

PART He-P 4030 LICENSING OF BYPRODUCT MATERIAL

He-P 4030.01 Requirements.

(a) No person shall manufacture, produce, receive, possess, use, transfer, own, or acquire byproduct materials, except as authorized pursuant to a license issued by the DHHS/RHS, or as otherwise provided in this chapter.

(b) In addition to the requirements of He-P 4030:

(1) All licensees are subject to the requirements of He-P 4001 through He-P 4003, He-P 4019 through He-P 4023, and He-P 4037;

(2) Licensees engaged in industrial radiographic operations are subject to the requirements of He-P 4034;

(3) Licensees using byproduct materials in the healing arts are subject to the requirements of He-P 4035;

(4) Licensees engaged in land disposal of byproduct material are subject to the requirements of He-P 4060 through He-P 4064;

(5) Licensees engaged in wireline and subsurface tracer studies are subject to the requirements of He-P 4039;

(6) Licensees engaged in the manufacture or transfer of certain items containing byproduct material are subject to He-P 4032;

(7) Licensees of broad scope other than human use are subject to He-P 4033; and

(8) General licenses are subject to He-P 4031;

(9) Licensees engaged in irradiator operations are subjected to the requirements of He-P 4036;

(10) Licensees that possess and use accelerator-produced radioactive material or discrete sources of radium-226 are subjected to the requirements of He-P 4030(a);

He-P 4030.02 Exemptions, Source Material.

(a) Any person shall be exempt from He-P 4030 to the extent that such person receives, possesses, uses, owns, or transfers source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than 1/20 of 1 percent (0.05 percent) of the mixture, compound, solution, or alloy.

(b) Any person shall be exempt from He-P 4030 to the extent that such person receives, possesses, uses, or transfers unrefined and unprocessed ore containing source material.

(c) Any person shall be exempt from He-P 4030 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 shall not contain more than 50 milligrams of thorium;
- e. Germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting provided that each lamp shall not contain more than 2 grams of thorium;
- f. Rare earth metals and compounds, mixtures, and products containing not more than 0.25 percent by weight thorium, uranium, or any combination of these; or
- g. Personnel neutron dosimeters, provided that each dosimeter shall not contain more than 50 milligrams of thorium;

(2) Source material contained in the following products:

- a. Glazed ceramic Tableware, provided that the glaze shall not contain more than 20 percent by weight source material;
- b. Glassware, containing not more than 10 percent by weight source material, but not including glass enamel or ceramic used in construction;
- c. Piezoelectric ceramic containing not more than 2 percent by weight source material; or
- d. Glass enamel or glass enamel frit containing not more than 10 percent by weight source material imported or ordered for importation into the United States, or initially distributed by manufacturers in the United States, before July 25, 1983;

(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 shall not exceed 4 percent by weight and that this exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such product or part;

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

- a. The counterweights are manufactured in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, authorizing distribution by the licensee pursuant to 10 CFR Part 40;
- b. Each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM";

c. Each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED";

d. This exemption shall not authorize the chemical, physical, or metallurgical treatment or processing of any such counterweights other than repair or restoration of any plating or other covering; and

e. For counterweights manufactured prior to December 31, 1969, the requirements specified in He-P 4030.02(c)(5)c. and d. shall be met if such counterweights are impressed with the legend: "CAUTION - RADIOACTIVE MATERIAL - URANIUM";

(6) Natural or depleted uranium metal used as shielding constituting part of any shipping container, provided that:

a. The shipping container is conspicuously and legibly impressed with the legend: "CAUTION - RADIOACTIVE SHIELDING - URANIUM"; and

b. The uranium metal is encased in mild steel or equally fire resistant metal of minimum wall thickness of 1/8 inch (3.2 mm);

(7) Thorium contained in finished optical lenses, provided that each lens does not contain more than 30 percent by weight of thorium, and does not include:

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, 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 shall contain not more than 0.005 microcurie of uranium; or

(9) Thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that:

a. The thorium shall be dispersed in the nickel-thoria alloy in the form of finely divided thoria such as thorium dioxide; and

b. The thorium content in the nickel-thoria alloy shall not exceed 4 percent by weight.

(d) The exemptions in He-P 4030.02(c) shall not authorize the manufacture of any of the products described.

Source. (See Revision Note at part heading for He-P 4030) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07

New. #8959, eff 8-7-07

He-P 4030.03 Exemptions, Byproduct Materials Other Than Source Materials.

(a) Except as provided in He-P 4030.03(b), any person shall be exempt from He-P 4030 to the extent that such person receives, possesses, uses, transfers, owns, or acquires products or materials containing byproduct material in concentrations not in excess of those listed in He-P 4093. This exemption shall not be deemed to authorize the import of byproduct material or products containing byproduct material.

(b) No person shall introduce byproduct material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under He-P 4030.03(a) or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State, or Licensing State except in accordance with a license issued under U.S. Nuclear Regulatory Commission 10 CFR 32.11.

(c) Except for persons who apply byproduct material, or persons who incorporate byproduct material into the following products, any person shall be exempt from this chapter to the extent that they receive, possess, use, transfer, own, or acquire the following products:

(1) Timepieces or hands or dials of timepieces which shall contain not more than the following specified quantities of radioactive material and which shall not exceed the following specified levels of radiation:

- a. 25 millicuries of tritium per timepiece;
- b. 5 millicuries of tritium per hand;
- c. 15 millicuries of tritium per dial to include bezels when used;
- d. 100 microcuries of promethium 147 per watch or 200 microcuries of promethium 147 per any other timepiece;
- e. 20 microcuries of promethium 147 per watch hand or 40 microcuries of promethium 147 per other timepiece hand;
- f. 60 microcuries of promethium 147 per watch dial or 120 microcuries of promethium 147 per other timepiece dial to include bezels when used; and
- g. The levels of radiation from hands and dials containing promethium 147 shall not exceed, when measured through 50 milligrams per square centimeter of absorber:
 1. For wrist watches, 0.1 millirad per hour at 10 centimeters from any surface;
 2. For pocket watches, 0.1 millirad per hour at 1 centimeter from any surface; and
 3. For any other timepiece, 0.2 millirad per hour at 10 centimeters from any surface;
- h. 0.037 megabecquerel (1 microcurie) of radium-226 per timepiece in intact timepieces manufactured prior to November 30, 2007.

(2) Precision balances containing not more than 1 millicurie of tritium per balance or not more than 0.5 millicurie of tritium per balance part manufactured before December 17, 2007;

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(3) Marine compasses containing not more than 750 millicuries of tritium gas and other marine navigational instruments containing not more than 250 millicuries of tritium gas manufactured before December 17, 2007;

(4) Electron tubes, provided that:

a. Each tube shall not contain more than one of the following specified quantities of byproduct material:

1. 150 millicuries of tritium per microwave receiver protector tube or 10 millicuries of tritium per any other electron tube;
2. 1 microcurie of cobalt 60;
3. 5 microcuries of nickel 63;
4. 30 microcuries of krypton 85;
5. 5 microcuries of cesium 137; and
6. 30 microcuries of promethium 147; and

b. The level of radiation due to byproduct material contained in each electron tube, 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 shall not exceed 1 milliampere per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber;

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

a. Each source shall contain no more than one exempt quantity set forth in He-P 4096;

b. Each instrument shall contain no more than 10 exempt quantities;

c. For purposes of He-P 4030.03(c)(9)b., an instrument's source(s) may contain either one type 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 He-P 4096, provided that the sum of such fractions shall not exceed unity; and

d. For purposes of He-P 4030.03(c)(9)b., 0.05 microcurie of americium-241 shall be considered an exempt quantity under He-P 4096; and

(6) a. Static elimination devices which contain, as a sealed source or sources, byproduct material consisting of a total of not more than 18.5 megabecquerel (500 microcurie) of polonium-210 per device;

b. Ion generating tubes designed for ionization of air that contain, as a sealed source or sources, byproduct material consisting of a total of not more than 18.5 megabecquerel (500 microcurie) of polonium-210 per device or of a total of not more than 1.85 gigabecquerel (50 millicurie) of hydrogen-3 (tritium) per device; and

c. Such devices authorized before October 23, 2012 for use under the general license then provided in He-P 4031.04, an equivalent regulations of Agreement States, or U.S. Nuclear Regulatory Commission and manufactured, tested, and labeled by the manufacturer in accordance with the specifications in a specific license issued by the DHHS/RHS or the U.S. Nuclear Regulatory Commission.

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

(e) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution gas and aerosol detectors, any person shall be exempt from the requirements in He-P 4030, He-P 4031, He-P 4032, He-P 4033, He-P 4034, and He-P 4036 to the extent that such person receives, possesses, uses, transfers, owns, or acquires:

(1) Byproduct material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards, provided that detectors containing radioactive material shall have been manufactured, imported, or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.26 of 10 CFR Part 32; or

(2) Naturally occurring material in gas and aerosol detectors designed to protect life or property from fire and airborne hazards provided that detectors containing naturally occurring material shall have been manufactured, imported, or transferred in accordance with a specific license issued by an Agreement State pursuant to equivalent conditions as in Section 32.26 of 10 CFR part 32.

(f) Except for persons who manufacture, process, or produce self-luminous products, any person shall be exempt from these rules to the extent that such person receives, possesses, uses, transfers, owns, or acquires:

(1) Tritium, Krypton 85, or Promethium 147 in self-luminous products manufactured, processed, imported, or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.22 of 10 CFR part 32; or

(2) Naturally occurring material in self-luminous products manufactured, processed, imported, or transferred in accordance with a specific license issued by an Agreement

State or Licensing State pursuant to equivalent conditions as in Section 32.22 of 10 CFR part 32.

(g) The exemptions in He-P 4030.03(f) shall not apply to Tritium, Krypton 85, Promethium 147, or naturally occurring material used in products for frivolous purposes or in toys or ornaments.

(h) Except as provided in He-P 4030.03(j) through (l), any person shall be exempt from these rules 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 He-P 4096.

(i) Any person who possesses byproduct material received or acquired under the general license formerly provided in He-P 2031 shall be exempt from the requirements for a license set forth in He-P 4030, He-P 4031, He-P 4032, He-P 4033, He-P 4034, and He-P 4036 to the extent that such person possesses, uses, transfers or owns such byproduct material.

(j) The provisions of He-P 4030.03(h) and (i) shall 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.

(k) No person shall, for purposes of commercial distribution, transfer byproduct material in the individual quantities set forth in He-P 4096, knowing or having reason to believe that such quantities of byproduct material will be transferred to persons exempt under He-P 4030.03(h) or (i) or equivalent regulations of the Nuclear Regulatory Commission, an Agreement State, or a Licensing State except in accordance with a specific license issued by the Nuclear Regulatory Commission pursuant to Section 32.18 of 10 CFR part 32, equivalent regulations of an Agreement State or a Licensing State.

(l) No person may, for purposes of producing an increased radiation level, combined quantities of byproduct material covered by this exemption so that the aggregate quantity exceeds the limits set forth in He-P 4096, except for byproduct material combined within a device placed in use before May 3, 1999, or otherwise permitted by the regulations in this part.

(m) A manufacturer, processor, or producer of a product or material is exempt from the requirements for a license set forth in He-P 4031, He-P 4032, He-P 4033, He-P 4034, He-P 4035, He-P 4036 to the extent that this person transfers byproduct material contained in a product or material in concentrations not in excess of those specified in He-P 4093 and introduced into the product or material by a licensee holding a specific license issued by the DHHS/RHS expressly authorized 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.

Source. (See Revision Note at part heading for He-P 4030) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07

New. #8959, eff 8-7-07

He-P 4030.04 Exemptions, U.S. Government Contractors. Any U.S. Nuclear Regulatory Commission and U.S. Department of Energy Contractor or subcontractor of the following categories operating within this state shall be exempt from this part to the extent that such

contractor or subcontractor under his contract receives, possesses, uses, transfers, owns, or acquires sources of radiation:

(a) Prime contractors performing work for the NRC or DOE at U.S. Government-owned or controlled sites;

(b) Prime contractors performing research in, or development, manufacture, storage, testing or transportation of, atomic weapons or components thereof;

(c) Prime contractors using or operating nuclear reactors or other nuclear devices in a U.S. Government-owned vehicle or vessel; and

(d) Any other prime contractor or subcontractor when the state and the NRC jointly determine that:

(1) Under the terms of the contract or subcontract, there is assurance that the work hereunder can be accomplished without undue risk to the public health and safety; and

(2) The exemption of such contractor or subcontractor is otherwise appropriate.

Source. (See Revision Note at part heading for He-P 4030) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07

New. #8959, eff 8-7-07

He-P 4030.05 Radioactive Drug: Capsules Containing Carbon-14 Urea for “In Vivo” Diagnostic Use for Humans.

(a) Except as provided in He-P 4030.05(b) and (c), any person is exempt from the requirements for a license set forth in He-P 4030 and He-P 4035, provided that such person receives, possesses, uses, transfers, owns, or acquires capsules containing 37 kBq (1 μ Ci) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each, for “in vivo” diagnostic use for humans.

(b) Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license pursuant to He-P 4035.

(c) Any person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution such capsules shall apply for and receive a specific license pursuant to He-P 4032.10.

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

Source. (See Revision Note at part heading for He-P 4030) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07

New. #8959, eff 8-7-07

He-P 4030.06 Types of Licenses. Licenses for byproduct materials shall be of the following:

(a) General licenses, as provided in He P 4031, which grant authority to persons for certain activities involving byproduct material, and are effective without the filing of an application with the DHHS/RHS or the issuance of licensing documents to the particular persons, although the filing of a certificate of registration with the DHHS/RHS may be required by the particular general license, as described in He-P 4031;

(b) Specific licenses which require the submission of an application to the DHHS/RHS and the issuance of a licensing document by the DHHS/RHS, under the provisions of this part and He P 4032, through He-P 4036, and He-P 4039; and

(c) Specific license by rule which is issued without the necessity of filing an application for a specific license in the following circumstances:

(1) When a site must be timely remediated of contamination by radioactive materials that are subject to licensing under these rules but are unlicensed; or

(2) When radioactive materials existing as a result of improper handling, spillage, accidental contamination, or unregulated or illegal possession, transfer, or receipt, must be stored and those materials have not been licensed under these rules.

Source. (See Revision Note at part heading for He-P 4030) #6942, eff 2-1-99; ss by #8488, eff 11-18-05; ss by #8959, eff 8-7-07

He-P 4030.07 Specific Licenses, Filing or Application. Application for specific licenses shall be filed in compliance with the following provisions:

(a) Applications for specific licenses shall be filed on a form prescribed by the DHHS/RHS in He-P 4004;

(b) The DHHS/RHS 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 DHHS/RHS 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 by the applicant or the licensee to act for and on his behalf;

(d) An application for a license may include a request for a license authorizing one or more activities;

(e) In the application, the applicant may incorporate by reference, information contained in previous applications, statements, or reports filed with the DHHS/RHS, provided such references are clear and specific;

(f) Applications and documents submitted to the DHHS/RHS may be made available for public inspection except that the DHHS/RHS shall 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 license to receive and possess radioactive material for commercial waste disposal by land burial or for the conduct of any other activity which the DHHS/RHS determines will affect the quality of the environment shall be filed at least 9 months

prior to commencement of construction of the plant or facility in which the activity will be conducted and shall be accompanied by an environmental report;

(h) Each application for a radioactive material license, other than a license exempted from He-P 4070 of this chapter, or an application for amendment of a license shall be accompanied by the fee prescribed in He-P 4070;

(i) 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 with the DPHS/RHS, the U.S. Nuclear Regulatory Commission "Registry of Radioactive Sealed Sources and Devices," 10 CFR 32.210, with an Agreement State, or for a source or a device containing radium-226 or accelerator-produced radioactive material with DPHS/RHS under provisions of He-P 4032.11; or

(2) Contain the information identified in He-P 4032.11(b); or

(3) For sources or devices containing naturally occurring or accelerator-produced radioactive material manufactured prior to November 30, 2007 that are not registered with the DPHS/RHS, the U.S. Nuclear Regulatory Commission 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 He-P 4032.11(b) or in 10 CFR 32.210(c), the applicant shall provide:

a. All available information identified in He-P 4032.11(b) or in 10 CFR 32.210(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 radiation safety features, the intended use and associated operating experience, and the results of a recent leak test.

(j) As provided by He-P 4030.09(b), certain applications for specific licenses filed under He-P 4030, must contain a proposed decommissioning funding plan or a certification of financial assurance for decommissioning; and

(k) For applications to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in He-P 4030.08, Table 4030.1, the following requirements pertain:

(1) Each application shall contain either:

a. An evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials would not exceed 1 rem effective dose equivalent or 5 rems to the thyroid; or

b. An emergency plan for responding to a release of radioactive material;

(2) The DHHS/RHS may use one or more of the following factors to support an evaluation submitted under He-P 4030.07(k)(1)a.:

- a. The radioactive material is physically separated so that only a portion could be involved in an accident;
- b. All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;
- c. The release fraction in the respirable size range would be lower than the release fraction shown in Table 4030.1 due to the chemical or physical form of the material;
- d. The solubility of the radioactive material would reduce the dose received;
- e. Facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in Table 4030.1;
- f. Operating restrictions or procedures would prevent a release fraction as large as that shown in Table 4030.1; or
- g. Other factors appropriate for the specific facility;

(3) An emergency plan for responding to a release of radioactive material submitted under He-P 4030.06(k)(1)b. shall include the following information:

- a. A description of the licensee's facility and area near the site;
- b. An identification of each type of radioactive material accident for which protective actions may be needed;
- c. A classification system for classifying accidents as alerts or site area emergencies;
- d. Identification of the means of detecting each type of accident in a timely manner;
- e. A description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment;
- f. A description of the methods and equipment to assess releases of radioactive materials;
- g. A description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying offsite response organizations and the DHHS/RHS, and also responsibilities for developing, maintaining, and updating the plan;
- h. A commitment to and description of the means to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers;
- i. A commitment to establish a control point;

j. A commitment to establish a notification and coordination plan such that the unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination;

k. Acknowledgment that the licensee shall also commit to notify the DHHS/RHS immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency;

l. A description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to offsite response organizations and to the DHHS/RHS;

m. A description of the frequency, performance objectives, and plans for the training that the licensee will provide workers on how to respond to an emergency including any special instructions and orientation tours the licensee would offer to fire, police, medical, and other emergency personnel, and documentation that the training shall:

1. Familiarize personnel with site-specific emergency procedures; and
2. Thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios;

n. A description of the means of restoring the facility to a safe condition after an accident;

o. Provisions for conducting quarterly communications checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies; and

p. A certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Pub. L. 99-499, if applicable to the applicant's activities at the proposed place of use of the radioactive material;

(4) The exercises required by He-P 4030.06(k)(3)o. shall provide for:

a. Quarterly communications checks with offsite response organizations which shall include the check and update of all necessary telephone numbers;

b. The invitation to offsite response organizations to participate in the biennial exercises;

c. Accident scenarios postulated as most probable for the specific site and which scenarios shall not be known to most exercise participants; and

d. Critiques of each exercise using individuals not having direct implementation responsibility for the plan and which shall evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response and which shall be corrected;

(5) The licensee shall allow the offsite response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to DHHS/RHS; and

(6) The licensee shall provide any comments received within the 60 days to the DHHS/RHS with the emergency plan.

(l) An application from a medical facility or educational institution to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use under He-P 4035 or equivalent Agreement State requirements shall include:

(1) A request for authorization for production of PET radionuclides or evidence of an existing license issued under He-P 4030 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 He-P 4032.05(a)(2);

(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 He-P 4032.05(b)(2); and

(4) Information identified in He-P 4032.05(a)(3) on the PET drugs to be noncommercially transferred to members of its consortium.

He-P 4030.08 Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release. These quantities shall be as set forth in Table 4030.1 below:

Table 4030.1 Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release

Radioactive Material	Release Fraction	Quantity (curies)
Actinium-228	0.001	4,000
Americium-241	0.001	2
Americium-242	0.001	2
Americium-243	0.001	2
Antimony-124	0.01	4,000
Antimony-126	0.01	6,000
Barium-133	0.01	10,000
Barium-140	0.01	30,000
Bismuth-207	0.01	5,000
Bismuth-210	0.01	600
Cadmium-109	0.01	1,000
Cadmium-113	0.01	80
Calcium-45	0.01	20,000
Californium-252	0.001	9 (20 mg)
Carbon-14 (carbon dioxide)	0.01	50,000

Radioactive Material	Release Fraction	Quantity (curies)
(non-carbon dioxide)	0.01	50,000
Cerium-141	0.01	10,000
Cerium-144	0.01	300
Cesium-134	0.01	2,000
Cesium-137	0.01	3,000
Chlorine-36	0.5	100
Chromium-51	0.01	300,000
Cobalt-60	0.001	5,000
Copper-64	0.01	200,000
Curium-242	0.001	60
Curium-243	0.001	3
Curium-244	0.001	4
Curium-245	0.001	2
Europium-152	0.01	500
Europium-154	0.01	400
Europium-155	0.01	3,000
Germanium-68	0.01	2,000
Gadolinium-153	0.01	5,000
Gold-198	0.01	30,000
Hafnium-172	0.01	400
Hafnium-181	0.01	7,000
Holmium-166m	0.01	100
Hydrogen-3	0.5	20,000
Iodine-125	0.5	10
Iodine-131	0.5	10
Indium-114m	0.01	1,000
Indium-192	0.001	40,000
Iron-55	0.01	40,000
Iron-59	0.01	7,000
Krypton-85	1.0	6,000,000
Lead-210	0.01	8
Manganese-56	0.01	60,000
Mercury-203	0.01	10,000
Molybdenum-99	0.01	30,000
Neptunium-237	0.001	2
Nickel-63	0.01	20,000
Niobium-94	0.01	300
Phosphorus-32	0.5	100
Phosphorous-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

Radioactive Material	Release Fraction	Quantity (curies)
Sodium-22	0.01	9,000
Sodium-24	0.01	10,000
Strontium-89	0.01	3,000
Strontium-90	0.01	90
Sulfur-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	0.0	1,000
Mixed corrosion products	0.01	10,000
Contaminated equipment beta-gamma	0.001	10,000
Irradiated material, any form other than solid noncombustible	0.01	1,000
Irradiated material, solid non-combustible	0.001	10,000
Mixed radioactive waste, beta-Gamma	0.01	1,000
Packaged mixed waste, beta-gamma ¹	0.001	10,000
Any other alpha emitter	0.001	2
Contaminated equipment alpha	0.0001	20
Packaged waste, alpha ¹	0.0001	20
Combinations of radioactive materials listed above ²	-	-

¹Waste packaged in Type B containers does not require an emergency plan.

²For 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 Schedule C exceeds one.

He-P 4030.09 Specific Licenses, Requirements for Issuance.

(a) A license application shall be approved if the DHHS/RHS 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 these rules in such a manner as to minimize danger to public health and safety or property; and
- (2) The applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety or property; and
- (3) The issuance of the license will not be inimical to the health and safety of the public;
- (4) The applicant satisfies any applicable special requirements in He-P 4031 through He-P 4035 and He-P 4039; and
- (5) In the case of an application for a license to receive and possess radioactive material for commercial waste disposal by land burial, the applicant satisfies any applicable special requirements in He-P 4062.

(b) In the case of an application for a license to receive and possess byproduct material for the conduct of any activity which the DHHS/RHS determines will significantly affect the quality of the environment, a license application for the facility in which the activity will be conducted shall be reviewed and approved by the DHHS/RHS before commencement of construction of the plant or the plant or facility in which the activity will be conducted, any clearing of land, excavation, or other substantial action that would adversely affect the environment of a site other than site exploration, necessary roads for site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values.

(c) Issuance of a license authorizing the activities of He-P 4030.09(b) shall be based upon a consideration by the DHHS/RHS of the environmental, economic, technical, and other benefits in comparison with the environmental costs 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.

(d) Commencement of construction in violation of He-P 4030.09(b) prior to review and approval by the DHHS/RHS shall be grounds for denial of a license to receive and possess byproduct material in such plant or facility. Commencement of construction as defined in He-P 4003.01 may include non-construction activities if the activity has a reasonable nexus to radiological safety and security. Construction as defined in He-P 4003.01 includes the installation of foundation, or in-place assembly, erection, fabrication, or testing for any structure, system, or component of a facility or activity subject to the rules in this part that have a reasonable nexus to radiological safety or security.

(e) Each applicant for a specific license authorizing the possession and use of special nuclear material, source material, or unsealed byproduct material in quantities and amounts in excess of those indicated in Table 4030.2 below shall submit a decommissioning funding plan.

Table 4030.2 Quantities and Amounts Requiring Decommissioning Funding Plan

Type of Material	Exceeding
Special Nuclear Material	105 times He-P 4091

Source Material	100 mCi in readily dispersible form
Byproduct Material (Unsealed)	Half-life greater than 120 days and in quantities exceeding 10^5 times the applicable quantities set forth in He-P 4091

(f) The decommissioning funding plan shall be submitted when a combination of isotopes is involved if R divided by 10^5 is greater than 1, where R is the sum of the ratios of quantity of each isotope to the applicable value in He-P 4091.

(g) Each applicant for or holder of a specific license authorizing possession and use of special nuclear material, source material, or radioactive material in excess of the values indicated in Table 4030.3 shall:

- (1) Submit to DHHS/RHS a decommissioning funding plan as described in He-P 4030.09(i); or
- (2) Submit to DHHS/RHS a certification that financial assurance for decommissioning shall be provided in the amount prescribed by Table 4030.3 below using one of the methods described in He-P 4030.09(j); and
- (3) Submit to DHHS/RHS as a part of the certification, a copy of the financial instrument obtained to satisfy the requirement of He-P 4030.09(j) and
- (4) If, in surveys made under He-P 4022.01(a), residual radioactivity in the facility and environment, including the subsurface, is detected at levels that would, if left uncorrected, prevent the site from meeting the He-P 4024.09(a) criteria for unrestricted use, the licensee shall submit a decommissioning funding plan within one year of when the survey is completed.

Table 4030.3 Financial Assurance Amounts for Decommissioning

Type of Radioactive Material	Exceeding	Assurance Amount
Special Nuclear Material	Greater than 10^4 but less than or equal to 10^5 times the applicable quantities as indicated in He-P 4091. For a combination of isotopes, if R, as defined in He-P 4030.09(f) divided by 10^3 is greater than 1 but R divided by 10^4 is less than or equal to 1.	\$1,125,000
	Greater than 10^3 but less than or equal to 10^4 times the applicable quantities as indicated in He-P 4091. For a combination of isotopes, if R, as defined in He-P 4030.09(f) divided by 10^4 is greater than 1 but R divided by 10^5 is less than or equal to 1.	\$225,000
Source Material	Greater than 10 mCi but less than or equal to 100 mCi in a readily dispersible form. For a combination of isotopes, if R, as defined in He-P 4030.09(f) divided by 10^3 is greater than 1 but R divided by 10^4 is less than or equal to 1.	\$113,000
Byproduct	Half-life greater than 120 days and in quantities:	

Type of Radioactive Material	Exceeding	Assurance Amount
Material	Greater than 10^4 but less than or equal to 10^5 times applicable quantities in unsealed form as indicated in He-P 4091. For a combination of isotopes, if R, as defined in He-P 4030.09(f) divided by 10^4 is greater than 1 but R divided by 10^5 is less than or equal to 1.	\$1,125,000
	Greater than 10^3 but less than or equal to 10^4 times the applicable quantities in unsealed form as indicated in He-P 4091. For a combination of isotopes, or if R, as defined in He-P 4030.09(f) divided by 10^4 is greater than 1 but R divided by 10^5 is less than or equal to 1.	\$225,000
	Greater than 10^{10} times the applicable quantities in sealed sources or plated sources. For a combination of isotopes, if R, as defined in He-P 4030.09(f) divided by 10^{10} is greater than 1.	\$113,000

(h) Certification may state that the appropriate assurance shall be obtained after the application has been approved and the license issued but prior to the receipt of licensed material.

(i)(1) Each decommissioning funding plan shall be submitted for review and approval and shall contain a detailed cost estimate for decommissioning, and a description of the method of assuring funds for such including means of adjusting cost estimates and associated funding levels over the life of the facility.

(a) A detailed cost estimate for decommissioning, in an amount reflecting:

1. The cost of an independent contractor to perform all decommissioning activities;
2. The cost of meeting the He-P 4024.09 criteria for unrestricted use, provided that, if the applicant or licensee can demonstrate its ability to meet the provisions of He-P 4024.10, the cost estimate may be based on meeting the He-P 4024.10 criteria;
3. The volume of onsite subsurface material containing residual radioactivity that will require remediation to meet the criteria for license termination; and
4. An adequate contingency factor.

(b) Identification of and justification for using the key assumptions contained in the Decommissioning Cost Estimate;

(c) A description of the method of assuring funds for decommissioning from He-P 4030(j) of this section, including means for adjusting cost estimates and associated funding levels periodically over the life of the facility;

(d) A certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning; and

(e) A signed original of the financial instrument obtained to satisfy the requirements of He-P 4030(j) of this section (unless a previously submitted and accepted financial instrument continues to cover the cost estimate for decommissioning).

(2) At the time of license renewal and at intervals not to exceed 3 years, the decommissioning funding plan must be resubmitted with adjustments as necessary to account for changes in costs and the extent of contamination. If the amount of financial assurance will be adjusted downward, this can not be done until the updated decommissioning funding plan is approved. The decommissioning funding plan must update the information submitted with the original or prior approved plan, and must specifically consider the effect of the following events on decommissioning costs:

(a) Spills of radioactive material producing additional residual radioactivity in onsite subsurface material;

(b) Waste inventory increasing above the amount previously estimated;

(c) Waste disposal costs increasing above the amount previously estimated;

(d) Facility modifications;

(e) Changes in authorized possession limits;

(f) Actual remediation costs that exceed the previous cost estimate;

(g) Onsite disposal; and

(h) Use of a settling pond.

(j) The financial instrument shall include the licensee's name, license number, and the name, address, and other contact information of the issuer, and, if a trust is used, the trustee. When any of the foregoing information changes, the licensee shall, within 30 days, submit financial instruments reflecting such changes. The financial instrument shall be a signed original or signed original duplicate, except where a copy of the signed original is specifically permitted. Financial assurance for decommissioning shall be provided by any one or more of the following methods:

(1) Prepayment;

(2) A surety method or insurance;

(3) An external sinking fund;

(4) Any other funding methods which shall be demonstrated by the applicant or licensee to provide comparable assurance to methods listed in He-P 4030.09(g)(1) through (3); and

(5) In the case of state, or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on Table 4030.3, and indicating that funds for decommissioning shall be obtained when necessary.

(k) The prepayment method in (j)(1) above shall be:

(1) In the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities;

(2) Deposited 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 that will retain their value over the projected operating life of the facility; and

(3) In an amount such that the principal plus accumulated earnings shall be sufficient to pay the necessary costs.

(l) The surety method or insurance in (j)(2) above shall be in the form of a surety bond, letter of credit, line of credit, secured interest or other guarantee method such that the costs shall be paid should the licensee default.

(m) Any surety or insurance under He-P 4030.09(1) shall contain the following conditions:

(1) The surety or insurance shall be open-ended or, if written for a specified term, such as 5 years, shall be renewed automatically unless 90 days or more prior to the renewal date, the issuer notifies the DHHS/RHS, the trust account, and the licensee of its intention not to renew;

(2) The surety or insurance shall provide that the beneficiary may automatically collect prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the DHHS/RHS within 30 days after receipt of notification of cancellation;

(3) The beneficiary of the surety or insurance shall be a trust account and trustee such as a state or federal government agency or entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a federal or state agency; and

(4) The surety or insurance shall remain in effect until the DHHS/RHS has terminated the license.

(n) An external sinking fund in (j)(3) shall be:

(1) In the form of a trust, escrow account, government fund, certificate of deposit or deposit of government securities;

(2) Established and maintained by the periodic deposit of a prescribed amount into an account segregated from licensee assets and outside the licensee's administrative control;

(3) In a total amount for which the periodic deposits plus accumulated earnings shall be sufficient to pay the necessary costs at the time termination of operation is expected;

(4) Deposited to at least annually; and

(5) Coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund.

(o) Each person licensed under He-P 4030 shall keep records of information important to the safe and effective decommissioning of the facility in a specific location reserved for this purpose until the site is released for unrestricted use and the license terminated by the DHHS/RHS.

(p) If records of relevant information are kept for other purposes, reference to these records and their locations shall be allowed to be kept with the records for decommissioning.

(q) Records important to decommissioning shall consist of:

(1) Recordings of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site, which may be limited to instances:

a. When contamination remains after any cleanup procedures; or

b. When there is reasonable likelihood that contaminants may have spread to inaccessible areas such as seepage into porous materials such as concrete;

(2) Information on identification of involved radionuclides, quantities, chemical and physical forms, and concentrations, if known;

(3) As-built drawings and modifications of structures and equipment in restricted areas where byproduct materials are used or stored, and of locations of possible inaccessible contamination such as buried pipes, but if drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations;

(4) Except for areas containing only sealed sources, provided the sealed sources have not leaked or no contamination remains after any leak, or byproduct material having only half lives of less than 65 days, a list contained in a single document and updated every 2 years, of the following:

a. All areas designated and formerly designated restricted areas as defined in He-P 4003;

b. All areas outside of restricted areas that require documentation under He-P 4030.09(q);

c. All areas outside of restricted areas where current and previous wastes have been buried as documented under He-P 4021.09; and

d. All areas outside of restricted areas that contain material such that, if the license expired, the licensee would be required to either decontaminate the area to meet the criteria for decommissioning in He-P 4024, or apply for approval for disposal under He-P 4023.02; and

(5) Recordings of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and recordings of the funding method used for assuring funds if either a funding plan or certification is used.

(r) Before licensed activities are transferred or assigned in accordance with He-P 4030.15, licensees shall transfer all records required by He-P 4030.09(o) to the new licensee, and the new licensee shall be responsible for maintaining these records until the license is terminated.

(s) No license issued or granted pursuant to the regulations in He-P 4030.09, He-P 4031 through He-P 4036, and He-P 4039 of this regulation shall be subject to all the provisions of the Title X Public Health Chapter 125-F, as amended, now or hereafter in effect, and to all valid rules, regulations and orders of the Agency.

(1) No license issued or granted pursuant to the regulations in He-P 4030.09, He-P 4031 through He-P 4036, and He-P 4039 of this regulation nor any right under a license 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 the Title X Public Health Chapter 125-F and shall give its consent in writing.

(2) An application for transfer of license must include:

a. The identity, technical and financial qualifications of the proposed transferee; and

b. Financial assurance for decommissioning information required by He-P 4030.09.

(t) In providing financial assurance under He-P 4030.09, each licensee shall use the financial assurance funds only for decommissioning activities and each licensee shall monitor the balance of funds held to account for market variations. The licensee shall replenish the funds, and report such actions to the DHHS/RHS, as follows:

(1) If, at the end of a calendar quarter, the fund balance is below the amount necessary to cover the cost of decommissioning, the licensee shall increase the balance to cover the cost, and shall do so within 30 days after the end of the calendar quarter.

(2) If, at any time, the fund balance falls below 75 percent of the amount necessary to cover the cost of decommissioning, the licensee shall increase the balance to cover the cost, and shall do so within 30 days of the occurrence.

(3) Within 30 days of taking the actions required by He-P 4030.09(t)(1) or (t)(2), the licensee shall provide a written report of such actions to the DHHS/RHS, and state the new balance of the fund.

(a) Upon a determination that an application meets the requirements of the act and the rules of the DHHS/RHS, the DHHS/RHS shall issue a specific license authorizing the proposed activity.

(b) The DHHS/RHS shall incorporate in any license issued pursuant to this part and He-P 4031 through 4036, and He-P 4039, at the time of issuance or thereafter, by appropriate rule or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of radioactive material 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;
- (3) Prevent loss or theft of material subject to this part; and
- (4) Security requirements for portable gauges.

(a) 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.

(c) Specific licenses shall be issued to named persons upon applications filed pursuant to He-P 4030 and He-P 4004.

(d) Each license issued pursuant to this part and parts He-P 4031 through 4036, and He-P 4039, shall be subject to all the provisions of the act, to all rules of the DHHS/RHS, and orders of the commissioner of the department of health and human services.

(e) Neither the license nor any right under the license issued or granted pursuant this part and parts He-P 4031 through 4036, and He-P 4039, shall be assigned or otherwise transferred in violation of the provision of the act.

(f) Each person licensed by the DHHS/RHS pursuant to this part shall confine his use and possession of the material licensed to conditions specified on the license, such as:

- (1) Standard licensing conditions as set forth in these rules, or
- (2) Conditions formulated specifically for an individual license.

(g) Each licensee shall notify the DHHS/RHS in writing when the licensee decides to permanently discontinue all activities involving materials authorized under the license.

(h) Each general licensee that is required to register by He-P 4031, and each specific licensee, shall notify the DHHS/RHS 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(15) 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.

(i) The notification specified in He-P 4030.10(h) shall indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of the filing of the petition.

(j) Each licensee shall notify the DHHS/RHS of radiological incidents and events, as follows:

(1) As soon as possible but not later than 4 hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed the limits specified in He-P 4020, or releases of licensed material that could exceed the limits specified in He-P 4020; and

(2) Within 24 hours after the discovery of any of the following events involving licensed material:

a. An unplanned contamination event that:

1. Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;

2. Involves a quantity of radioactive material greater than 5 times the lowest annual limit on intake specified in He-P 4090 for the material; and

3. Requires access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination;

b. An event in which equipment is disabled or fails to function as designed when:

1. The equipment is required by the rules or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding the limits specified by He-P 4020, or to mitigate the consequences of an accident;

2. The equipment is required to be available and operable when it is disabled or fails to function; and

3. No redundant equipment is available and operable to perform the required safety function;

c. An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body; and

d. An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:

1. The quantity of radioactive material involved is greater than 5 times the lowest annual limit on intake specified in for the material; and

2. The damage affects the integrity of the licensed material or its container.

(k) Licensees shall make reports required by He-P 4030.10(j)(1) and (2) by telephone to the DHHS/RHS via the New Hampshire state police communications center at 603 271-3636.

(l) To the extent that the information is available at the time of notification, the information provided in the telephonic report pursuant to (k) above shall include:

- (1) The caller's name and call back telephone number;
- (2) A description of the event, including date and time;
- (3) The exact location of the event;
- (4) The isotopes, quantities, and chemical and physical form of the licensed material involved; and
- (5) Any personnel radiation exposure data available.

(m) Each licensee who makes a report required by He-P 4030.10(j)(1) and (2) shall submit a written follow-up report within 30 days of the initial report, which includes the following information:

- (1) A description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;
- (2) The exact location of the event;
- (3) The isotopes, quantities, and chemical and physical form of the licensed material involved;
- (4) Date and time of the event;
- (5) Corrective actions taken or planned and the results of any evaluations or assessments; and
- (6) The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

(n) Relative to records, each person who receives radioactive material pursuant to a license issued pursuant He-P 4030 through He-P 4039 shall:

- (1) Keep records showing the receipt, transfer, and disposal of the radioactive material, as follows:
 - a. The licensee shall retain each record of receipt of byproduct material as long as the material is possessed and for 3 years following transfer or disposal of the material;
 - b. The licensee who transferred the material shall retain each record of transfer for 3 years after each transfer unless otherwise specified in this chapter; and
 - c. The licensee who disposed of the material shall retain each record of disposal of byproduct material until the license that authorizes disposal of the material is terminated;

(2) Retain each record that is required by this chapter or by license condition for the period specified by the applicable rule or license condition, except that if a retention period is not otherwise specified by rule or license condition, the record shall be retained until the license authorizing the activity that is subject to the recordkeeping requirement is terminated;

(3) Retain records required to be maintained pursuant to this chapter in the following format:

- a. The original;
- b. A reproduced copy, if such reproduced copy is duly authenticated by authorized personnel;
- c. Microform, if such microform is duly authenticated by authorized personnel and is capable of producing a clear and legible copy after storage for the period specified by the rules; or
- d. Stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period;

(4) Ensure that all pertinent information, including stamps, initials, and signatures, are included on all required records, including letters, drawings, specifications;

(5) Maintain adequate safeguards against tampering with and loss of records;

(6) Prior to termination of a license authorizing possession of radioactive material with a half-life greater than 120 days, in an unsealed form, forward the following records to the DHHS/RHS:

- a. Records of disposal of licensed material made under He-P 4023; and
- b. Records required by He-P 4021.03(c)(4);

(7) At the time of transfer of a radioactive material license authorizing possession of radioactive material with a half-life of greater than 120 days, in an unsealed form, transferred or assigned in accordance with He-P 4030.15 to a new licensee, transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated, the following:

- a. Records of disposal of licensed material made under He-P 4023; and
- b. Records required by He-P 4021.03(c)(4); and

(8) Prior to license termination, forward the records required by He-P 4030.09(o) – (t).

(o) 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 He-P 4035.32. The licensee shall record the results of each test and retain each record for 3 years after the record is made.

(p)(1) Authorization under He-P 4030.10(p) 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 DPHS/RHS, agreement State, FDA, and other Federal requirements governing radioactive drugs;

(2) Each licensee authorized under He-P 4030.10(p) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

a. Satisfy the labeling requirements in He-P 4032.05(a)(4) 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;

b. 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 He-P 4032.05(d).

(3) A licensee that is a pharmacy authorized under He-P 4030.07(l) 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:

a. An authorized nuclear pharmacist that meets the requirements in He-P 4032.05(b)(2), or

b. An individual under the supervision of an authorized nuclear pharmacist as specified in He-P 4035.11.

(4) A pharmacy, authorized under He-P 4030.07(l) 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 He-P 4032.05(b)(4).

He-P 4030.11 Specific Licenses, Expiration.

(a) Except as provided in He-P 4030.12, each specific license shall expire at the end of one year.

(b) Each licensee shall notify the DHHS/RHS, in writing, and request termination of the license when the licensee decides to terminate all activities involving byproduct material authorized under the license. This notification and request for termination of the license shall include the reports and information specified in He-P 4030.11(d)(4) and (5).

(c) No less than 30 days before the expiration date specified in the license, the licensee shall either:

(1) Submit an application for license renewal under He-P 4030.12; or

(2) Notify the DHHS/RHS, in writing, if the licensee decides not to renew the license.

(d) If a licensee does not submit an application for license renewal under He-P 4030.11, the licensee shall, on or before the expiration date specified in the license:

- (1) Terminate use of radioactive material;
- (2) Remove radioactive contamination in accordance with He-P 4023;
- (3) Dispose of radioactive material in accordance with He-P 4023;
- (4) Submit a completed DHHS/RHS Form RHS-10; and
- (5) Submit a radiation survey report of the licensed permanent location(s) of use and storage to confirm that the removable and fixed contamination levels are in accordance with levels specified in He-P 4021.21, as follows:
 - a. Report levels of radiation in units of microrads per hour of beta and gamma radiation at 1 centimeter and gamma radiation at 1 meter from surfaces;
 - b. Report levels of radioactivity, including alpha, in:
 1. Units of transformations per minute per 100 square centimeters or microcuries per 100 square centimeters removable and fixed on surfaces;
 2. Microcuries per milliliter in water; and
 3. Picocuries per gram in contaminated solids such as soils or concrete; and
 - c. Specify the survey or measurement instrument(s) used for conducting the survey and certify that each instrument was properly calibrated and tested.

(e) If no residual radioactive contamination attributable to activities conducted under the license is detected, the licensee shall submit a certification that no detectable radioactive contamination of the location(s) was found.

(f) If detectable levels of residual radioactive contamination attributable to activities conducted under the license are found, the license shall continue to be in effect beyond the expiration date, with respect to possession of residual radioactive material present as contamination until such time as the DHHS/RHS notifies the licensee in writing that the license is terminated. During this time the licensee shall be subject to the provisions of He-P 4030.11(h).

(g) If detectable levels of residual radioactive contamination attributable to activities conducted under the license are found, the licensee shall submit a plan for decontamination of the residual radioactive contamination which shall include in addition to the information submitted under He-P 4030.11(d)(4) and (5), any expected levels of residual radioactive contamination which will remain at the time the license is terminated.

(h) Each licensee who possesses residual radioactive material under He-P 4030.11(d)(3), following the expiration date specified in the license, shall:

- (1) Limit actions involving radioactive material to those related to decontamination and other activities related to preparation for release for unrestricted use; and

(2) Continue to control entry to restricted areas until the licensee has met the provisions of He-P 4020 for release for unrestricted use and the DHHS/RHS has notified the licensee in writing that the license is terminated.

Source. (See Revision Note at part heading for He-P 4030) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07

New. #8959, eff 8-7-07

He-P 4030.12 Specific Licenses, Renewal.

(a) Applications for renewal of specific licenses shall be filed in accordance with He-P 4030.07.

(b) In any case in which a licensee, not less than 30 days prior to expiration of his existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until the application has been finally determined by the DHHS/RHS.

(c) If a licensee does not submit an application for license renewal, the licensee shall comply with the provisions of He P 4030.10.

Source. (See Revision Note at part heading for He-P 4030) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07

New. #8959, eff 8-7-07

He-P 4030.13 Specific Licenses, Amendment at Request of Licensee. Applications for amendment of a license shall:

(a) Be filed in accordance with He-P 4030.07; and

(b) Specify the respects in which the licensee desires its license to be amended and the grounds for such amendment.

Source. (See Revision Note at part heading for He-P 4030) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07

New. #8959, eff 8-7-07

He-P 4030.14 Specific Licenses, DHHS/RHS Action of Applications to Renew or Amend. In considering an application by a licensee to renew or amend its license, the DHHS/RHS shall apply the criteria set forth in this chapter for granting of an initial license.

Source. (See Revision Note at part heading for He-P 4030) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07

New. #8959, eff 8-7-07

He-P 4030.15 Specific Licenses, Inalienability. No license issued or granted under this part and no right to possess or utilize radioactive material granted by any license issued pursuant

to this part shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the DHHS/RHS, after securing full information, find that the transfer is in accordance with the provisions of the act, and gives its consent in writing. An application for transfer of license shall include:

- (a) The identity, technical and financial qualifications of the proposed transferee; and
- (b) Financial assurance for decommissioning information required by He-P 4024.09, He-P 4024.10, and He-P 4030.09.

Source. (See Revision Note at part heading for He-P 4030) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07

New. #8959, eff 8-7-07

He-P 4030.16 Specific Licenses, Transfer of Material.

(a) No licensee shall transfer radioactive material except as authorized pursuant to Part He-P 4030.

(b) Except as otherwise provided in its license and subject to the provisions of He-P 4030.16(c) and (d), any licensee may transfer radioactive material:

- (1) To the DHHS/RHS only after receiving prior approval from the DHHS/RHS;
- (2) To the U.S. Nuclear Regulatory Commission;
- (3) To any person exempt from He-P 4000 to the extent permitted under such exemption;
- (4) To any person authorized to receive such material under terms of a general license or its equivalent or a specific license or equivalent licensing document, issued by the DHHS/RHS, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State, or to any person otherwise authorized to receive such material by the Federal government of any agency thereof, the DHHS/RHS, an Agreement State, or a Licensing State; or
- (5) As otherwise authorized by the DHHS/RHS in writing.

(c) Before transferring radioactive material to a specific licensee of the DHHS/RHS, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State prior to receipt of the radioactive material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

(d) The following methods for the verification required by He-P 4030.16(c) shall be acceptable:

- (1) The transferor may have in its possession, and have read, a current copy of the transferee's specific license or registration certificate;
- (2) The transferor may have in its possession a written certification by the transferee that it is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date;

(3) For emergency shipments the transferor may accept oral certification by the transferee that it is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date, provided, that the oral certification is confirmed in writing within 10 days;

(4) The transferor may obtain other sources of information compiled by a reporting service from official records of the DHHS/RHS, the U.S. Nuclear Regulatory Commission, or the licensing agency of an Agreement State or a Licensing State as to the identity of licensees and the scope and expiration dates of licenses and registration; or

(5) When none of the methods of verification described in He-P 4030.16(d)(1) to (4) are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the DHHS/RHS, the U.S. Nuclear Regulatory Commission, or the licensing agency of an Agreement State or a Licensing State that the transferee is licensed to receive the radioactive material.

(e) Preparation for shipment and transport of radioactive material shall be in accordance with the provisions of He-P 4037.

Source. (See Revision Note at part heading for He-P 4030) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07

New. #8959, eff 8-7-07

He-P 4030.17 Specific Licenses, Modification, Revocation, and Termination.

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

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

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

(d) The DHHS/RHS shall terminate a specific license upon request submitted by the licensee to the DHHS/RHS in writing, provided that the licensee shall meet the requirements of He-P 4030.16.

Source. (See Revision Note at part heading for He-P 4030) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07

New. #8959, eff 8-7-07

He-P 4030.18 Reciprocal Recognition of Specific Licenses.

(a) Subject to He-P 4000, any person who holds a specific license from the NRC, an Agreement State, or a Licensing State, as defined in He-P 4003.01(i) and (ch), respectively, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, shall hereby be granted a general license to conduct the activities authorized in such licensing document within this state, except in areas of exclusive federal jurisdiction, for a period not in excess of 180 days in any calendar year, provided that:

- (1) The licensing document does not limit the activity authorized by such document to specified installations or locations; and
- (2) The out-of-state licensee notifies DHHS/RHS in writing at least 3 working days prior to engaging in such activity and receives DHHS/RHS approval.

(b) The DHHS/RHS shall grant the approval required by (a)(2) above when a general licensee meets all of the requirements under He-P 4030.18.

(c) The notification required by (a)(2) above shall indicate the location, period, and type of proposed possession and use within this state.

(d) The notification shall be accompanied by a copy of the pertinent licensing document, a copy of the licensee's operating and emergency procedures, an annual fee as specified in He-P 4070, and a completed Form RHS-15 containing the following:

- (1) Name of licensee;
- (2) Address of licensee;
- (3) Contact person;
- (4) Telephone number;
- (5) Name of person(s) who will conduct licensed activities;
- (6) Description of activities to be conducted in New Hampshire under the general license;
- (7) Location at which activities will be conducted;
- (8) Date and time on which activities will be conducted;
- (9) A list of sealed sources and devices containing sealed sources, which will be possessed, used, installed, serviced or tested in New Hampshire;
- (10) Number of specific license and name of agency issuing license; and
- (11) The licensee's dated signature certifying that they have read the provisions under He-P 4030.18.

(e) If, for a specific case, the 3-day period required by (a)(2) above would endanger the public's health and safety, the licensee may, upon application to DHHS/RHS, obtain permission to proceed sooner.

(f) The out-of-state licensee shall submit in its initial request for reciprocity the applicable New Hampshire annual license fee in accordance with He-P 4070, Table 4070.1, Annual Fees for Radioactive Material Licenses.

(g) The reciprocity fee required by (f) above shall cover a period of one year from the time of application, at which time a new fee submittal shall be required.

(h) The requirement in (f) above shall not waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in He-P 4030.18(a).

(i) The out-of-state licensee shall comply with all:

- (1) Applicable rules of DHHS/RHS; and
- (2) Terms and conditions of the licensee's licensing document, except any such terms and conditions which are contrary to applicable rules of DHHS/RHS.

(j) The out-of-state licensee shall supply additional information, either telephonically or in writing, as requested by DHHS/RHS for the purposes of protecting public and worker health and safety and ensuring the safe use of radioactive sources within the state.

(k) The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in this section except by transfer to a person:

- (1) Specifically licensed by DHHS/RHS or by the U.S. Nuclear Regulatory Commission to receive such material; or
- (2) Exempt from the requirements for a license for such material under He-P 4030.03.

(l) Before radioactive materials are used at a temporary job site within the state at any federal facility, the jurisdictional status of the job site shall be determined by the licensee.

(m) If the jurisdictional status of a temporary job site within the state at a federal facility is unknown, the licensee shall contact the federal agency to determine if the job site is under exclusive federal jurisdiction.

(n) In areas of exclusive federal jurisdiction, the general licensee shall be subject to all applicable rules, regulations, orders and fees of the NRC.

(o) Authorization for possession and use of radioactive materials at temporary job sites under exclusive federal jurisdiction shall be obtained from the NRC by either:

- (1) Filing a NRC Form-241 in accordance with 10 CFR 150.20(b); or
- (2) Applying for a specific NRC license.

(p) Before radioactive material is used by a specific licensee at a temporary job site in another state, authorization shall be obtained for the state if it is an Agreement State, or from the

NRC for any non-Agreement State, either by filing for reciprocity or applying for and obtaining a specific license.

(q) Notwithstanding the provisions of He-P 4030.18(a), any person who holds a specific license issued by the NRC, an Agreement State, or a Licensing State authorizing the holder to manufacture, install, or service a device described in He-P 4031.04(c) within an area subject to the jurisdiction of the licensing body shall be considered by DHHS/RHS to have a general license to install and service such device in this state provided that:

(1) Such person shall file a report with the DHHS/RHS within 30 days after the end of each calendar quarter in which any device is transferred to or serviced in this state;

(2) The report required by (q)(1) above shall identify each general licensee by:

a. Name and address;

b. The type of device transferred; and

c. The quantity and type of radioactive material contained in the device;

(3) The device shall have been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license, or equivalent licensing document, issued to such person by the NRC, an Agreement State, or a Licensing State;

(4) 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;"

(5) In the event that a label, as specified in (q)(4) above, is missing or damaged, such person shall affix a label in accordance with the regulations of the authority which licensed manufacture of the device; and

(6) The holder of the specific license shall furnish to each general licensee to whom the licensee transfers such device or on whose premises he or she installs such device a copy of the general license contained in He-P 4031.02.

(r) In accordance with RSA 125-F:10, the DHHS/RHS shall withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by another agency, 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.

(s) A licensee to whom action has been taken as described in He-P 4030.18(r) shall be afforded a hearing within 15 days on application, in the form of a written request, to the DHHS requesting such hearing.

(t) A hearing held relative to action taken under He-P 4030.18(r) shall be conducted in accordance with He-C 200.

Source. (See Revision Note at part heading for He-P 4030) #6942, eff 2-1-99; ss by #7919, eff 7-18-03; ss by #8488, eff 11-18-05; ss by #8959, eff 8-7-07