Consent edit.



PART He-P 4030 LICENSING OF RADIOACTIVE MATERIAL

Statutory Authority RSA 125-F:5,V

**Readopt with amendment He-P 4030.01, effective 1/15/16 (Document #11006), to read as follows:**

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 department of health and human services radiological health section (DHHS/RHS), or as otherwise provided in this chapter.

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

(1) All licensees shall be subject to the requirements of He-P 4001, He-P 4003, He-P 4019 through He-P 4024, He-P 4037, and He-P 4090 or its equivalent 10 CFR 20 Appendix B, through He-P 4096;

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

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

(4) Licensees engaged in land disposal of byproduct material shall be subject to the requirements of He-P 4062;

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

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

(7) Licensees of broad scope for other than human use shall be subject to He-P 4033;

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

(9) Licensees engaged in irradiator operations shall be subject to the requirements of He-P 4036; and

(10) Licensees that possess and use accelerator-produced byproduct material or discrete sources of radium 226 shall be subject to the requirements of He-P 4030.

(c) All applications, supplements, and supporting documents submitted to DHHS/RHS shall:

(1) Be the original document and one copy;

(2) Be dated and include an original signature of the applicant, licensee, the applicant or licensee's management that performs decision making functions for the applicant or licensee, or a person duly authorized in writing by the applicant, licensee or the applicant or licensee's management to make binding commitments and to sign documents on the licensee or applicant's behalf.

(3) The signed application shall include a certificate of the applicant's or the licensee's information, as follows:

"I certify under penalty of law that this document and all attachments were prepared in conformity with the New Hampshire Rules for the Control of Radiation under my direction or supervision. The information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations.";

(4) Include the certificate in He-P 4030.01(c)(2) above as part of any document submitted to DHHS/RHS with the application, or filed thereafter; and

(5) Be mailed to DHHS/RHS as specified in He-P 4001.08.

(d) Documentation including attached sheets of information, supplements, sketches, and drawings may be submitted on paper sized 8 ½ x 11 inches, any larger drawings shall be folded to size 8 ½ x 11 inches.

**Readopt with amendment He-P 4030.03, effective 1/15/16 (Document #11006), as amended effective 6/2/20 (Document #13047), to read as follows:**

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

(a) Except as provided in He-P 4030.03(i)-(k), or an equivalent regulation of an agreement state, or the Nuclear Regulatory Commission, any person shall be exempt from He-P 4030, He-P 4031 through He-P 4034, He-P 4036, and He-P 4039 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 an agreement state, or the Nuclear Regulatory Commission, except in accordance with a license issued pursuant to 10 CFR 32.11.

(c) Except for persons who apply byproduct material, or incorporate byproduct material into the following products, or persons who initially transfer for sale or distribution the following products containing byproduct material, any person shall be exempt from this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires the following products:

(1) Timepieces or hands or dials of timepieces which shall contain not more than the following specified quantities of byproduct 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;

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; and

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;

(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 containing byproduct material shall not exceed 1 millirad 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)(5), 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)(5), 0.05 microcurie of americium 241 shall be considered an exempt quantity under He-P 4096;

(6) Other radiation producing devices which contain not more than the following specified quantities of radioactive material:

a. Static elimination devices which contain, as a sealed source or sources, byproduct material consisting of a total of not more than 18.5 megabecquerels (500 microcuries) 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 megabecquerels (500 microcuries) of polonium 210 per device or of a total of not more than 1.85 gigabecquerels (50 millicuries) of hydrogen 3 (tritium) per device; and

c. Devices authorized before October 23, 2012 for use under the general license then provided in He-P 4031.04, or the equivalent regulations of agreement states, or Nuclear Regulatory Commission regulations pursuant to 10 CFR 31.3, and which were manufactured, tested, and labeled by the manufacturer in accordance with the specifications in a specific license issued by DHHS/RHS, or an agreement state or the Nuclear Regulatory Commission; or

(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.

(d) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution, gas and aerosol detectors containing byproduct material, any person shall be exempt from the requirements in He-P 4019, He-P 4020, He-P 4021, He-P 4030 through He-P 4036, and He-P 4039 to the extent that such person receives, possesses, uses, transfers, owns, or acquires:

(1) Byproduct material in gas and aerosol detectors designed to protect health, safety, or property, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under Nuclear Regulatory Commission pursuant to 10 CFR Part 32.26, which license authorizes the initial transfer of the product for use under 10 CFR 32.26, and a certificate of registration in accordance with 10 CFR 32.210; and

(2) Gas and aerosol detectors manufactured or distributed before November 30, 2007, in accordance with a specific license issued by He-P 4032.10 authorizing distribution to persons exempt from regulatory requirements. This exemption shall not apply to any person who desires to manufacture, process, or produce gas and aerosol detectors containing byproduct material, or to initially transfer such products for use under He-P 4030.03(d) after November 30, 2007.

(e) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution self-luminous products, any person shall be exempt from these rules 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, or initially transferred in accordance with a specific license issued by the Nuclear Regulatory Commission pursuant to 10 CFR Part 32.22. This exemption does not apply to tritium, krypton 85, or promethium 147 used in products primarily for frivolous purposes, or in toys, or adornments.

(f) Any person who desires to manufacture, process or produce, or initially transfer for sale or distribution, self-luminous products containing tritium, krypton 85, or promethium 147 for use under He-P

4030.03(e), shall apply for a license issued by the Nuclear Regulatory Commission pursuant to 10 CFR Part 32.22, and for a certificate of registration pursuant to 10 CFR Part 32.210.

(g) Except as provided in He-P 4030.03(i) and (k), 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.

(h) Any person who possesses byproduct material received or acquired before September 25, 1971, under the general license formerly provided in He-P 4031, shall be exempt from the requirements for a license set forth in He-P 4030 through He-P 4034, He-P 4036 and He-P 4039 to the extent that such person possesses, uses, transfers or owns such byproduct material.

(i) The provisions of He-P 4030.03(g) and (h) shall not authorize the production, packaging, or repackaging, or transfer of byproduct material for purposes of commercial distribution, or the incorporation of byproduct material into products intended for commercial distribution.

(j) 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, or an agreement state, except in accordance with a specific license issued by the Nuclear Regulatory Commission pursuant to 10 CFR 32.18, or equivalent regulations of an agreement state.

(k) For the purpose of producing an increased radiation level, no person shall combine 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 He-P 4030.

(l) A manufacturer, processor, or producer of a product or material, shall be exempt from the requirements for a license set forth in He-P 4031 through He-P 4036 and He-P 4039 to the extent that the person transfers byproduct material contained in a product or material in concentrations not in excess of those specified in He-P 4093 and introduced in the product or material by a licensee holding a specific license issued by DHHS/RHS expressly authorizing such introduction. This exemption shall 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 for application to, a human being.

(m) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material 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 an ionized atmosphere, any person shall be exempt from the requirements for a license set forth in He-P 4019 through He-P 4024, He-P 4030 through He-P 4036, and He-P 4039, or the requirements of an agreement state and the Nuclear Regulatory Commission in section 81 of the Atomic Energy Act, to the extent that:

(1) Such persons receive, possess, use, transfer, own, or acquire byproduct material, in these certain detecting measuring, gauging, or controlling devices, and certain devices for producing an ionized atmosphere, and manufactured, processed, produced or initially transferred in accordance with a specific license issued under He-P 4030.03 or an agreement state, or the Nuclear Regulatory Commission 10 CFR Part 32.30;

(2) Persons who desire to manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material for use under He-P 4030.03(m),

shall apply for a license in accordance with the Nuclear Regulatory Commission pursuant to 10 CFR Part 32.30, and for a certificate of registration in accordance with 10 CFR 32.210; and

(3) This exemption shall not apply to sources not incorporated into a device, such as calibration and reference sources.

**Readopt with amendment He-P 4030.07, effective 1/15/16 (Document #11006), as amended effective 6/2/20 (Document #13047), to read as follows:**

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

(a) A completed application form for a specific license shall:

(1) Be filed on one of the following forms:

a. DHHS/RHS-1 "Application for Radioactive Material License" (July 2022) and DHHS/RHS-1 Supplement A "Training and Experience" (~~July 2022~~July 2022);

b. DHHS/RHS–1M "Application for Radioactive Material License – Medical" (~~July 2022~~July 2022), and the following supplements as applicable:

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1. DHHS/RHS-1M Supplement A "Radiation Safety Officer Training or Associate Radiation Safety Officer Training, Experience and Preceptor Attestation," (July 2022), in accordance with He-P He-P 4035.61;

2. DHHS/RHS-1M Supplement B-Diagnostic "Authorized User Training and Experience and Preceptor Attestation" (July 2022), in accordance with He-P 4035.63, He-P 4035.64, or He-P 4035.65;

3. DHHS/RHS-1M Supplement B-Sources "Authorized User Training, Experience and Preceptor Attestation" (July 2022), in accordance with He-P 4035.68;

4. DHHS/RHS-1M Supplement B-Therapy "Authorized User Training, Experience and Preceptor Attestation" (July 2022), in accordance with He-P He-P 4035.59, He-P 4035.66, HE-P 4035.67, or He-P 4035.69;

5. DHHS/RHS-1M Supplement C "Authorized Medical Physicist or Ophthalmic Physicist Training, Experience and Preceptor Attestation" (July 2022), in accordance with He-P 4035.32(f) or He-P 4035.70; or

6. DHHS/RHS-1M Supplement D "Authorized Nuclear Pharmacist Training, Experience and Preceptor Attestation" (July 2022), in accordance with He-P 4035.74; or

c. DHHS/RHS–3 "Application for Radioactive Material License–Source Material". (July 2022)

(2) If submitted on DHHS/RHS-1M "Application for Radioactive Material License–Medical" (July 2022), then the following shall apply:

a. Answers to questions 7 through 23 shall be made on separately attached sheets which identify the item number by a heading located in the lower right corner of each page, and which includes the date of the application and the question number with which it is associated;

b. If answers to questions 7 through 23 are made following an appendix to the medical licensing guide, then the date of the referenced guide and the appendix letter should be specified;

c. All documentation including, attached sheets of information, supplements, sketches and drawings, shall be identified indicating the correlating item number on the DHHS/RHS-1M "Application for Radioactive Material License–Medical" (July 2022), by a heading which includes the item number and the purpose of the document submitted;

d. All applicable sections of He-P 4035 shall be listed to describe the radioisotopes and quantities of licensed material used, including those used in: remote afterloader units, teletherapy units, gamma stereotactic radiosurgery units and in a list to be provided that specifies any emerging technologies devices;

e. If a supplement for a radiation safety officer is submitted, it shall identify the name, license, or permit number of a supervising individual's training if the individual is a radiation safety officer, an authorized user, an authorized medical physicist or an authorized nuclear pharmacist, or if more than one supervising individual is required by He-P 4035, separate sheets shall be used to document each individual's training;

f. If a supplement requires a preceptor attestation, the attestation shall be:

1. Completed and signed by the individual's preceptor;

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2. ~~And i~~If more than one preceptor is necessary to document experience, then a separate preceptor attestation shall be obtained from each preceptor; and

3. Each preceptor shall provide, direct or verify the individual's training and experience, but such preceptor does not need to be the individual's supervisor;

g. If a supplement for a medical physicist is submitted training and work experience shall be listed and shall have been conducted in clinical radiation facilities that provide high-energy external beam therapy photons and electrons with energies greater than or equal to 1 million electron volts and brachytherapy services. The following training and work experience shall be documented as follows:

1. The required one year full-time medical physicist training and one year of full time work experience as required by He-P 4035 shall be not concurrent years; and

2. The supervising medical physicist shall meet the training and experience requirements in He-P 4035.70 and He-P 4035.73 for the use for which the individual is seeking authorization; and

h. Any supervising authorized user shall have the experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status as required in He-P 4035.

(b) DHHS/RHS shall at any time after the filing of the original application, and before the expiration of the license, require further statements or information when necessary for DHHS/RHS to determine whether the application should be granted or denied, or whether a license should be modified or revoked.

(c) Each application submitted shall meet the requirements of He-P 4030.01(c).

(d) An application for a license may include a supplement for a license authorizing one or more activities.

(e) Applications, supplements and documents submitted to DHHS/RHS may be made available for public inspection except that 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.

(f) An application for a license to receive and possess byproduct material for commercial waste disposal by land burial or for the conduct of any other activity which might negatively affect the quality of the environment according to the criteria set forth in 10 CFR 30.32(f) and 10 CFR 51, 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.

(g) Each application for a byproduct material license, other than a license exempted from He-P 4070, or a request for an amendment of a license filed in accordance with He-P 4030.13, shall be accompanied by the fee prescribed in He-P 4070.

(h) Except as provided in He-P 4030.07(h)(2), (h)(3), and (h)(4), an application for a specific license to use, manufacture, process, or produce byproduct material in the form of a sealed source, in a device that contains the sealed source, or gas or aerosol detectors containing byproduct material manufactured after November 30, 2007, shall meet the following requirements in (1) and (2), or in (3), or in (4) below:

(1) For sealed sources and devices allowed to be distributed without registration of safety information in accordance with He-P 4030.07(h)(3) below, the applicant shall supply only the manufacturer, model number, radionuclide, and quantity; and

(2) If it is not feasible to identify each sealed source and device individually, the applicant shall propose constraints on the number and type of sealed source and devices to be used and the conditions under which they will be used, in lieu of identifying each sealed source and device; and one of the following:

a. Identify the sealed source or device that contains a sealed source by manufacturer and model number registered with DHHS/RHS, an agreement state, or in the Nuclear Regulatory Commission "Registry of Radioactive Sealed Sources and Devices" pursuant to 10 CFR 32.210, or for a source or a device containing radium 226 or accelerator-produced radioactive material with DHHS/RHS under provisions of He-P 4032.11; or

b. Include in the application the information identified in He-P 4032.11(b); or

(3) For sources or devices manufactured before October 23, 2012 that are not registered with DHHS/RHS, with an agreement state, or with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210, and for which the applicant is unable to provide all categories of information specified in He-P 4032.11(b) or 10 CFR 32.210(c), the applicant shall provide both:

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 a 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 shall 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; or

(4) For sealed sources and devices allowed to be distributed without registration of safety information, the applicant shall supply only the manufacturer, model number, radionuclide, and quantity, in the following cases calibration and reference sources containing no more than:

a. 37 megabecquerels (1 millicurie), for beta and/or gamma emitting radionuclides; or

b. 370 kilobecquerels (10 microcuries), for alpha emitting radionuclides.

(i) As provided by He-P 4030.09(b), certain applications for specific licenses filed under He-P 4030 and He-P 4032 through He-P 4035 shall contain a proposed decommissioning funding plan pursuant to He-P 4030(e) or a certification of financial assurance for decommissioning.

(j) Applications to possess byproduct 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, shall meet all of the requirements below:

(1) Each application shall contain one of 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) In order to be approved, the evaluation in He-P 4030.07(j)(1)a. above shall include one of the following precautions or safety measures:

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 4030.07(j)(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 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 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 DHHS/RHS;

m. A description of the frequency, performance objectives, and plans for the training that the licensee shall 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 byproduct material;

(4) The exercises required by He-P 4030.07(j)(3)o. above 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 deficiencies found by the critiques which shall be corrected by the licensee;

(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 DHHS/RHS with the emergency plan.

(k) An application from a medical facility or an 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, or Nuclear Regulatory Commission 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 equivalent requirements of an agreement state, or the Nuclear Regulatory Commission 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) If the applicant is a pharmacy, identification of individual(s) authorized to prepare the PET radioactive drugs, and documentation that the individual(s) meet(s) 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 commercially transferred to members of its consortium.

**Readopt with amendment He-P 4030.10, effective 1/15/16 (Document #11006), as amended effective 6/2/20 (Document #13047), to read as follows:**

He-P 4030.10 Specific Licenses, Issuance.

(a) Upon a determination that an application meets the requirements of the applicable sections of He-P 4000, He-P 4030, and RSA 125-F, DHHS/RHS shall issue a specific license authorizing the proposed activity.

(b) DHHS/RHS shall incorporate into 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 byproduct material as it deems appropriate or necessary in order to:

(1) Protect the public health and minimize danger to life 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 this part.

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

(d) Each license issued pursuant to this part and parts He-P 4031 through 4036, and He-P 4039, shall be subject to all of the provisions of RSA 125-F and to the administrative rules in chapter He-P 4000. Said licenses shall also be subject to any temporary orders issued pursuant to the governor's state of emergency by the commissioner when necessary to protect the health and safety of employees, the general public, or the security of certain types of radioactive materials during the declared state of emergency.

(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 RSA 125-F.

(f) Each person licensed by DHHS/RHS pursuant to this part shall confine his or her 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 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 DHHS/RHS in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 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 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 of intake specified in He-P 4090 or the equivalent 10 CFR 20 Appendix B for the material; and

3. Requires access to the area to be 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 to DHHS/RHS required by He-P 4030.10(j)(1) and (2) above, by telephone 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) or (2) shall submit to DHHS/RHS 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 byproduct 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 source or byproduct material, as follows:

a. The licensee shall retain each record of receipt of source or byproduct material as long as the material is possessed and for 3 years following transfer or disposal of the source or byproduct material;

b. The licensee who transferred the radioactive material shall retain each record of transfer of source or byproduct material until DHHS/RHS terminates each license that authorizes the activity that is subject to recordkeeping requirement;

c. The licensee who disposed of the source or byproduct material shall retain each record of disposal of radioactive material until the license that authorizes disposal of the material is terminated; and

d. If source or byproduct material is combined or mixed with other licensed material and subsequently treated in a manner that makes direct correlation of a receipt record with transfer, export, or disposition record impossible, the licensee shall use evaluative techniques, such as, first-in-first-out, to make the records that are required by He-P 4030 account for 100 percent of the material received;

(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 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 to DHHS/RHS as required by He-P 4030.09(o) – (r).

(o) Relative to licensees preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators, each licensee shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium- 85 contamination, respectively, in accordance with He-P 4035.32(a) through (d). The licensee shall record the results of each test and retain each record for 3 years after the record is made. The licensee shall report the results of any test that exceeds the permissible concentration listed in He-P 4035.32(a) at the time of the generator elution, in accordance with He-P 4035.32(e).

(p) Relative to licensees authorized under He-P 4030.07(k) to produce:

(1) PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall not relieve the licensee from complying with applicable DHHS/RHS, or agreement state, or federal requirements governing radioactive drugs; and

(2) PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium, the licensees shall satisfy:

a. 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 the licensees consortium; and

b. The requirement for using instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of the licensees' consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements of He-P 4032.05(d).

(q) Relative to pharmacies authorized under He-P 4030.07(k) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium, each pharmacy shall require that any individual who prepares PET radioactive drugs shall be:

(1) An authorized nuclear pharmacist that meets the requirements in He-P 4032.05(b)(2);

(2) An individual under the supervision of an authorized nuclear pharmacist as specified in He-P 4035.11; or

(3) An individual working as an authorized nuclear pharmacist who meets the requirements of He-P 4032.05(b)(2).

(r) Relative to portable gauge licensees, each licensee shall:

(1) Secure the portable gauges such that each portable gauge license shall use a minimum of 2 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; and

(2) Maintain utilization logs for 3 years for each source of radiation which contains the following information:

a. A description, including the make, model, and serial number of each sealed source and each device in which the sealed source is located;

b. The location and dates of use, including the dates removed and returned to storage; and

c. The identity and signature of the user of the device.

(s) Relative to licensee's survey instruments, each licensee shall:

(1) Keep sufficient calibrated and operable radiation survey instruments at each location where sources of radiation are present to make the radiation surveys required by He-P 4022;

(2) Have each radiation survey instrument calibrated:

a. At energies appropriate for use and at intervals not to exceed 12 months or after instrument servicing, except for battery changes;

b. For linear scale instruments, at 2 points located approximately one-third and two-thirds of full scale on each scale. For logarithmic scale instruments, at mid-range of each decade, and at 2 points of at least one decade. For digital instruments, at 3 points between 0.02 and 10 millisieverts (2 and 1,000 mrem) per hour; and

c. So that an accuracy within plus or minus 20 percent at the calibration source can be demonstrated at each point checked; and

(3) Maintain records of the annual calibrations of its radiation survey instruments and retain each record for 3 years after it is made.

**Readopt with amendment He-P 4030.01, effective 1/15/16 (Document #11006), to read as follows:**

He-P 4030.11 Specific Licenses, Expiration.

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

(b) Each licensee shall notify 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 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 4030.12, 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-10 "Certificate-Disposition of Radioactive Material" (July 2022) in accordance with He-P 4030.01(c); 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 microrad 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 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 DHHS/RHS has notified the licensee in writing that the license is terminated.

**Readopt with amendment He-P 4030.01, effective 1/15/16 (Document #11006), to read as follows:**

He-P 4030.12 Specific Licenses, Renewal.

(a) Except as provided in (b) below, in order to renew a license, a licensee shall file a completed application for renewal of specific licenses annually using DHHS/RHS-1.1 "Application for Annual Renewal of Radioactive Material License" (July 2022); and submit the applicable fee as required by He-P 4070.

(b) Not more often than once every 7 years after filing an application according to He-P 4030.07, the licensee shall renew the license by submitting a completed application as listed in He-P 4030.07(a) and applicable supplements, as requested by DHHS/RHS in order to fully review the license. The completed application shall comply with He-P 4030.07.

(c) 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 as stated in (a) or (b) above, 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 DHHS/RHS.

(d) If a licensee does not submit an application for license renewal, the licensee shall comply with the provisions of He-P 4030.10(n) and He-P 4030.17(d).

(e) Each application submitted shall meet the requirements of He-P 4030.01(c).

**Readopt with amendment He-P 4030.01, effective 1/15/16 (Document #11006), to read as follows:**

He-P 4030.18 Reciprocal Recognition of Specific Licenses.

(a) Subject to He-P 4000, any person who holds a specific license from the Nuclear Regulatory Commission, an agreement state, as defined in He-P 4003.01 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 shall not limit the activity authorized by such document to specified installations or locations; and

(2) The out-of-state licensee shall notify DHHS/RHS as described in (d) below at least 3 working days prior to engaging in such activity and receive DHHS/RHS approval, except as provided in (e) below.

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

(c) The notification required by He-P 4030.18(a)(2) above shall indicate the location, period, and type of proposed possession and use within this state.

(d) The notification to DHHS/RHS, as specified in He-P 4001.08, shall be accompanied by a copy of the pertinent out of state licensing document, a copy of the licensee's operating and emergency procedures, an annual fee as specified in He-P 4070, and a completed DHHS/RHS-15 "Radioactive Material Reciprocity Application" (July 2022) with the following certification:

"I hereby certify that all information provided in this application is true and complete, I have read and understand the provisions under He-P 4030.18, and I understand that activities, including storage, conducted in New Hampshire under this general license are limited to 180 days during any calendar year."

(e) If, for a specific case, the 3-day period required by He-P 4030.18(a)(2) above would endanger the public health and safety, the licensee shall request a waiver from DHHS/RHS 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.

(g) The reciprocity fee required by (f) above shall cover a period of one year.

(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 byproduct sources within the state.

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

(1) Specifically licensed by DHHS/RHS, an agreement state, or by the 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 byproduct 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 Nuclear Regulatory Commission.

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

(1) Filing a Nuclear Regulatory Commission Form-241 in accordance with 10 CFR 150.20(b); or

(2) Applying for a specific Nuclear Regulatory Commission license.

(p) Before byproduct material is used by a specific licensee at a temporary job site in another state, authorization shall be obtained from that state if it is an agreement state, or from the Nuclear Regulatory Commission 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 an agreement state, or the Nuclear Regulatory Commission, 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 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 He-P 4030.18(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 byproduct 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 Nuclear Regulatory Commission or an agreement 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 He-P 4030.18(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, 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 protect the public health and minimize the danger to life 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 DHHS/RHS 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.

**Appendix B**

| **Rule** | **Specific State or Federal Statute or Regulations the Rule Implements** |
|---|---|
| He-P 4030.01 | 10 CFR 30.3, 40.3, 70.3 |
| He-P 4030.03 | 10 CFR 30.11, 30.14, 30.15, 30.18, 30.19, 30.20 |
| He-P 4030.07 | 10 CFR 30.32, 40.31, 10 CFR 32.210 |
| He-P 4030.10 | 10 CFR 30.34 |
| He-P 4030.11 | 10 CFR 30.36, 40.42, 70.38 |
| He-P 4030.12 | 10 CFR 30.37, 40.43, 70.33 |
| He-P 4030.18 | 10 CFR 150.20 |