

R313. Environmental Quality, Radiation Control.

R313-22. Specific Licenses.

R313-22-75. Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices Which Contain Radioactive Material.

(9) Manufacture, preparation, or transfer for commercial [and] distribution of radioactive drugs [~~radiopharmaceuticals~~] containing radioactive material for medical use under R313-32 [~~group licenses~~].

(a) An application for a specific license to manufacture and distribute radiopharmaceuticals containing radioactive material for use by persons licensed pursuant to Rule R313-32 will be approved if:

(i) the applicant satisfies the general requirements specified in Section R313-22-33;

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

(A) registered or licensed with the U.S. Food and Drug Administration (FDA) as a drug manufacturer;

(B) registered or licensed with a state agency as a drug manufacturer;

(C) licensed as a pharmacy by a State Board of Pharmacy; or

(D) operating as a nuclear pharmacy within a medical institution.

(iii) the applicant submits information on the radionuclide; the chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radioactive drugs by medical use licensees; and

(iv) the applicant satisfies the following labeling requirements:

(A) A label is 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. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL"; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half life greater than 100 days, the time may be omitted.

(B) A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

(b) A licensee described by Subsections R313-22-75(9)(a)(ii)(C) or (D):

(i) May prepare radioactive drugs for medical use, as defined in Rule R313-32 (incorporating 10 CFR 35.2 by reference), provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in Subsections R313-22-75(9)(b)(ii) and (iv), or an individual under the supervision of an authorized nuclear pharmacist as specified in Rule R313-32 (incorporating 10 CFR 35.27 by reference).

(ii) May allow a pharmacist to work as an authorized nuclear pharmacist if:

(A) this individual qualifies as an authorized nuclear pharmacist as defined in Rule R313-32 (incorporating 10 CFR 35.2 by reference);

(B) this individual meets the requirements specified in Rule R313-32 (incorporating 10 CFR 35.55(b) and 10 CFR 35.59 by reference) 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 Subsection R313-22-75(9)(b)(iv).

(iii) The actions authorized in Subsections R313-22-75(9)(b)(i) and (ii) are permitted in spite of more restrictive language in license conditions.

(iv) May designate a pharmacist, as defined in Rule R313-32 (incorporating 10 CFR 35.2 by reference), as an authorized nuclear pharmacist if the individual is identified as of January 1, 1997 as an "authorized user" on a nuclear pharmacy license issued by the Executive Secretary under Subsection R313-22-75(9).

~~[(v) Shall provide to the Executive Secretary a copy of each individual's certification by the Board of Pharmaceutical Specialties, the Nuclear Regulatory Commission or Agreement State license, or the permit issued by a licensee of broad scope, and a copy of the state pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, pursuant to Subsections R313-22-75(9)(b)(ii)(A) and (B), the individual to work as an authorized nuclear pharmacist.]~~

(v) Shall provide to the Executive Secretary:

(A) a copy of each individual's certification by a specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or Agreement State as specified in Rule R313-32 (incorporating 10 CFR 35.55(a) by reference) with the written attestation signed by a preceptor as required by Rule R313-32 (incorporating 10 CFR 35.55(b)(2) by reference); or

(B) the Nuclear Regulatory Commission or Agreement State license; or

(C) the permit issued by a licensee of broad scope; and

(D) and a copy of the state pharmacy licensure or registration, no later than 30 days after the date that the

licensee allows, pursuant to Subsections R313-22-75(9)(b)(ii)(A) and R313-22-75(9)(b)(ii)(C), the individual to work as an authorized nuclear pharmacist.

(c) A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall 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. In addition, the licensee shall:

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

(ii) check each instrument for constancy and proper operation at the beginning of each day of use.

(d) Nothing in Subsection R313-22-75(9) relieves the licensee from complying with applicable FDA, or Federal, and State requirements governing radioactive drugs.

(10) Manufacture and distribution of sources or devices containing radioactive material for medical use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed [~~pursuant to~~] under Rule R313-32 [~~(incorporating 10 CFR 35.18)~~] for use as a calibration, transmission, or reference source or for the uses listed in Rule R313-32 (incorporating 10 CFR 35.400, 10 CFR 35.500, [~~and~~] 10 CFR 35.600, and 35.1000 by reference) will be approved if:

(a) the applicant satisfies the general requirements in Section R313-22-33;

(b) the applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

(i) the radioactive material contained, its chemical and physical form and amount,

(ii) details of design and construction of the source or device,

(iii) procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents,

(iv) for devices containing radioactive material, the radiation profile of a prototype device,

(v) details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests,

(vi) procedures and standards for calibrating sources and devices,

(vii) legend and methods for labeling sources and devices as

to their radioactive content, and

(viii) instructions for handling and storing the source or device from the radiation safety standpoint, these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device; provided that instructions which are too lengthy for a label may be summarized on the label and printed in detail on a brochure which is referenced on the label;

(c) the label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity and date of assay, and a statement that the source or device is licensed by the Executive Secretary for distribution to persons licensed pursuant to Rule R313-32 (incorporating 10 CFR 35.18, 10 CFR 35.400, 10 CFR 35.500, and 10 CFR 35.600 by reference) or under equivalent regulations of the Nuclear Regulatory Commission, an Agreement State or a Licensing State; provided that labeling for sources which do not require long term storage may be on a leaflet or brochure which accompanies the source;

(d) 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 six months, the applicant shall include in the application sufficient information to demonstrate that a 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

(e) in determining the acceptable interval for test of leakage of radioactive material, the Executive Secretary shall consider information that includes, but is not limited to:

- (i) primary containment or source capsule,
- (ii) protection of primary containment,
- (iii) method of sealing containment,
- (iv) containment construction materials,
- (v) form of contained radioactive material,
- (vi) maximum temperature withstood during prototype tests,
- (vii) maximum pressure withstood during prototype tests,
- (viii) maximum quantity of contained radioactive material,
- (ix) radiotoxicity of contained radioactive material, and
- (x) operating experience with identical sources or devices or similarly designed and constructed sources or devices.

KEY: specific licenses, decommissioning, broad scope, radioactive materials

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