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

He-P 4032.01 Purpose.

(a) This part prescribes requirements for the issuance of specific licenses to persons who manufacture or initially transfer items containing byproduct material for sale or distribution to:

(1) Persons exempted from the licensing requirements of He-P 4030; or

(2) Persons generally licensed under He-P 4031 or He-P 4035.

(b) This part shall prescribe requirements for manufacturers or initial transferors of sealed source or devices containing sealed sources which are to be used by persons specifically licensed under He-P 4030 and U.S. Nuclear Regulatory Commission (NRC) in 10 CFR Part 37 or equivalent regulations of the NRC, an agreement state or a licensing state.

He-P 4032.02 Scope. The provisions and requirements of this part shall be in addition to, and not in substitution for, other requirements of He-P 4000. In particular, the provisions of He-P 4030 apply to applications, licenses and certificates of registration subject to He-P 4032, and the provisions of the Nuclear Regulatory Commission in 10 CFR Part 37 apply to applications and licenses subject to He-P 4032.

He-P 4032.03 Licensing the Manufacture and Distribution of Devices to Persons Generally Licensed.

(a) An application for a specific license to manufacture or initially transfer devices containing byproduct material, excluding special nuclear material, to persons generally licensed under He-P 4031.04, or equivalent regulations of the NRC, or an agreement state as established by the Atomic Energy Act of 1954, or a licensing state shall be approved if:

(1) The applicant satisfies the general requirements of He-P 4030.09;

(2) The applicant submits complete information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device which shall ensure that:

a. The device can be safely operated by persons not having training in radiological protection;

b. Under ordinary conditions of handling, storage, and the use of the device, the byproduct material contained in the device cannot be released or inadvertently removed from the device;

c. Under ordinary conditions of handling, storage, and the use of the device, it is unlikely that any person will receive in one year a dose in excess of 10% of the annual limits specified in He-P 4020.05; and

d. Under accident conditions (such as fire and explosion) associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the organ doses in Table 4032.1 below:

Table 4032.1 Organ Doses Under Accident Conditions

Body Part	Organ Dose
Whole body; head and trunk; active blood-forming organs; gonads, or lens of eye	15 rems (150 mSv)
Hands and forearms; feet and localized areas of skin averaged over areas no longer than 1 square centimeter	200 rems (2 Sv)
Other organs	50 rems (500 mSv);

(3) Each device bears a durable, legible, clearly visible label or labels, which contain in a clearly identified and separate statement:

a. Instructions and precautions necessary to ensure safe installation, operation, and servicing of the device or identification of operating and service manuals used to provide this information;

b. The requirement, or exemption of a requirement, for leak testing, or for testing any on-off mechanism and indicator, to include the maximum time interval for such testing, the identification of radioactive material by isotope, the quantity of radioactivity, and the date of determination of the quantity; and

c. The information called for in the following statement in the same form:

1. "The receipt, possession, use and transfer of this device Model_____ Serial No._____ are subject to a general license or the equivalent and the regulations of the NRC, the Agreement State or the Licensing State which has regulatory authority.";

2. "This label shall be maintained on the device in a legible condition.";

3. "Removal of this label is prohibited.";

4. The words, "CAUTION - RADIOACTIVE MATERIAL"; and

5. The name of the manufacturer or distributor;

(4) Each device having a separable source housing that provides the primary shielding for the source also bears on the source housing, a durable label containing:

a. The device model number and serial number;

b. The isotope and quantity;

c. The words, "CAUTION - RADIOACTIVE MATERIAL";

d. The radiation symbol described in He-P 4022.11; and

e. The name of the manufacturer or initial distributor;

(5) Each device meeting the criteria of He-P 4031.04(e)(15), bears a permanent, such as embossed, etched, stamped, or engraved, label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, "CAUTION-RADIOACTIVE MATERIAL", and, if practicable, the radiation symbol described in He-P 4022.11; and

(6) The device has been registered in the NRC Sealed Source and Device Registry.

(b) Should an applicant under He-P 4032.03(a)(3)b. desire that a device be required to be leak tested or tested for proper operation of the on-off mechanism and indicator, at intervals greater than 6 months, DHHS/RHS shall consider at least the following information in determining the acceptable interval:

(1) Primary containment (source capsule);

(2) Protection of primary containment;

(3) Method of sealing containment;

(4) Containment construction materials;

(5) Form of contained radioactive material;

(6) Maximum temperature withstood during prototype test;

(7) Maximum pressure withstood during prototype tests;

(8) Maximum quantity of contained radioactive material;

(9) Radiotoxicity of contained radioactive material; and

(10) Operating experience with identical devices or similarly designed and constructed devices.

(c) In the event the applicant under He-P 4032.03(a) desires that the general licensee under He-P 4031, or under equivalent regulations of the NRC, an agreement state, or a licensing state, be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of byproduct material, service the device, test the on-off mechanism and indicator, or remove the device from installation, the applicant shall:

(1) Include written instructions to be followed by the general licensee;

(2) Include the estimated calendar-quarter doses associated with such activity or activities, and bases for such estimates; and

(3) Demonstrate that performance of such activity or activities by an individual untrained in radiological protection is unlikely to cause that individual to receive a calendar-quarter dose in excess of 10% of the limits specified in He-P 4020.

(d) If a device containing byproduct material is to be transferred for use under the general license contained in He-P 4031.04(b), each person that is licensed under He-P 4032.03 shall provide to each person to whom a device is to be transferred, prior to transferring the device, the following:

(1) A copy of the general license contained in He-P 4031.04(b), except if paragraphs He-P 4031.04(e)(2) through (e)(4) or He-P 4031.04(e)(15) do not apply to the particular device, those paragraphs may be omitted;

(2) A copy of He-P 4031.02, He-P 4030.10(n), He-P 4021.12, He-P 4021.13, and He-P 4021.19;

(3) A list of the services that can only be performed by a specific licensee;

(4) Information on acceptable disposal options including estimated costs of disposal; and

(5) An indication that DHHS/RHS shall take enforcement action for improper disposal.

(e) If the transfer specified in He-P 4032.03(d) is through an intermediate person, the information to be provided as described in He-P 4032.03(d) shall also be provided to the intended user prior to initial transfer to the intermediate person.

(f) If byproduct material is to be transferred in a device for use under the equivalent general license of an agreement state or equivalent regulations of the NRC, or a licensing state each person that is licensed under He-P 4032.03 shall provide to each person to whom a device is to be transferred, prior to transferring the device, the following:

(1) A copy of the agreement state's regulations equivalent to He-P 4031.04, He-P 4031.02, He-P 4030.10(n), He-P 4021.12, and He-P 4021.13, a copy of 10 CFR §§31.5, 31.2, 30.51, 20.2201, and 20.2202, or

(2) A copy of He-P 4031.04, He-P 4030.02, He-P 4030.10(n), He-P 4021.12, and He-P 4021.13, except if certain paragraphs of these rules do not apply to the particular device, those paragraphs may be disregarded;

a. If a copy of the agreement state's regulations equivalent to New Hampshire rules as listed in this paragraph, is provided to a prospective general licensee in lieu of the applicable agreement state's, licensing state's or NRC regulations, the copy of the agreement state's, licensing state's or equivalent regulations of the NRC shall be accompanied by a note explaining that use of the device is regulated by the agreement state, licensing state or NRC, as applicable; and

b. If certain paragraphs of the regulations do not apply to the particular device, those paragraphs may be omitted;

(3) A list of the services that can only be performed by a specific licensee;

(4) Information on acceptable disposal options including estimated costs of disposal; and

(5) The name or title, address, and phone number of the contact at the agreement state or licensing state regulatory agency or NRC from which additional information may be obtained.

(g) If the transfer specified in He-P 4032.03(f) is through an intermediate person, the information to be provided as described in He-P 4032.03(f) shall also be provided to the intended user prior to initial transfer to the intermediate person.

(h) In lieu of the requirements of He-P 4032.03(d) through (g) above, the applicant may propose an alternative approach to informing customers, subject to approval by DHHS/RHS. In its review of such a request, DHHS/RHS shall ensure that the proposed alternative approach to informing customers:

(1) Meets the essential objectives of He-P 4032.03(d) through (g);

(2) Provides the same information as required by He-P 4032.03(d) through (g); and

(3) Is not harmful to public health and safety.

(i) Each device that is transferred after November 17, 2005, shall meet the labeling requirements in He-P 4032.03(a)(3) through (5).

(j) If a notification of bankruptcy has been made under He-P 4030.10(h) or the license is to be terminated, each person licensed under He-P 4032.03 shall provide, upon request, to DHHS/RHS, the NRC, any appropriate agreement state, or licensing state records of final disposition required under He-P 4032.03(l) and (m).

(k) Each person licensed under He-P 4032.03 to initially transfer devices to generally licensed persons shall:

(1) Report, in a clear and legible report, to DHHS/RHS all transfers of such devices to persons for use under the general license in He-P 4031.03 and all receipts of devices from persons licensed under He-P 4031.03 including:

a. The identity of each general licensee by name and mailing address, and address location of use. If there is no mailing address for the location of use, an alternative address for the general licensee shall be submitted along with information on the actual location of use;

b. The name, title, and telephone number of the individual identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the applicable rules, and who may constitute a point of contact between DHHS/RHS and the general licensee;

c. The date of transfer;

d. The type, model number, and serial number of device transferred;

e. The quantity and type of byproduct material contained in the device;

f. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the general licensee shall provide the same

information for both the intended user and each intermediate person, which shall clearly designate and identify the intermediate person(s); and

g. The identity of the specific licensee submitting the report, including the license number of the specific licensee;

(2) Report, in a clear and legible report, to DHHS/RHS all receipts of devices from persons licensed under He-P 4031.03, including, for devices received from persons generally licensed under He-P 4031.03:

a. The identity of the general licensee by name and address;

b. The type, model number, and serial number of the device received;

c. The date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor; and

(3) Report to DHHS/RHS the identity of the general licensee, the device, and the changes to information on the device label, if the licensee authorized under He-P 4032.03 makes changes to a device possessed by a general licensee authorized under He-P 4031.04(b), such that the label must be changed to update required information;

(4) Report to DHHS/RHS if no transfers have been made to or from persons generally licensed under He-P 4031.04(b) during the reporting period;

(5) Report to the NRC, on NRC Form 653 "Transfers of Industrial Devices Report" or in a clear and legible report containing all data required by the form, all transfers of such devices to persons for use under the NRC general license in section 31.5 of 10 CFR 31;

(6) Report to the responsible agreement state, licensing state agency or the NRC all transfers of such devices to persons for use under a general license in the agreement state's licensing state's or NRC regulations equivalent to He-P 4031;

(7) Identify in the report required by He-P 4032.03(k)(5) or (6), the following:

a. The identity of each general licensee by name and mailing address, and address location of use; if there is no mailing address for the location of use, an alternative address for the general licensee shall be submitted along with information on the actual location of use;

b. The name, title, and telephone number of the individual identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the applicable rules, and who may constitute a point of contact between the agency and the general licensee;

c. The date of transfer;

d. The type, model, and serial number of the device transferred;

e. The quantity and type of byproduct material contained in the device; and

f. The identity of the specific licensee submitting the report, including the license number of the specific licensee;

(8) Report to the NRC, on NRC Form 653 "Transfers of Industrial Devices Report" or in a clear and legible report containing all data required by the form, all receipts of such devices from persons authorized under the NRC general license in section 31.5 of 10 CFR 31;

(9) Report to the responsible agreement state, or licensing state agency or the NRC all receipts of such devices from persons authorized under a general license in the agreement state's, licensing state's or NRC regulations equivalent to He-P 4031.04;

(10) Include in the report for devices received from persons generally licensed under agreement state, licensing state, or NRC regulations equivalent to He-P 4031.04:

a. The identity of the general licensee by name and address;

b. The type, model number, and serial number of the device received;

c. The date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor; and

d. The identity of the specific licensee submitting the report, including the license number of the specific licensee;

(11) Report to the responsible agreement state or licensing state agency or the NRC, the identity of the general licensee, the device, and the changes to information on the device label, if the licensee authorized under He-P 4032.03 makes changes to a device possessed by a general licensee authorized under regulations equivalent to He-P 4031.04(b), such that the label must be changed to update required information;

(12) Report to the NRC, if no transfers have been made to or from NRC general licensees during the reporting period;

(13) Report to the agreement state or licensing state agency or the NRC regulated state if no transfers have been made to or from that agreement state or licensing state or the NRC regulated state during the reporting period;

(14) Keep records showing:

a. The name of each general licensee or intermediate person to whom transfers of byproduct material in devices for use pursuant to the general license provided in He-P 4031.04, or equivalent regulations of the NRC, an agreement state or licensing state have been made;

b. Address of each general licensee or intermediate person to whom transfers of byproduct material in devices for use pursuant to the general license provided in He-P 4031.04, or equivalent regulations of the NRC, an agreement state or licensing state have been made;

c. The point of contact for each general licensee or intermediate person to whom transfers of byproduct material in devices for use pursuant to the general license provided

in He-P 4031.04, or equivalent regulations of the NRC, an agreement state or licensing state have been made;

d. The date of each transfer of byproduct material;

e. Identification of the radioisotope contained in each device transferred;

f. The quantity of radioactivity in each device transferred;

g. The identity of any intermediate person; and

h. The requirements of He-P 4031 specifics for this transfer;

(15) Cover each calendar quarter in its reports submitted under He-P 4032;

(16) Submit reports required in He-P 4032.03 within 30 days of the end of the calendar quarter; and

(17) Indicate in reports required in He-P 4032.03, the period covered by the report.

(l) In the event that one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the licensee shall provide the same information for both the intended user and each intermediate person, and shall clearly designate the identity of the intermediate person(s); and

(m) Each person licensed under He-P 4032.03 shall maintain all information concerning transfers and receipts of devices that supports the reports required by this section.

(n) Records required by (m) shall be maintained for a period of 3 years following the date of the recorded event.

He-P 4032.04 Licensing the Introduction of Byproduct Material Into Products in Exempt Concentrations.

(a) In addition to the requirements in He-P 4030.09, a specific license authorizing the introduction of byproduct material into a product or material owned by or in the possession of the licensee or another to be transferred to persons exempt under paragraph He-P 4030.03 shall be issued if:

(1) The applicant submits:

a. A description of the product or material into which the byproduct material will be introduced;

b. The intended use of the byproduct material and the product into which it is introduced;

c. The method of introduction;

d. The initial concentration of the byproduct material in the product or material;

e. The control methods to ensure that no more than the specified concentration is introduced into the product or material;

f. The estimated time interval between introduction and transfer of the product or material; and

g. The estimated concentration of the byproduct material in the product or material at the time of transfer by the licensee; and

(2) The applicant provides written statements in the application that:

a. The concentrations of byproduct material at the time of transfer will not exceed the concentration in He-P 4093;

b. That reconcentration of the byproduct material in concentrations exceeding those in He-P 4093 is not likely;

c. That use of lower concentrations is not feasible; and material shall not be incorporated in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

(b) Each person licensed under He-P 4032.04 shall file an annual report with DHHS/RHS.

(c) The annual report in (b) above shall:

(1) Identify:

a. The type and quantity of each product or material into which radioactive material has been introduced during the reporting period;

b. Name and address of the person who owned or possessed the product or material into which byproduct material has been introduced at the time of introduction;

c. The type and quantity of radionuclide introduced into each such product or material; and

d. The initial concentrations of the radionuclide in the product or material at the time of transfer of the byproduct material by the licensee;

(2) Indicate if no transfers of byproduct material have been made pursuant to He-P 4032.04 during the reporting period;

(3) Cover the year ending June 30; and

(4) Be filed within 30 days thereafter.

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 distribute 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 207.20(a);

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 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 group licensees in accordance with He-P 4037.04; and

(4) The applicant satisfies the following labeling requirements:

a. A label shall be affixed to each transport radiation shield 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 4032.03(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 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;

(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;

b. This individual meets the requirements specified in He-P 4035 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 defined in He-P 4003.01(df) as an authorized nuclear pharmacist as defined in He-P 4035, 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) with the written attestation signed by a preceptor as required by He-P 4035.74(b)(2); or

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

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

d. The permit issued by a licensee 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; or

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; and

(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; and

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

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

He-P 4032.06 Manufacture and Distribution of Generators or Reagent Kits for Preparation of Radiopharmaceuticals Containing Byproduct Material.

(a) An application for a specific license to manufacture and distribute generators or reagent kits containing byproduct material or reagent kits not containing byproduct material used for preparation of radiopharmaceuticals by persons licensed pursuant to He-P 4035 shall be approved if:

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

(2) The applicant submits evidence that:

a. The generator or reagent kit is to be manufactured, labeled, and packaged in accordance with the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), a biological product license issued by FDA, or a “Notice of

Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA; or

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

(3) The applicant submits the following information:

a. The radionuclide;

b. The chemical and physical form;

c. The packaging including maximum activity per package; and

d. The shielding provided by the packaging of the byproduct material contained in the generator or reagent kit;

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

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

a. Radiation safety information on the procedures to be followed and the equipment and shielding to be used in eluding the generator or processing byproduct material with the reagent kit; and

b. A statement that this generator or reagent kit is approved for use by persons licensed by the DHHS/RHS pursuant to He-P 4035 or under equivalent licenses of the Nuclear Regulatory Commission, an agreement state or licensing state.

(b) The labels, leaflets, or brochures required by He-P 4032.06(a)(4) and (a)(5) are in addition to the labeling required by FDA and they may be separate from, or if approved by the FDA may be combined with, the labeling required by FDA.

He-P 4032.07 Manufacture and Distribution of Sources or Devices Containing Byproduct Material for Medical Use.

(a) An application for a specific license to manufacture and distribute sources and devices containing byproduct material to persons licensed pursuant to He-P 4035 for use as a calibration, transmission, or reference source, or sources for the uses in manual brachytherapy, or sealed sources for diagnosis, or sealed source for the use in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit in accordance with He-P 4035 shall be approved if:

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

(2) The applicant submits the following radiation safety information for each type of source or device:

a. The byproduct material contained, its chemical and physical form, and amount;

b. Details of design and construction of the source or device;

c. Procedures for, and results of, prototype tests to demonstrate that the source or device maintains its integrity under stresses likely to be encountered in normal use and accidents;

d. For devices containing byproduct material, the radiation profile of a prototype device;

e. Details of quality control procedures to ensure that production sources and devices meet the standards of the design and prototype tests;

f. Procedures and standards for calibrating sources and devices;

g. Legend and methods for labeling sources and devices for their radioactive content; and

h. Instruction for handling and storing the source or device from the radiation safety standpoint, as follows:

1. These instructions shall be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device; or

2. If the instructions are too lengthy for such label, they may be summarized on the label and printed in detail on a brochure which is referenced on the label;

(3) The label affixed to the source or device, or to the permanent storage container for the source or device, contains the following information:

a. The radionuclide;

b. Quantity;

c. Date of assay; and

d. A statement that includes the name of source or device which is licensed by DHHS/RHS for distribution to persons licensed pursuant to He-P 4035 or under equivalent licenses of the Nuclear Regulatory Commission, an agreement state, or licensing state; and

(4) The source or device has been registered in the Sealed Source and Device Registry.

(b) In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than 6 months:

(1) The application shall include sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source; and

(2) In determining the acceptable interval for test of leakage of radioactive material, DHHS/RHS will consider information that includes, but is not limited to:

a. Primary containment (source capsule);

b. Protection of primary containment;

c. Method of sealing containment;

d. Containment construction materials;

e. Form of contained radioactive material;

f. Maximum temperature withstood during prototype tests;

g. Maximum pressure withstood during prototype tests;

h. Maximum quantity of contained radioactive material;

i. Radiotoxicity of contained radioactive material; and

j. Operating experience with identical sources or devices or similarly designed and constructed sources or devices.

He-P 4032.08 Special Requirements for the Manufacture, Assembly, Repair, or initially transfer of Luminous Safety Devices for Use in Aircraft. An application for a specific license to manufacture, assemble, or repair luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under He-P 4031.02(h) shall be approved if:

(a) The applicant satisfies the general requirements specified in He-P 4030.09; and

(b) The applicant satisfies the requirements of 10 CFR 32.53, 32.54, 32.55 and 32.56.

He-P 4032.09 Licensing the Distribution of Byproduct Material in Exempt Quantities.

(a) An application for specific license to distribute byproduct material other than source or byproduct material to persons exempted from licensing pursuant to He-P 4030.08 may be approved if:

(1) The byproduct material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being;

(2) The byproduct material is in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and

(3) The applicant submits copies of prototype labels and brochures and DHHS/RHS approves such labels and brochures.

(b) The license for exempt quantities issued under He-P 4032.09 shall be subject to the following conditions:

(1) No more than 10 exempt quantities as listed in He-P 4092.01, which may be composed of fractional parts, shall be sold or transferred in a single transaction, provided that the sum of the fractional parts shall not exceed one;

(2) Each exempt quantity shall be separately and individually packaged;

(3) No more than 10 packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to He-P 4030.03;

(4) The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem per hour;

(5) The immediate container of each quantity or separately packaged fractional quantity of radioactive material shall bear a durable, legible label which:

a. Identifies the radionuclide and the quantity of radioactivity; and

b. Bears the words "Radioactive Material"; and

(6) In addition to the labeling information required by He-P 4032.09, the label affixed to the immediate container, or an accompanying brochure, shall:

a. State that the contents are exempt from licensing state requirements;

b. Bear the words "Radioactive Material – Not for Human Use – Introduction into Foods, Beverages, Cosmetics, Drugs, or Medicinal, or into Products Manufactured for Commercial Distribution is Prohibited – Exempt Quantities Should Not be Combined"; and

c. Set forth additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the byproduct material.

(c) Each person licensed under He-P 4032.09 shall maintain records identifying, by name and address, each person to whom byproduct material is transferred for use under He-P 4030.03 or the equivalent regulations of the Nuclear Regulatory Commission or an agreement state or licensing state, and the kinds and quantities of byproduct material transferred.

(d) An annual summary report shall be filed with DHHS/RHS, as follows:

(1) Each report shall state the total quantity of each radionuclide transferred under the specific license;

(2) Each report shall cover the year ending June 30;

(3) Each report shall be filed within 30 days after the end of the quarter; and

(4) If no transfers of byproduct material have been made pursuant to this section during the reporting period, the report shall so indicate.

He-P 4032.10 Licensing the Incorporation of Byproduct Material Other than Source or Byproduct Material into Gas and Aerosol Detectors.

(a) In addition to the requirements set forth in He-P 4030.09, an application for a specific license authorizing the incorporation of byproduct material other than source or byproduct material into gas and aerosol detectors to be distributed to persons exempt under He-P 4030.03 shall only be approved if the application satisfies requirements equivalent to those contained in 10 CFR 32.26.

(b) The maximum quantity of radium-226 in each device shall not exceed 0.1 microcurie.

He-P 4032.11 Special Requirements for License to Manufacture, Import or Initially Distribute Sealed Sources or Devices Containing Sealed Sources to Persons Having a Specific License.

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

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

(2) The licensee subject to He-P 4032.11 shall not transfer a sealed source or device containing a sealed source to any person except in accordance with the requirements of He-P 4030.16.

(b) Any manufacturer or initial distributor of a sealed source or device containing a sealed source whose product is intended for use under a specific license may submit a request to DHHS/RHS for evaluation of radiation safety information about its product and for its registration, as follows:

(1) A request for evaluation of a sealed source or device containing a sealed source shall be submitted in duplicate and shall include information required by He-P 4032.11(b)(2) or (3), as applicable, demonstrating that the radiation safety properties of such source or device will not endanger public health and safety or property;

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

a. Proposed uses for the sealed source;

b. Chemical and physical form and maximum quantity of byproduct material in the sealed source;

c. Details of design of the sealed source, radiation and its shielding including blueprints, engineering drawings, or annotated drawings;

d. Details of construction of the sealed source including a description of materials used in construction;

e. Radiation profile of a prototype sealed source;

f. Procedures for and results of prototype testing;

g. Details of quality control procedures to be followed in manufacture;

h. A description or facsimile of labeling to be affixed to the sealed source;

i. Leak testing procedures; and

j. Any additional information, including experimental studies and tests, required by DHHS/RHS to facilitate a determination of the safety of the sealed source, as required by He-P 4030.09;

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

a. Proposed uses for the device;

b. Manufacturer, model number, chemical and physical form, and maximum quantity of radioactivity in the sealed source or sources to be used in the device;

c. Details of design of the sealed source, including blueprints, engineering drawings, or annotated drawings;

d. Details of construction of the sealed source, including a description of materials used in construction;

e. Radiation profile of a prototype device;

f. Procedures for and results of prototype testing;

g. Details of quality control procedures to be followed in manufacture;

h. A description or facsimile of labeling to be affixed to the device;

i. Leak testing procedures;

j. A description of potential hazards in installation, service, manufacture, handling, use, and operation of the device;

k. Information about installation, service, and maintenance procedures;

l. Handling, operating, and safety instructions; and

m. Any additional information, including experimental studies and tests, required by DHHS/RHS to facilitate a determination of the safety of the device as required by He-P 4030.09;

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

a. The statements and representations, including the quality control program, described in the request; and

b. The provisions of the evaluation sheet prepared by DHHS/RHS and submitted to the U.S. Department of Health and Human Services, for filing in the "Radioactive Material

Reference Manual" or in the U.S. Nuclear Regulatory Commission, for filing in the "Registry of Radioactive Sealed Sources and Devices." and

(5) The request for review shall be mailed to DHHS/RHS office, "ATTN: SSDR".

(c) DHHS/RHS shall apply the radiation safety criteria described in 10 CFR 32.210(d).

(d) After completion of the evaluation, DHHS/RHS shall issue a certificate of registration to the applicant described in 10 CFR 32.210(e).

(e) Authority to manufacture or initially distribute a sealed source or device to specific licensees shall be provided in the license without the issuance of a certificate of registration described in 10 CFR 32.210(g).

(f) After the certificate is issued, DHHS/RHS shall conduct an additional review described in 10 CFR.32.210(h).

(g) When inactivating certificates of registration of sealed sources and devices, DHHS/RHS shall apply the inactivation criteria described in 10 CFR 32.211.

He-P 4032.12 Prohibition. 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-P4030.03 or equivalent regulations of an Agreement State, the Nuclear Regulatory Commission or Licensing State, except in accordance with a license issued pursuant to He-P 4032.04 or the general license provided in He-P 4030.18.

He-P 4032.13 Serialization of Nationally Tracked Sources.

(a) Each licensee who manufactures a nationally tracked source after February 6, 2007 shall assign a unique serial number to each nationally tracked source. Serial numbers shall be composed only of alpha-numeric characters.

He-P 4032.14 Special Requirements for License to Manufacture or Initially Transfer Calibration Sources Containing Americium-241 or Radium-226 for Distribution to Persons Generally Licensed Under He-P 4031.04(r).

(a) An application for a specific license to manufacture or initially transfer calibration or reference sources containing americium-241 or radium-226 for distribution to persons generally licensed under He-P 4031.04(r), shall be approved if:

(1) The applicant satisfies the general requirements of He-P 4030.09;

(2) The applicant submits sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including:

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

b. Details of construction and design;

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

d. Procedures for and results of prototype testing of sources, which are designed to contain more than 185 becquerel (0.005 microcurie) of americium-241 or radium-226, to demonstrate that the americium-241 or radium-226 contained in each source will not be released or be removed from the source under normal conditions of use;

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

f. Description of labeling to be affixed to the source or the storage container for the source; and

g. Any additional information, including experimental studies and tests, required by DHHS/RHS to facilitate a determination of the safety of the source;

(3) Each source will contain no more than 185 kilobecquerel (5 microcurie) of americium-241 or radium-226; and

(4) DHHS/RHS determines, with respect to any type of source containing more than 185 becquerel (0.005 microcurie) of americium-241 or radium-226, that:

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

b. The source has been subjected to and has satisfactorily passed the appropriate tests prescribed by He-P 4032.14(d).

(b) Each person licensed under He-P 4032.14 shall affix to each source, or storage container for the source, a label which shall contain sufficient information relative to safe use and storage of the source and shall include the following statement or information:

"The receipt, possession, use and transfer of this source, Model __, Serial No. __, are subject to a general license and the regulations of the DHHS/RHS, the NRC, an Agreement State, or a Licensing State. Do not remove this label. CAUTION--RADIOACTIVE MATERIAL-- THIS SOURCE CONTAINS (AMERICIUM-241) OR (RADIUM-226). DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE (Name of Manufacturer or Transferor)."

(c) Each person licensed under He-P 4032.14 shall perform a dry wipe test upon each source containing more than 3.7 kilobecquerel (0.1 microcurie) of americium-241 or radium-226 before transferring the source to a general licensee under He-P 4031.04(r). This test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure. The radioactivity on the paper shall be measured using methods capable of detecting 185 becquerel (0.005 microcurie) of americium-241 or radium-226. If a source has been shown to be leaking or losing more than 185 becquerel (0.005 microcurie) of americium-241 or radium-226 by the methods described in He-P 4032(c), the source shall be rejected and shall not be transferred to a general license under He-P 4031.04(r), or equivalent regulations of the NRC, an agreement state or a licensing state.

(d) The applicant shall subject at least five prototypes of each source that is designed to contain more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 to tests as follows:

(1) The initial quantity of radioactive material deposited on each source is measured by direct counting of the source;

(2) The sources are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment or binding of americium-241 or radium-226, such as physical handling, moisture, and water immersion;

(3) The sources are inspected for evidence of physical damage and for loss of americium-241 or radium-226, after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in He-P 4032.14(d)(4); and

(4) Source designs are rejected for which the following has been detected for any unit: Removal of more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 from the source or any other evidence of physical damage.

He-P 4032.15 Manufacture and Distribution of Byproduct Material for Certain In Vitro Clinical or Laboratory Testing Under General License. An application for a specific license to manufacture or distribute byproduct material for use under the general license of He-P 4031.06 shall be approved if:

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

(b) The radioactive material is to be prepared for distribution in prepackaged units of:

(1) Carbon-14 in units not exceeding 370 kilobecquerel (10 microcurie) each;

(2) Cobalt-57 in units not exceeding 370 kilobecquerel (10 microcurie) each;

(3) Hydrogen-3 (tritium) in units not exceeding 1.85 megabecquerel (50 microcurie) each;

(4) Iodine-125 in units not exceeding 370 kilobecquerel (10 microcurie) each;

(5) Mock Iodine-125 in units not exceeding 1.85 kilobecquerel (0.05 microcurie) of iodine-129 and 185 becquerel (0.005 microcurie) of americium-241 each;

(6) Iodine-131 in units not exceeding 370 kilobecquerel (10 microcurie) each;

(7) Iron-59 in units not exceeding 740 kilobecquerel (20 microcurie) each; and

(8) Selenium-75 in units not exceeding 370 kilobecquerel (10 microcurie) each.

(c) Each prepackaged unit bears a durable, clearly visible label:

(1) Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 370 kilobecquerel (10 microcurie) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 1.85 megabecquerel (50 microcurie) of hydrogen-3 (tritium); 740 kilobecquerel (20 microcurie) of iron-59; or Mock Iodine-125 in units not exceeding 1.85 kilobecquerel (0.05 microcurie) of iodine-129 and 185 becquerel (0.005 microcurie) of americium-241 each; and

(2) Displaying the radiation caution symbol described in He-P 4022.11(c). and the words, "CAUTION, RADIOACTIVE MATERIAL", and "Not for Internal or External Use in Humans or Animals".

(d) The following statement or information shall appear on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

> "This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories, or hospitals and only for *in vitro* clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the DHHS/RHS or the NRC or of a state with which the NRC has entered into an agreement for the exercise of regulatory authority. (Name of Manufacturer)."

(e) The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such byproduct material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the source shall also contain directions to the licensee regarding the waste disposal requirements set out in He-P 4023.01 of these rules.

He-P 4032.16 Ice Detection Devices Containing Strontium-90; Requirements for License to Manufacture or Initially Transfer. An application for a specific license to manufacture or initially transfer ice detection devices containing strontium-90 for distribution to persons generally licensed under the Nuclear Regulatory Commission 10 CFR 31.10 shall be approved if:

(a) The applicant satisfies the general requirements specified in He-P 4030.09; and

(b) The applicant satisfies the requirements of 10 CFR 32.61 and 32.62.