certificate of registration shall expire at the end of the specified day in the month and year stated therein.

120.029: Renewal of Notice of Registration

(A) Application for renewal of registration shall be filed in accordance with 105 CMR 120.025 or 105 CMR 120.026.

(B) In any case in which a registrant not less than 30 days prior to the expiration of his existing notice of registration has filed an application in proper form for renewal, such existing notice of registration shall not expire until the application status has been finally determined by the Agency.

120.030: Report of Changes

The registrant shall notify the Agency in writing before making any change which would render the information contained in the application for registration and/or the certificate of registration no longer accurate. In the case of disposition of an x-ray system, such notification should specify the recipient of the system. In the case of modification involving a structural change, or the addition or relocation of an x-ray system, the Director of the Radiation Control Program may require the registrant to submit the information contained in 105 CMR 120.420: *Appendix A* and/or 105 CMR 120.421: *Appendix C*.

120.031: Approval Not Implied

No person, in any advertisement, shall refer to the fact that he or his facility is registered with the Agency pursuant to the provisions of 105 CMR 120.025 or 120.026, and no person shall state or imply that any activity under such registration has been approved by the Agency.

120.032: Assembler and/or Transfer Obligation

(A) Any person who sells, leases, transfers, lends, disposes, assembles, or installs radiation machines in this Commonwealth shall notify the Agency within 15 days of:
(1) The name and address of persons who have received these machines;
(2) The manufacturer, model, and serial number of each radiation machine transferred; and,
(3) The date of transfer of each radiation machine.

120.032: continued

(4) In the case of diagnostic x-ray system which contain certified components, a copy of the assembler's report prepared in compliance with requirements of the Federal Diagnostic X-Ray Standard (21 CFR 1020.30 (d)) shall be submitted to the Agency within 15 days following completion of the assembly. Such report shall suffice in lieu of any other by the assembler.

(B) No person shall make, sell, lease, transfer, lend, assemble, or install radiation machines or the supplies used in connection with such machines unless such supplies and equipment when properly placed in operation and use shall meet the requirements of 105 CMR 120.000.

120.033: Out-of-state Radiation Machines

(A) Whenever any radiation machine is to be brought into the Commonwealth, for any temporary use, the person proposing to bring such machine into the Commonwealth shall give written notice to the Agency at least ten working days before such machine is to be used in the Commonwealth. The notice shall include:

(1) The type of radiation machine;
(2) The nature, duration, and scope of use;
(3) The exact location(s) where the radiation machine is to be used; and,
(4) States in which this machine is registered.

(B) The person referred to in 105 CMR 120.033 shall:

(1) Comply with all applicable regulations of the Agency;
(2) Register the radiation machine(s) with the Agency; and,
(3) Submit payment of the required fee for registration.

(C) A pre-operational inspection may be required at the discretion of the Director of the Radiation Control Program.

(D) If, for a specific case, the ten working day period is not practical, notification to the Agency by telephone and hardcopy, permission to proceed sooner may be granted.

120.040: Notification to Fire Department

The user shall notify the local fire department of the presence on his premises of any radioactive material that may present special fire-fighting problems or require special precautionary measures in case of fire or other natural catastrophe, and he shall establish effective liaison with the fire department in regards to this matter.

120.100: LICENSING OF RADIOACTIVE MATERIAL

120.101: Purpose and Scope

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

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

120.102: 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 120.100 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

(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;

120.103: continued

(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";[1]

(c) each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED";[1] 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 ⅛ 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 microcuric 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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[1] 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.

120.104: Radioactive Material Other Than Source Material

(A) Exempt Concentrations.

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

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

(3) A manufacturer, processor, or producer of a product or material is exempt from the requirements for a license set forth in 105 CMR 120.100 to the extent that this person transfers byproduct material contained in a product or material in concentrations not in excess of those specified in 105 CMR 120.195: *Appendix A* and introduced into the product or material by a licensee holding a specific license issued by NRC expressly authorizing such introduction. This exemption does not apply to the transfer of byproduct material contained in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

(4) No person may introduce byproduct 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) or equivalent regulations of the NRC, or an Agreement State except in accordance with a specific license issued pursuant to 10 CFR 32.11.

(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 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 material for purposes of commercial distribution, or the incorporation of byproduct material into products intended for commercial distribution.

(3) No person may, for purposes of commercial distribution, transfer byproduct material in the individual quantities set forth in 105 CMR 120.196: *Appendix B*, Table 1, knowing or having reason to believe that such quantities of byproduct material will be transferred to persons exempt under 105 CMR 120.104(B) or equivalent regulations of the NRC, an Agreement State except in accordance with a specific license issued by the NRC pursuant to 10 CFR Part 32, § 32.18 which license states that the byproduct 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.[2]

(4) Any person who possesses byproduct 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 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 Table I*, except for byproduct material combined within a device placed in use before May 3, 1999, or as otherwise permitted by 105 CMR 120.100.

(C) Exempt Items.

(1) Certain Items Containing Byproduct 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 120.100 to the extent that he receives, possesses, uses, transfers, owns, or acquires the following products:

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

120.104: continued

(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.
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 μGy) per hour at ten centimeters from any surface.
   b. For pocket watches, 0.1 millirad (1 μGy) per hour at one centimeter from any surface.
   c. For any other timepiece, 0.2 millirad (2 μGy) per hour at ten centimeters from any surface.
8. One microcurie (37 kBq) of radium-226 per timepiece in intact timepieces manufactured prior to November 30, 2007.

(b) Precision balances containing not more than one millicurie (37 MBq) of tritium per balance or not more than 0.5 millicurie (18.5 MBq) of tritium per balance part manufactured before December 17, 2007.

(c) Marine compasses containing not more than 750 millicuries (27.8 GBq) of tritium gas and other marine navigational instruments containing not more than 250 millicuries (9.25 GBq) of tritium gas manufactured before December 17, 2007.

(d) Ionization chamber smoke detectors containing not more than 1 microcurie (μCi) of americium-241 per detector in the form of a foil and designed to protect life and property from fires.

(e) Electron tubes; provided, that each tube does not contain more than one of the following specified quantities of byproduct material:

1. 150 millicuries (5.55 GBq) of tritium per microwave receiver protector tube or 10 millicuries (370 MBq) of tritium per any other electron tube.
2. 1 microcurie (37 kBq) of cobalt-60.
3. 5 microcuries (185 kBq) of nickel-63.
4. 30 microcuries (1.11 MBq) of krypton-85.
5. 5 microcuries (185 kBq) of cesium-137.
6. 30 microcuries (1.11 MBq) of promethium-147.

And provided further, that the radiation dose rate from each electron tube containing byproduct material will not exceed one millirad (ten μGy) 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)(h), "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.

(f) 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

120.104: continued

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.

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

(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 120.100 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 120.100 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, produce, or initially transfer for sale or distribution gas and aerosol detectors containing byproduct material, any person is exempt from the requirement of a license set forth in 105 CMR 120.100 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 byproduct material shall have been manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 32, § 32.26, which license authorizes the initial transfer of the product for use under 105 CMR 120.104(C)(3). 105 CMR 120.104(C)(3) 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 32.26 authorizing distribution to persons exempt from regulatory requirements.

(b) Any person who desires to manufacture, process, or produce gas and aerosol detectors containing byproduct material, or to initially transfer such products for use pursuant 105 CMR 120.104(C)(3)(a), should apply for a license pursuant to10 CFR 32.26, which license states that the product may be initially transferred by the licensee to persons exempt from the regulations pursuant to 105 CMR 120.104(C)(3)(a) or equivalent regulations of an Agreement State.

(4) Radioactive Drug: Capsules Containing Carbon-14 Urea for *In Vivo* Diagnostic Use for Humans.

(a) Except as provided in 105 CMR 120.104(C)(4)(b) and (c), any person is exempt from the requirements for a license set forth in M.G.L. c. 111, § 5P and from the regulations in 105 CMR 120.100 and 105 CMR 120.500 provided that such person receives, possesses, uses, transfers, owns, or acquires capsules containing 37 kBq (1μ 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)(4) relieves persons from complying with applicable FDA, other Federal, and State requirements governing receipt, administration, and use of drugs.

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) through (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;

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

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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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(B) 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) through (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 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, or an Agreement State to perform such activities;

(d) shall maintain records showing compliance with the requirements of 105 CMR 120.122(D)(3)(b) and (c). The records shall show the results of tests. The records also shall show the dates of performance of, and the names of persons performing, testing, installation, servicing, and removal from installation concerning the radioactive material, its shielding or containment. The licensee shall retain these records as follows:

1. each record of a test for leakage of radioactive material required by 105 CMR 120.122(D)(3)(b) shall be retained for three years after the next required leak test is performed or until the sealed source is transferred or disposed of;
2. each record of a test of the "on-off" mechanism and indicator required by 105 CMR 120.122(D)(3)(b) shall be retained for three years after the next required test of the "on-off" mechanism and indicator is performed or until the sealed source is transferred or disposed of; and
3. each record that is required by 105 CMR 120.122(D)(3)(c) shall be maintained for a period of three years from the date of the recorded event or until the device is transferred or disposed of;

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(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, or an Agreement 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 CFR110;

(h) 1. shall transfer or dispose of the device containing radioactive material only by export as provided in105 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, or an Agreement State that authorizes waste collection or as otherwise approved under 105 CMR 120.122(D)(3)(h)3.

2. shall furnish a report to the Agency within 30 days after the transfer of a device to a specific licensee or export. The report shall contain:

a. the identification of the device by manufacturer's (or initial transferor's) name, model number, and serial number;

b. the name, address, and license number of the person receiving the device (license number not applicable if exported); and

c. the date of the transfer.

3. shall obtain written Agency approval before transferring the device to any other specific licensee not specifically identified in 105 CMR 120.122(D)(3)(h)1.; however, a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if, the holder:

a. Verifies that the specific license authorizes the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use;

b. Removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by 105 CMR 120.122(D)(3)(a)) so that the device is labeled in compliance with 105 CMR 120.240; however the manufacturer, model number, and serial number must be retained;

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

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

(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;

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

(k) shall respond to written requests from the Agency to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by submitting a letter to the Director, Radiation Control Program, Massachusetts Department of Public Health, and provide written justification as to why it cannot comply;

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

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

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

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(o) may not hold devices that are not in use for longer than two years. If devices with shutters are not being used, the shutter must be locked in the closed position. The testing required by 105 CMR 120.122(D)(3)(b) need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage before use or transfer and the shutter tested before use. Devices kept in standby for future use are excluded from the two-year time limit if the general licensee performs quarterly physical inventories of these devices while they are in standby.

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

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

(C) General License for Certain Items and Self-luminous Products Containing Radium-226.

(1) A general license is hereby issued to any person to acquire, receive, possess, use, or transfer, in accordance with the provisions of 105 CMR 120.122(E)(2), (3), and (4), 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 105 CMR 120.122(E)(1)(a), 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 (one 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 (one microcurie) of radium-226. For the purposes of 105 CMR 120.122(E)(1)(e), "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 105 CMR 120 122(E)(1) are exempt from the provisions of 105 CMR 120.750, 120.200, and120.142 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 120.100.

(3) Any person who acquires, receives, possesses, uses, or transfers byproduct material in accordance with the general license in 105 CMR 120.122(E)(1):

(a) Shall notify the Agency 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 Agency within 30 days.

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

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

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

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

(4) The general license in 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.

(D) 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.

(E) 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.

(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) through (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) through (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.

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CAUTION - RADIOACTIVE MATERIAL
THIS SOURCE CONTAINS (AMERICIUM-241) (PLUTONIUM)[3].
DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____
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.
DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____
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.

(F) General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing.[4]

(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) through (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.
(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:

[3] Showing only the name of the appropriate material.
[4] 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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(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 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.

_____
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.

_____
Name of Manufacturer

120.122: continued

(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.

(G) 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(I)(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 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 or her 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.

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(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 registered in the U.S. Nuclear Regulatory Commission "Registry of Radioactive Sealed Sources and Devices" under 10 CFR 32.210, with an Agreement State, or for a source or a device containing radium-226 or accelerator-produced radioactive material with a State under provisions comparable to 105 CMR 120.128(N);

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

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

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

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

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.

120.125: continued

(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.

(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 10^3 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). The decommissioning funding plan must also be submitted when a combination of isotopes is involved if R divided by 10^3 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 (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 (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: *Appendix B*, Table II in unscaled 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: *Appendix B*, Table II in unscaled 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	Greater than 10 mCi but less than 100 mCi of source material	$225,000
-3	Greater than 10^{10} times the applicable quantities in 105 CMR 120.196: *Appendix B*, 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 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 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 I* or combination of radioactive material listed therein as given in 105 CMR 120.196: *Appendix B, Table I*, 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.

120.126: Special Requirements for Issuance of Certain Specific Licenses for Radioactive Material

Uses of Sealed Sources in Industrial Radiography. In addition to the requirements set forth in 105 CMR 120.125, a specific license for use of sealed sources in industrial radiography will be issued if:

(1) the applicant will have an adequate program for training radiographic personnel and submits to the Agency a schedule or description of such program which specifies the:

(a) initial training;

(b) periodic training;

(c) on-the-job training; and,

(d) means to be used by the licensee to determine the radiographic personnel's knowledge and understanding of and ability to comply with Agency regulations and licensing requirements, and the operating and emergency procedures of the applicant.

(2) the applicant has established and submits to the Agency satisfactory written operating and emergency procedures described in 105 CMR 120.360;

(3) the applicant will have an internal inspection system adequate to assure that 105 CMR 120.001, 120.020, 120.200, 120.300, 120.750, 120.770, license provisions, and the applicant's operating and emergency procedures are followed by radiographic personnel; the inspection system shall include the performance of internal inspections at intervals not to exceed three months and the retention of records of such inspections for five years;

(4) the applicant submits to the Agency a description of the overall organizational structure pertaining to the industrial radiography program, including specified delegations of authority and responsibility for operation of the program;

(5) the applicant who desires to conduct his own leak tests has established adequate procedures to be followed in testing sealed sources for possible leakage and contamination and submits to the Agency a description of such procedures including:

(a) instrumentation to be used;

(b) method of performing tests; and,

(c) pertinent experience of the individual who will perform the test; and,

(6) the licensee shall conduct a program for inspection and maintenance of radiographic exposure devices and storage containers to assure proper functioning of components important to safety.

120.127: Special Requirements for Specific Licenses of Broad Scope

105 CMR 120.127 prescribes requirements for the issuance of specific licenses of broad scope for radioactive material and certain regulations governing holders of such licenses.

120.127: continued

(A) The different types of broad scope licenses are set forth in 105 CMR 120.127(A):

(1) A "Type A specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive material specified in the license, but not exceeding quantities specified in the license, for any authorized purpose. The quantities specified are usually in the multicurie range.

(2) A "Type B specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in 105 CMR 120.197: *Appendix C*, for any authorized purpose. The possession limit for a Type B license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in 105 CMR 120.197: *Appendix C*, Column I. If two or more radionuclides are possessed thereunder, the possession limit for each is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in 105 CMR 120.197: *Appendix C*, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

(3) A "Type C specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use, and transfer of any chemical or physical form of radioactive material specified in 105 CMR 120.197: *Appendix C*, for any authorized purpose. The possession limit for a Type C license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in 105 CMR 120.197: *Appendix C*, Column II. If two or more radionuclides are possessed thereunder, the possession limit is determined for each as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in 105 CMR 120.197: *Appendix C*, Column II, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

(B) An application for a Type A specific license of broad scope will be approved if:

(1) the applicant satisfies the general requirements specified in 105 CMR 120.125;

(2) the applicant has engaged in a reasonable number of activities involving the use of radioactive material; and

(3) the applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to assure safe operations, including:

(a) the establishment of a radiation safety committee composed of such persons as a radiation safety officer, a representative of management, and persons trained and experienced in the safe use of radioactive material;

(b) the appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; and

(c) the establishment of appropriate administrative procedures to assure:

1. control of procurement and use of radioactive material;

2. completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and,

3. review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with 105 CMR 120.127(B)(3)(c)2. prior to use of the radioactive material.

(C) An application for a Type B specific license of broad scope will be approved if:

(1) the applicant satisfies the general requirements specified in 105 CMR 120.125; and,

(2) the applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to assure safe operations, including:

(a) the appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; and

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(b) the establishment of appropriate administrative procedures to assure;
1. control of procurement and use of radioactive material;
2. completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and,
3. review, approval, and recording by the radiation safety officer of safety evaluations of proposed uses prepared in accordance with 105 CMR 120.127(C)(2)(b)2. prior to use of the radioactive material.

(D) An application for a Type C specific license of broad scope will be approved if:
(1) the applicant satisfies the general requirements specified in 105 CMR 120.125;
(2) the applicant submits a statement that radioactive material will be used only by, or under the direct supervision of, individuals who have received:
(a) a college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering; and
(b) at least 40 hours of training and experience in the safe handling of radioactive material, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used; and
(3) the applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, record keeping, material control and accounting, and management review necessary to assure safe operations.

(E) Specific licenses of broad scope are subject to the following conditions:
(1) Unless specifically authorized, persons licensed pursuant to 105 CMR 120.127 shall not:
(a) conduct tracer studies in the environment involving direct release of radioactive material;
(b) receive, acquire, own, possess, use, or transfer devices containing 100,000 curies (3.7 PBq) or more of radioactive material in sealed sources used for irradiation of materials;
(c) conduct activities for which a specific license issued by the Agency under 105 CMR 120.126, 120.128 or 120.500, and 120.800 is required; or,
(d) add or cause the addition of radioactive material to any food, beverage, cosmetic, drug, or other product designed for ingestion or inhalation by, or application to, a human being.
(2) Each Type A specific license of broad scope issued under this Part shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee.
(3) Each Type B specific license of broad scope issued under 105 CMR 120.127 shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety officer.
(4) Each Type C specific license of broad scope issued under 105 CMR 120.127 shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals who satisfy the requirements of 105 CMR 120.127(D).

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:

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

(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:

(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.]

120.128: continued

CAUTION - RADIOACTIVE MATERIAL

_____

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.]

(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:

120.128: continued

1. a copy of the general license contained in 105 CMR 120.122(D); if 105 CMR 120.122(D)(3)(b) through (d) 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;
   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).

120.128: continued

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 Commission's, 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).

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.

120.128: continued

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 through 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, 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 reference sources containing americium-241, 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 submits sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including:

(a) Chemical and physical form and maximum quantity of americium 241 or radium-226 in the source;

(b) Details of construction and design;

(c) Details of the method of incorporation and binding of the americium-241 or radium-226 in the source;

(d) Procedures for and results of prototype testing of sources, which are designed to contain more than 0.005 microcurie of americium-241 or radium-226, to demonstrate that the americium-241 or radium-226 contained in each source will not be released or be removed from the source under normal conditions of use;

(e) Details of quality control procedures to be followed in manufacture of the source;

(f) Description of labeling to be affixed to the source or the storage container for the source;

(g) Any additional information, including experimental studies and tests, required by the Commission to facilitate a determination of the safety of the source.

(3) Each source will contain no more than 5 microcuries of americium-241 or radium-226.

(4) The Agency determines, with respect to any type of source containing more than 0.005 microcurie of americium-241 or radium-226, that:

(a) The method of incorporation and binding of the americium-241 or radium-226 in the source is such that the americium-241 will not be released or be removed from the source under normal conditions of use and handling of the source; and

(b) The source has been subjected to and has satisfactorily passed the prototype tests prescribed by 10 CFR 32.102, Schedule C.

(5) 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:

120.128: continued

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

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

_____
Name of manufacturer or initial transferor

(6) 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 105 CMR 120.122(G). 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 105 CMR 120.122(G) or equivalent regulations of NRC or an Agreement State.

(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 radioactivity does not exceed ten microcuries (370 kBq) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 50 microcuries (1.85 MBq) of hydrogen-3 (tritium); 20 microcuries (740 kBq) of iron-59; or Mock Iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each; or cobalt-57 in units not exceeding 0.37 megabecquerel (10 microcuries) and

(b) displaying the radiation caution symbol described in 105 CMR 120.237(A) and the words, "CAUTION, RADIOACTIVE MATERIAL", and "Not for Internal or External Use in Humans or Animals".

(4) The following statement or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

120.128: continued

This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for *in vitro* clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the U.S. Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority.

_____
Name of manufacturer

(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(I) 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.

(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 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: *Registration Requirements and Minimal Professional Standards for Nuclear Pharmacies*; or

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.

120.128: continued

(2) A licensee pursuant to 105 CMR 120.128(J)(1)(b)3. or (b)4. or (b)5.:

(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 (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,

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 (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:

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 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

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 105 CMR 120.128(J)(2)(b)1. and 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.

120.128: continued

(K) Manufacture and Distribution of Generators or Reagent Kits for Preparation of Radiopharmaceuticals Containing Radioactive Material.[5] An application for a specific license to manufacture and distribute generators or reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons licensed pursuant to 105 CMR 120.100 for the uses listed in 105 CMR 120.547 will be approved if:

(1) the applicant satisfies the general requirements specified in 105 CMR 120.125;

(2) the applicant submits evidence that:

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

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

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

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

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

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

(b) a statement that this generator or reagent kit, as appropriate, is approved for use by persons licensed by the Agency pursuant to 105 CMR 120.533 or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State. The labels, leaflets, or brochures required by 105 CMR 120.128(K) are in addition to the labeling required by the Food and Drug Administration (FDA) and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

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

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[5] Although the Agency does not regulate the manufacture and distribution of reagent kits that do not contain radioactive material, it does regulate the use of such reagent kits for the preparation of radiopharmaceuticals containing radioactive material as part of its licensing and regulation of the users of radioactive material. Any manufacturer of reagent kits that do not contain radioactive material who desires to have his reagent kits approved by the Agency for use by persons licensed pursuant to 105 CMR 120.547 may submit the pertinent information specified in 105 CMR 120.128(K).

120.128: continued

(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 120.532, 120.559, 120.568, and 120.570 or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State;

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

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

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

(M) Requirements for License to Manufacture and Distribute Industrial Products Containing Depleted Uranium for Mass-volume Applications.

(1) An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to 105 CMR 120.121(E) or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State will be approved if:

(a) the applicant satisfies the general requirements specified in 105 CMR 120.125;
(b) the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive a radiation dose in excess of 10% of the annual limits specified in 105 CMR 120.211(A); and,
(c) the applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.

(2) In the case of an industrial product or device whose unique benefits are questionable, the Agency will approve an application for a specific license under 105 CMR 120.128(M) only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

(3) The Agency may deny any application for a specific license under 105 CMR 120.128(M) if the end use(s) of the industrial product or device cannot be reasonably foreseen.

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(4) Each person licensed pursuant to 105 CMR 120.128(M)(1) shall:

(a) maintain the level of quality control required by the license in the manufacture of the industrial product or device, and in the installation of the depleted uranium into the product or device;

(b) label or mark each unit to:

1. identify the manufacturer of the product or device and the number of the license under which the product or device was manufactured, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and

2. state that the receipt, possession, use, and transfer of the product or device are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or an Agreement State;

(c) assure that the depleted uranium before being installed in each product or device has been impressed with the following legend clearly legible through any plating or other covering: "Depleted Uranium";

(d) 1. furnish a copy of the general license contained in 105 CMR 120.121(E) and a copy of form MRCP 120.100-1 to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license contained in 105 CMR 120.121(E); or,

2. furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to 105 CMR 120.121(E) and a copy of the U.S. Nuclear Regulatory Commission's or Agreement State's certificate, or alternatively, furnish a copy of the general license contained in 105 CMR 120.121(E) and a copy of form MRCP 120.100-1 to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission or an Agreement State, with a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or an Agreement State under requirements substantially the same as those in 105 CMR 120.121(E);

(e) report to the Agency all transfers of industrial products or devices to persons for use under the general license in 105 CMR 120.121(E). Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Agency and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under 105 CMR 120.121(E) during the reporting period, the report shall so indicate;

(f) 1. report to the U.S. Nuclear Regulatory Commission all transfers of industrial products or devices to persons for use under the U.S. Nuclear Regulatory Commission general license in 10 CFR Part 40, § 40.25.

2. report to the responsible State agency all transfers of devices manufactured and distributed pursuant to 105 CMR 120.128(M) for use under a general license in that State's regulations equivalent to 105 CMR 120.121(E);

3. such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Agency and the general licensee, the type and model number of the device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such product or device is transferred to the generally licensed person;

4. 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; and

5. if no transfers have been made to general licensees within a particular Agreement State during the reporting period, this information shall be reported to the responsible Agreement State agency upon the request of that agency; and

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(g) keep records showing the name, address, and point of contact for each general licensee to whom he transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in 105 CMR 120.121(E) or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State. The records shall be maintained for a period of two years and shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements of 105 CMR 120.100.

(N) Special Requirements for License to Manufacture, Import or Initially Distribute Sealed Sources or Devices Containing Sealed Sources to Persons Having a Specific License.

(1) An application for license to manufacture, import (NARM only) or initially distribute sealed sources or devices containing sealed sources for initial transfer to persons having a specific license to receive such sealed sources or devices will be approved subject to the following conditions:

(a) the applicant satisfies the general requirements specified in 105 CMR 120.125;

(b) the licensee subject to 105 CMR 120.128(N) shall not transfer a sealed source or device containing a sealed source to any person except in accordance with the requirements of 105 CMR 120.140.

(2) Any manufacturer, importer or initial distributor of a sealed source or device containing a sealed source whose product is intended for use under a specific license may submit a request to the Agency for evaluation of radiation safety information about its product and for filing an evaluation sheet in the U.S. Nuclear Regulatory Commission "Registry of Radioactive Sealed Sources and Devices".

(a) A request for evaluation of a sealed source or device containing a sealed source shall be submitted in duplicate and shall include information required by 105 CMR 120.128(N)(2)(b) or (c), as applicable, demonstrating that the radiation safety properties of such source or device will not endanger public health and safety or property.

(b) A request for evaluation of a sealed source shall include the following radiation safety information:

1. proposed uses for the sealed source;
2. chemical and physical form and maximum quantity of radioactive material in the sealed source;
3. details of design of the sealed source, radiation and its shielding including blueprints, engineering drawings or annotated drawings;
4. details of construction of the sealed source including a description of materials used in construction;
5. radiation profile of a prototype sealed source;
6. procedures for and results of prototype testing;
7. details of quality control procedures to be followed in manufacture;
8. a description or facsimile of labeling to be affixed to the sealed source;
9. leak testing procedures; and,
10. any additional information, including experimental studies and tests, required by the Agency to facilitate a determination of the safety of the sealed source, as required by 105 CMR 120.125.

(c) A request for evaluation of a device containing a sealed source shall include the following radiation safety information:

1. proposed uses for the device;
2. manufacturer, model number, chemical and physical form and maximum quantity of radioactivity in the sealed source or sources to be used in the device;
3. details of design of the sealed source, including blueprints, engineering drawings or annotated drawings;
4. details of construction of the sealed source including a description of materials used in construction;
5. radiation profile of a prototype device;
6. procedures for and results of prototype testing;
7. details of quality control procedures to be followed in manufacture;
8. a description or facsimile of labeling to be affixed to the device;
9. leak testing procedures;

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10. a description of potential hazards in installation, service, maintenance, handling, use and operation of the device;
11. information about installation, service and maintenance procedures;
12. handling, operating and safety instructions; and
13. any additional information, including experimental studies and tests, required by the Agency to facilitate a determination of the safety of the device as required by 105 CMR 120.125.

(d) When evaluating a sealed source or device, the Agency will apply the radiation safety criteria described in 10 CFR 32.210(d), published January 1, 1993, exclusive of subsequent amendments or editions.

(e) The person submitting a request for evaluation of a product shall manufacture and distribute the product in accordance with:

1. the statements and representations, including the quality control program, described in the request; and
2. the provisions of the evaluation sheet prepared by the Agency and submitted to the U.S. Nuclear Regulatory Commission, for filing in the "Registry of Radioactive Sealed Sources and Devices".

120.130: Issuance of Specific Licenses

(A)(1) Upon a determination that an application meets the requirements of M.G.L. c. 111, §§ 3, 5M through 5P and 105 CMR 120.000 and upon payment of the required fee as specified in 105 CMR 120.130(A)(2), the Agency will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

(2) Each initial application for a license or a certificate of registration for which a fee is established by the Executive Office for Administration and Finance in 801 CMR 4.00 shall be accompanied by a non-refundable fee, payable to the Commonwealth of Massachusetts, in the amount specified for the corresponding annual fee. Thereafter, the Radiation Control Program will issue an annual fee invoice based on the applicable annual fee specified in 801 CMR 4.00. Fees are payable within 30 days after receipt of a fee invoice.

(B) The Agency may incorporate in any license at the time of issuance, or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of radioactive material subject to 105 CMR 120.100 as it deems appropriate or necessary in order to:

(1) minimize danger to public health and safety or property;
(2) require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary; and
(3) prevent loss or theft of material subject to 105 CMR 120.100.

120.131: Specific Terms and Conditions of Licenses

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

(B) No license issued or granted under 105 CMR 120.000 and no right to possess or utilize radioactive material granted by any license issued pursuant to 105 CMR 120.131 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 through 5P, and to all valid rules, regulations, and orders of the Agency, and shall give its consent in writing.

(C) Each person licensed by the Agency pursuant to 105 CMR 120.100 shall confine use and possession of the material licensed to the locations and purposes authorized in the license. Preparation for shipment and transport of byproduct material shall be in accordance with the provisions of 10 CFR part 71 and 105 CMR 120.770.

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

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

(1) the licensee;

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

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

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

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

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

(I) (1) Authorization under 105 CMR 120.128(A) 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(A) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

1. Satisfy the labeling requirements in 105 CMR 120.128(J)(1)(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.

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

(3) A licensee that is a pharmacy authorized under 105 CMR 120.128(A) 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:

1. an authorized nuclear pharmacist that meets the requirements in 105 CMR 120.128(J)(2)(b); or

2. 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(A) 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).

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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) Exceptions to the General License.

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

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

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

NON-TEXT PAGE

120.196 Table III: continued

Radioactive Material [1]	Release fraction	Quantity(Ci)
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
Radium-226	0.001	100
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
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 β-γ	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, β-γ	0.01	1,000
Packaged mixed waste [3]	0.001	10,000
Contaminated equipment, alpha	0.0001	20
Any other alph emitter	0.001	2
Packaged waste alpha [2]	0.0001	20
Combinations of radioactive materials listed [1]	----	----

[1] 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.

[2] 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.

[3] Waste packaged in Type B containers does not require an emergency plan.

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
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

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 (five 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 of the whole body or to the skin of any extremity.

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

(C) (1) When the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent must be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the Agency. The assigned deep-dose equivalent must be for the part of the body receiving the highest exposure. The assigned shallow-dose equivalent must be the dose averaged over the contiguous ten square centimeters of skin receiving the highest exposure. The deep-dose equivalent, lens-dose equivalent, and shallow-dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable;

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

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

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

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

(D) Derived air concentration (DAC) and annual limit on intake (ALI) values are specified in 105 CMR 120.296: *Appendix B*, Table I and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits. *See* 105 CMR 120.267.

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

(F) The licensee or registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person during the current year. *See* 105 CMR 120.265(E).

120.212: Compliance with Requirements for Summation of External and Internal Doses

(A) If the licensee is required to monitor pursuant to both 105 CMR 120.226(A) and (B), the licensee shall demonstrate compliance with the dose limits by summing external and internal doses. If the licensee or registrant is required to monitor only pursuant to 105 CMR 120.226(A) or only pursuant to 105 CMR 120.226(B), then summation is not required to demonstrate compliance with the dose limits. The licensee may demonstrate compliance with the requirements for summation of external and internal doses pursuant to 105 CMR 120.212(B), (C) and (D). The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.

(B) Intake by Inhalation. If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep dose equivalent divided by the total effective dose equivalent limit, and one of the following, does not exceed unity:

(1) the sum of the fractions of the inhalation ALI for each radionuclide;

(2) the total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by 2,000; or

(3) the sum of the calculated committed effective dose equivalents to all significantly irradiated organs or tissues (T) calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit. For purposes of this requirement, an organ or tissue is deemed to be significantly irradiated if, for that organ or tissue, the product of the weighting factors, w_T, and the committed dose equivalent, $H_{T,50}$, per unit intake is greater than 10% of the maximum weighted value of $H_{T,50}$, that is, $w_T H_{T,50}$, per unit intake for any organ or tissue.

(C) Intake by Oral Ingestion. If the occupationally exposed individual receives an intake of radionuclides by oral ingestion greater than 10% of the applicable oral ALI, the licensee shall account for this intake and include it in demonstrating compliance with the limits.

(D) Intake through Wounds or Absorption through Skin. The licensee shall evaluate and, to the extent practical, account for intakes through wounds or skin absorption. The intake through intact skin has been included in the calculation of DAC for hydrogen-3 and does not need to be evaluated.

120.213: Determination of External Dose from Airborne Radioactive Material

(A) Licensees shall, when determining the dose from airborne radioactive material, include the contribution to the deep dose equivalent, lens dose equivalent, and shallow dose equivalent from external exposure to the radioactive cloud. *See* 105 CMR 120.296: *Appendix B*, footnotes 1 and 2.

(B) Airborne radioactivity measurements and DAC values shall not be used as the primary means to assess the deep dose equivalent when the airborne radioactive material includes radionuclides other than noble gases or if the cloud of airborne radioactive material is not relatively uniform. The determination of the deep dose equivalent to an individual shall be based upon measurements using instruments or individual monitoring devices.

120.214: Determination of Internal Exposure

(A) For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee shall, when required pursuant to 105 CMR 120.226, take suitable and timely measurements of:

(1) concentrations of radioactive materials in air in work areas; or

(2) quantities of radionuclides in the body; or

(3) quantities of radionuclides excreted from the body; or

(4) combinations of these measurements.

(B) Unless respiratory protective equipment is used, as provided in 105 CMR 120.233, or the assessment of intake is based on bioassays, the licensee shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.

120.239: Exceptions to Posting Requirements

(A) A licensee or registrant is not required to post caution signs in areas or rooms containing radioactive materials for periods of less than eight hours, if each of the following conditions is met:

(1) the radioactive materials are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to radioactive materials in excess of the limits established in 105 CMR 120.200; and,

(2) the area or room is subject to the licensee's or registrant's control.

(B) Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs pursuant to 105 CMR 120.242 provided that patient could be released from confinement pursuant to 105 CMR 120.540.

(C) Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs, provided that:

(1) A patient being treated with a permanent implant could be released from confinement pursuant 105 CMR 120.540; or

(2) A patient being treated with a therapeutic radiopharmaceutical could be released from confinement pursuant 105 CMR 120.540.

(D) A room or area is not required to be posted with a caution sign because of the presence of a sealed source provided the radiation level at 30 centimeters from the surface of the sealed source container or housing does not exceed 0.05 mSv (0.005 rem) per hour.

(E) A room or area is not required to be posted with a caution sign because of the presence of radiation machines used solely for diagnosis in the healing arts.

(F) Rooms in hospitals or clinics that are used for teletherapy are exempt from the requirement to post caution signs under 105 CMR 120.238 if:

(1) Access to the room is controlled pursuant to 105 CMR 120.573; and,

(2) Personnel in attendance take necessary precautions to prevent the inadvertent exposure of workers, other patients, and members of the public to radiation in excess of the limits established in 105 CMR 120.200.

120.240: Labeling Containers and Radiation Machines

(A) The licensee shall ensure that each container of licensed material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL." The label shall also provide information, such as the radionuclides present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment, to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

(B) Each licensee shall, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

(C) Each registrant shall ensure that each radiation machine is labeled in a conspicuous manner which cautions individuals that radiation is produced when it is energized.

120.241: Exemptions to Labeling Requirements

A licensee is not required to label:

(A) containers holding licensed material in quantities less than the quantities listed in 105 CMR 120.297: *Appendix C*; or

(B) containers holding licensed material in concentrations less than those specified in 105 CMR 120.296: *Appendix B*, Table III; or

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(C) containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by 105 CMR 120.200; or

(D) containers when they are in transport and packaged and labeled in accordance with the regulations of the U.S. Department of Transportation[1]; or

(E) containers that are accessible only to individuals authorized to handle or use them, or to work in the vicinity of the containers, if the contents are identified to these individuals by a readily available written record. Examples of containers of this type are containers in locations such as water-filled canals, storage vaults, or hot cells. The record shall be retained as long as the containers are in use for the purpose indicated on the record; or

(F) installed manufacturing or process equipment, such as piping and tanks.

120.242: Procedures for Receiving and Opening Packages

(A) Each licensee or registrant who expects to receive a package containing quantities of radioactive material in excess of a Type A quantity, as defined in 105 CMR 120.772 and 105 CMR 120.795: *Appendix A*, shall make arrangements to receive:
(1) the package when the carrier offers it for delivery; or,
(2) the notification of the arrival of the package at the carrier's terminal and to take possession of the package expeditiously.

(B) Each licensee or registrant shall:
(1) monitor the external surfaces of a labeled package for radioactive contamination unless the package contains only radioactive material in the form of gas or in special form as defined in 105 CMR 120.005;
(2) monitor the external surfaces of a labeled[2] package for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in 105 CMR 120.772 and 105 CMR 120.795: *Appendix A*; and
(3) monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.

(C) The licensee or registrant shall perform the monitoring required by 105 CMR 120.242 as soon as practicable after receipt of the package, but not later than three hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours, or if there is evidence of degradation of package integrity, such as a package that is crushed, wet, or damaged. If a package is received after working hours, and has no evidence of degradation of package integrity, the package shall be monitored no later than three hours from the beginning of the next working day.

(D) The licensee or registrant shall immediately notify the final delivery carrier and, by telephone and telegram, mailgram, or facsimile, the Agency when:
(1) removable radioactive surface contamination exceeds the limits of 105 CMR 120.786(J); or
(2) External radiation levels exceed the limit of 105 CMR 120.783.

(E) Each licensee or registrant shall:
(1) establish, maintain, and retain written procedures for safely opening packages in which radioactive material is received; and,
(2) ensure that the procedures are followed and that due consideration is given to special instructions for the type of package being opened.

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[1] Labeling of packages containing radioactive materials is required by the U.S. Department of Transportation if the amount and type of radioactive material exceeds the limits for an excepted quantity or article as defined and limited by U.S. Department of Transportation regulations 49 CFR 173.403(m) and (w) and 173.424.

[2] Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations 49 CFR 172.403 and 172.436-440.

120.254: Treatment or Disposal by Incineration

A licensee may treat licensed material by incineration only in the form and concentration specified in 105 CMR 120.255 or as specifically approved by the Agency pursuant to 105 CMR 120.252.

120.255: Disposal of Specific Wastes

(A) A licensee or registrant may dispose of the following licensed or registered material as if it were not radioactive:
(1) 1.85 kBq (0.05 μCi), or less, of hydrogen-3 or carbon-14 per gram of medium used for liquid scintillation counting; and
(2) 1.85 kBq (0.05 μCi), or less, of hydrogen-3 or carbon-14 per gram of animal tissue, averaged over the weight of the entire animal.

(B) A licensee or registrant shall not dispose of tissue pursuant to 105 CMR 120.255(A)(2) in a manner that would permit its use either as food for humans or as animal feed.

(C) The licensee or registrant shall maintain records in accordance with 105 CMR 120.269.

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 CMR120.256 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) (1) 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.
(2) Any licensee shipping byproduct material as defined in 105 CMR 120.005: Byproduct Material(2) and (3) intended for ultimate disposal at a land disposal facility licensed under 105 CMR 120.800 or equivalent NRC or Agreement State regulations must document the information required on the NRC's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with Appendix G of 10 CFR Part 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.

120.257: Compliance with Environmental and Health Protection Regulations

Nothing in 105 CMR 120.251, 120.253, 20.254, or 120.256 relieves the licensee from complying with other applicable federal, state and local regulations governing any other toxic or hazardous properties of materials that may be disposed of in accordance with 105 CMR 120.251, 120.253, 120.254, or 120.256.

120.258: Disposal of Certain Byproduct Material

(A) Licensed material as defined in 105 CMR 120.005: Byproduct Material(2) and (3) may be disposed of in accordance with 105 CMR 120.800, 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 105 CMR 120.005: Byproduct Material(2) and (3), 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.

RECORDS

120.261: General Provisions

(A) Each licensee or registrant shall use the SI units becquerel, gray, sievert and coulomb per kilogram, or the special units curie, rad, rem and roentgen, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by 105 CMR 120.261.

(B) Not withstanding the requirements of 105 CMR 120.261(A), when recording information on shipment manifests, as required in 105 CMR 120.256, information must be recorded in SI units or in SI units and special units as specified in 105 CMR 120.261(A).

(C) The licensee or registrant shall make a clear distinction among the quantities entered on the records required by 105 CMR 120.200, such as, total effective dose equivalent, total organ dose equivalent, shallow dose equivalent, lens dose equivalent, deep dose equivalent, or committed effective dose equivalent.

120.262: Records of Radiation Protection Programs

(A) Each licensee or registrant shall maintain records of the radiation protection program, including:

(1) the provisions of the program; and,

(2) audits and other reviews of program content and implementation.

(B) The licensee or registrant shall retain the records required by 105 CMR 120.262(A)(1) until the Agency terminates each pertinent license or registration requiring the record. The licensee or registrant shall retain the records required by 105 CMR 120.262(A)(2) for three years after the record is made.

120.263: Records of Surveys

(A) Each licensee or registrant shall maintain records showing the results of surveys and calibrations required by 105 CMR 120.225 and 120.242(B). The licensee or registrant shall retain these records for three years after the record is made.

(B) The licensee or registrant shall retain each of the following records until the Agency terminates each pertinent license or registration requiring the record:

(1) records of the results of surveys to determine the dose from external sources of radiation used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents;

(2) records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose;

(3) records showing the results of air sampling, surveys, and bioassays required pursuant to 105 CMR 120.233(A)(3)(a) and (b); and,

(4) records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

120.264: Records of Tests for Leakage or Contamination of Sealed Sources

Records of tests for leakage or contamination of sealed sources required by 105 CMR 120.223 shall be kept in units of becquerel or microcurie and maintained for inspection by the Agency for five years after the records are made.

120.265: Determination and Records of Prior Occupational Dose

(A) For each individual who is likely to receive, in a year, an occupational dose requiring monitoring pursuant to 105 CMR 120.226, the licensee or registrant shall:

(1) Determine the occupational radiation dose received during the current year; and

(2) Attempt to obtain the records of cumulative occupational radiation dose.

(B) Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant shall determine:

(1) The internal and external doses from all previous planned special exposures; and

(2) All doses in excess of the limits, including doses received during accidents and emergencies, received during the lifetime of the individual; and

NON-TEXT PAGE

120.283: continued

(3) levels of radiation or concentrations of radioactive material in:
(a) a restricted area in excess of applicable limits in the license or registration;
(b) an unrestricted area in excess of ten times the applicable limit set forth in this part or in the license or registration, whether or not involving exposure of any individual in excess of the limits in 105 CMR 120.221; or,
(4) for licensees subject to the provisions of U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those standards.

(B) Contents of Reports.
(1) Each report required by 105 CMR 120.283(A) shall describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:
(a) estimates of each individual's dose;
(b) the levels of radiation and concentrations of radioactive material involved;
(c) the cause of the elevated exposures, dose rates, or concentrations; and,
(d) corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, ALARA constraints generally applicable environmental standards, and associated license or registration conditions.
(2) Each report filed pursuant to 105 CMR 120.283(A) shall include for each occupationally exposed individual: the name, social security number, and date of birth. With respect to the limit for the embryo/fetus in 105 CMR 120.218: *Dose Equivalent to an Embryo/Fetus*, the identifiers should be those of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable portion of the report.

(C) All licensees or registrants who make reports pursuant to 105 CMR 120.283(A) shall submit the report in writing to the Agency.

120.284: Reports of Planned Special Exposures

The licensee or registrant shall submit a written report to the Agency within 30 days following any planned special exposure conducted in accordance with 105 CMR 120.216, informing the Agency that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by 105 CMR 120.266.

120.285: Reports to Individuals of Exceeding Dose Limits

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

120.286: 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 120.500, radioactive material in quantities exceeding any one of the following quantities:

120.286: continued

Radionuclide, Activity

Radionuclide	Activity	
	Ci	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

[*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 30th each year. The licensee or registrant shall submit the report to the Agency.

120.287: Notifications and Reports to Individuals

(A) Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in 105 CMR 120.750.

(B) When a licensee or registrant is required pursuant to 105 CMR 120.283 to report to the Agency any exposure of an individual to radiation or radioactive material, the licensee or registrant shall also notify the individual. Such notice shall be transmitted at a time not later than the transmittal to the Agency, and shall comply with the provisions of 105 CMR 120.754(A).

120.288: Reports of Leaking or Contaminated Sealed Sources

The licensee shall immediately notify the Agency if the test for leakage or contamination required pursuant to 105 CMR 120.223 indicates a sealed source is leaking or contaminated. A written report of a leaking or contaminated source shall be submitted to the Agency within five days. The report shall include the equipment involved, the test results and the corrective action taken.

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 (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:

120.296: continued

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 2.4×10^9 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 7.3×10^7. The factor of 7.3×10^7 (ml) includes the following components: the factors of 50 and 2 described above and a factor of 7.3×10^5 (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 7.3×10^6 (ml). The factor of 7.3×10^6 (ml) is composed of a factor of 7.3×10^5 (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

Name	Symbol	Atomic No.	Name	Symbol	Atomic No.
Actinium	Ac	89	Molybdenum	Mo	42
Aluminium	Al	13	Neodymium	Nd	60
Americium	Am	95	Neptunium	Np	93
Antimony	Sb	51	Nickel	Ni	28
Argon	Ar	18	Niobium	Nb	41
Arsenic	As	33	Nitrogen	N	7
Astatine	At	85	Osmium	Os	76
Barium	Ba	56	Oxygen	O	8
Berkelium	Bk	97	Palladium	Pd	46
Beryllium	Be	4	Phosphorus	P	15
Bismuth	Bi	83	Platinum	Pt	78
Bromine	Br	35	Plutonium	Pu	94
Cadmium	Cd	48	Polonium	Po	84
Calcium	Ca	20	Potassium	K	19
Californium	Cf	98	Prascodymium	Pr	59
Carbon	C	6	Promethium	Pm	61
Cerium	Ce	58	Protactinium	Pa	91
Cesium	Cs	55	Radium	Ra	88
Chlorine	Cl	17	Radon	Rn	86
Chromium	Cr	24	Rhenium	Re	75
Cobalt	Co	27	Rhodium	Rh	45
Copper	Cu	29	Rubidium	Rb	37
Curium	Cm	96	Ruthenium	Ru	44
Dysprosium	Dy	66	Samarium	Sm	62
Einsteinium	Es	99	Scandium	Sc	21
Erbium	Er	68	Selenium	Se	34
Europium	Eu	63	Silicon	Si	14
Fermium	Fm	100	Silver	Ag	47
Fluorine	F	9	Sodium	Na	11
Francium	Fr	87	Strontium	Sr	38
Gadolinium	Gd	64	Sulfur	S	16
Gallium	Ga	31	Tantalum	Ta	73
Germanium	Ge	32	Technetium	Tc	43
Gold	Au	79	Tellurium	Te	52
Hafnium	Hf	72	Terbium	Tb	65
Holmium	Ho	67	Thallium	Tl	81
Hydrogen	H	1	Thorium	Th	90
Indium	In	49	Thulium	Tm	69
Iodine	I	53	Tin	Sn	50
Iridium	Ir	77	Titanium	Ti	22
Iron	Fe	26	Tungsten	W	74
Krypton	Kr	36	Uranium	U	92
Lanthanum	La	57	Vanadium	V	23
Lead	Pb	82	Xenon	Xe	54
Lutetium	Lu	71	Ytterbium	Yb	70
Magnesium	Mg	12	Yttrium	Y	39
Manganese	Mn	25	Zinc	Zn	30
Mendelevium	Md	101	Zirconium	Zr	40
Mercury	Hg	80			

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Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/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_2) Submersion[1]: Use above values as HT and T_2 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 ^{7}Be	1E+3	2E+2	6E-8	2E-10	"	"
			LLI wall (1E+3)	"	"	"	2E-5	2E-4
		Y, see ^{7}Be	"	1E+1	6E-9	2E-11	"	"
6	Carbon-11[2]	Monoxide	"	1E+6	5E-4	2E-6	"	"
		Dioxide	"	2E+5	9E-5	3E-7	"	"
		Compounds	2E+3	2E+3	1E-6	3E-9	3E-5	3E-4
6	Carbon-14	Monoxide	"	2E+6	7E-4	2E-6	"	"
7	Nitrogen-13[3]	Submersion[1]	"	"	4E-6	2E-8		
8	Oxygen-15[2]	Submersion[1]	"	"	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[3]	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, Co, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Sc, Y, Ti, Zr, V, Nb, Ta, Mn, Tc, and Re	"	9E+4	4E-5	1E-7	"	"
		Y, lanthanum fluoride	"	8E+4	3E-5	1E-7	"	"
11	Sodium-22	D, all compounds	4E+2	6E+2	3E-7	9E-10	6E-6	6E-5
11	Sodium-24	D, all compounds	4E+3	5E+3	2E-6	7E-9	5E-5	5E-4
12	Magnesium-28	D, all compounds except those given for W	7E+2	2E+3	7E-7	2E-9	9E-6	9E-5
		W, oxides, hydroxides, carbides, halides, and nitrates	"	1E+3	5E-7	2E-9	"	"
13	Aluminum-26	D, all compounds except those given for W	4E+2	6E+1	3E-8	9E-11	6E-6	6E-5
		W, oxides, hydroxides, carbides, halides, and nitrates	"	9E+1	4E-8	1E-10	"	"
14	Silicon-31	D, all compounds except those given for W and Y	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3

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Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
		W, oxides, hydroxides, carbides, and nitrates	-	3E+4	1E-5	5E-8	-	-
		Y, aluminosilicate glass	-	3E+4	1E-5	4E-8	-	-
14	Silicon-32	D, see ^{31}Si	2E+3	2E+2	1E-7	3E-10	-	-
			LLI wall (3E+3)	-	-	-	4E-5	4E-4
		W, see ^{31}Si	-	1E+2	5E-8	2E-10	-	-
		Y, see ^{31}Si	-	5E+0	2E-9	7E-12	-	-
15	Phosphorus-32	D, all compounds except phosphates given for W	6E+2	9E+2	4E-7	1E-9	9E-6	9E-5
		W, phosphates of Zn^{2+}, S^{2+}, Mg^{2+}, Fe^{3+}, Bi^{3+}, and lanthanides	-	4E+2	2E-7	5E-10	-	-
15	Phosphorus-33	D, see ^{32}P	6E+3	8E+3	4E-6	1E-8	8E-5	8E-4
		W, see ^{32}P	-	3E+3	1E-6	4E-9	-	-
16	Sulfur-35	Vapor		1E+4	6E-6	2E-8	-	-
		D, sulfides and sulfates except those given for W	1E+4	2E+4	7E-6	2E-8	-	-
			LLI wall (8E+3)	-	-	-	1E-4	1E-3
		W, elemental sulfur,	6E+3					
		sulfides of Sr, Ba, Ge, Sn, Pb, As, Sb, Bi, Cu, Ag, Au, Zn, Cd, Hg, W, and Mo. Sulfates of Ca, Sr, Ba, Ra, As, Sb, and Bi	-	2E+3	9E-7	3E-9	-	-
17	Chlorine-36	D, chlorides of H, Li, Na, K, Rb, Cs, and Fr	2E+3	2E+3	1E-6	3E-9	2E-5	2E-4
		W, chlorides of lantha- nides, Be, Mg, Ca, Sr, Ba, Ra, Al, Ga, In, Tl, Ge, Sn, Pb, As, Sb, Bi, Fe, Ru, Os, Co, Rh, Ir, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Sc, Y, Ti, Zr, Hf, V, Nb, Ta, Cr, Mo, W, Mn, Tc, and Re	-	2E+2	1E-7	3E-10	-	--
17	Chlorine-38[1]	D, see ^{36}Cl	2E+4	4E+4	2E-5	6E-8	-	
			St wall (3E+4)	-	-	-	3E-4	3E-3
		W, see ^{36}Cl	-	5E+4	2E-5	6E-8	-	-
17	Chlorine-39[2]	D, see ^{36}Cl	2E+4	5E+4	2E-5	7E-8	-	-
			St wall (4E+4)	-	-	-	5E-4	5E-3