PART He-P 4032 SPECIFIC LICENSES FOR MANUFACTURE OR TRANSFER OF CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

Statutory Authority RSA 125-F:5,V

He-P 4032.05 Manufacture, Preparation, or Distribution of Radiopharmaceuticals Containing Byproduct Material for Medical Use.

(a) An application for a specific license to manufacture, prepare, or transfer for commercial distribution of radiopharmaceuticals containing byproduct material for use by persons licensed pursuant to He-P 4035 shall be approved if:

(1) The applicant satisfies the requirements specified in He-P 4030.09;

(2) The applicant submits evidence that the applicant is at least one of the following:

a. Registered with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207 Subpart B;

b. Registered or licensed with a state or federal agency as a drug manufacturer;

c. Licensed as a pharmacy by a state board of pharmacy;

d. Operating as a nuclear pharmacy within a federal medical institution; or

e. A Positron Emission Tomography (PET) drug production facility licensed by a state or federal agency;

(3) The applicant submits the following information:

a. The radionuclide;

b. The chemical and physical form;

c. The packaging including maximum activity per vial, syringe, generator, or other container of the radioactive drug; and

d. The shielding provided by the packaging of the byproduct material shall be appropriate for safe handling and storage of radiopharmaceuticals by medical use licensees; and

(4) The applicant commits to the following labeling requirements:

a. A label shall be affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution;

b. The label shall include:

1. The radiation symbol and the words “CAUTION, RADIOACTIVE MATERIAL” or “DANGER, RADIOACTIVE MATERIAL”;

2. The name of the radioactive drug or its abbreviation; and

3. The quantity of radioactivity at a specified date and time, except in the case of radioactive drugs with a half-life greater than 100 days, for which the time may be omitted;

c. A label shall be affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution;

d. The label required in He-P4032.05(a)(4)c. shall include:

1. The radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL"; and

2. An identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label; and

e. The labels, leaflets, or brochures required by He-P 4032.05(a)(4) shall be in addition to the labeling required by the Food and Drug Administration (FDA), and shall be separate from or, if approved by the FDA may be combined with, the labeling required by FDA.

(b) A licensee described by He-P 4032.05(a)(2)c. or (a)(2)d.:

(1) Shall prepare radioactive drugs for medical use, and shall ensure that the radioactive drug is prepared by an authorized nuclear pharmacist, as specified in He-P 4032.05(b)(2) and (b)(3), or an individual under the supervision of an authorized nuclear pharmacist, as specified in He-P 4035.11;

(2) Shall allow a pharmacist to work as an authorized pharmacist only if:

a. This individual qualifies as an authorized nuclear pharmacist as defined in He-P 4035.03;

b. This individual meets the requirements specified in He-P 4035.53 and He-P 4035.74(c) and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

c. This individual is designated as an authorized nuclear pharmacist in accordance with He-P 4032.05(b)(3);

(3) Shall name a pharmacist as an authorized nuclear pharmacist as defined in He-P 4035.03, only if:

a. The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material; and

b. The individual practiced at a pharmacy at a government agency or federally recognized Indian Tribe before November 30, 2007 or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC;

(4) Shall provide to DHHS/RHS:

a. A copy of each individual's certification by a specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an agreement state as specified in He-P 4035.74(a); or

b. The Nuclear Regulatory Commission or agreement state license; or

c. A Nuclear Regulatory Commission master materials licensee permit; or

d. The permit issued by a licensee, or Nuclear Regulatory Commission master materials permittee of broad scope, or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist; or

e. Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a government agency or federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the Nuclear Regulatory Commission; and

f. A copy of the state pharmacy licensure or registration, no later than 30 days after the date that the licensee allows pursuant to He-P 4032.05(b)(2)a. and (b)(2)c., the individual to work as an authorized nuclear pharmacist;

(c) The actions authorized in He-P 4032.05(b)(1) and (b)(2) are permitted in spite of more restrictive language in license conditions.

(d) A licensee authorized under He-P 4032.05 shall:

(1) Possess and use instrumentation to measure the radioactivity of radioactive drugs;

(2) Have procedures for use of the instrumentation;

(3) Measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-, emitting radioactive drugs prior to transfer for commercial distribution;

(4) Perform tests before initial use, periodically, and following repair, on each measurement instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument, and make adjustments when necessary;

(5) Check each measurement instrument for constancy and proper operation at the beginning of each day of use; and

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

(e) Nothing in this section relieves the licensee from complying with applicable FDA, other federal, and state requirements governing radioactive drugs.