PART He-P 4030 LICENSING OF RADIOACTIVE MATERIAL

Readopt with amendment He-P 4030.07, effective 7/29/22 (Document #13421), 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);

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

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~~68, or He-P 4035.71;

3. DHHS/RHS-1M Supplement B-Sources "Authorized User Training, Experience and Preceptor Attestation" (July 2022), in accordance with He-P 4035.~~68~~59, He-P 4035.67. He-P 4035.69, or~~and~~ He-P 4035.71;

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~~65, He-P 4035.66, or~~and~~ He~~E~~-P 4035.~~67~~71~~, 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 on the application 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 on the application 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;

2. 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~~one 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 shall~~should~~ be granted or denied, or whether a license shall~~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 related to safety and security of radioactive materials or to confidential information about the license application or statements on the license~~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

(i) Except as provided in He-P 4030.07(i)(1) and (i)(2), 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) or in (2) below:

(~~3~~1) 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

(24) 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, and 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.

(ij) 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.

(kj) 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 for the application to be approved, the evaluation in He-P 4030.07(ij)(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(ij)(1)b. shall include the following information:

a. A description of the licensee's facility and the uncontrolled 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 accidental 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~~i)(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.

(~~l~~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 N~~uclear R~~egulatory C~~ommission~~ 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 N~~uclear R~~egulatory C~~ommission~~ 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.

Appendix

Rule	State or Federal Statute or Federal Regulation Implemented
He-P 4030.07	10 CFR 30.32, 10 CFR 40.31, 10 CFR 32.210