

any lot that has been sampled and rejected as a result of the procedures in paragraph (c)(2) of this section, unless:

(i) A procedure for defining sub-lot size, independence, and additional testing procedures is contained in the license issued under § 32.61; and

(ii) Each individual sub-lot is sampled, tested, and accepted in accordance with paragraphs (c)(2) and (e)(2)(i) of this section and any other criteria as may be required as a condition of the license issued under § 32.61.

[30 FR 9905, Aug. 10, 1965, as amended at 39 FR 22130, June 20, 1974; 39 FR 26397, July 19, 1974; 43 FR 6923, Feb. 17, 1978; 77 FR 43694, July 25, 2012]

§ 32.71 Manufacture and distribution of byproduct material for certain in vitro clinical or laboratory testing under general license.

An application for a specific license to manufacturer or distribute byproduct material for use under the general license of § 31.11 of this chapter will be approved if:

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter.

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

(1) Iodine-125 in units not exceeding 10 microcuries each.

(2) Iodine-131 in units not exceeding 10 microcuries each.

(3) Carbon-14 in units not exceeding 10 microcuries each.

(4) Hydrogen-3 (tritium) in units not exceeding 50 microcuries each.

(5) Iron-59 in units not exceeding 20 microcuries each.

(6) Selenium-75 in units not exceeding 10 microcuries each.

(7) Mock Iodine-125 in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each.

(8) Cobalt-57 in units not exceeding 0.37 megabecquerel (10 microcuries) 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 0.37 megabecquerel (10 micro-

curies) of iodine-131, iodine-125, selenium-75, or carbon-14; 1.85 megabecquerels (50 microcuries) of hydrogen-3 (tritium); or 0.74 megabecquerel (20 microcuries) of iron-59; or Mock Iodine-125 in units not exceeding 1.85 kilobecquerels (0.05 microcurie) of iodine-129 and 0.185 kilobecquerel (0.005 microcurie) of americium-241 each; or cobalt-57 in units not exceeding 0.37 megabecquerel (10 microcuries); and

(2) Displaying the radiation caution symbol described in § 20.1901(a) of this chapter and the words, "Caution, Radioactive Material", and "Not for Internal or External Use in Humans or Animals."

(d) The following statement, or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:¹

The radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, 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 U.S. Nuclear Regulatory Commission or of a State with which the Commission 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 must also contain directions to the licensee regarding the

¹Labels authorized by the regulations in effect on September 26, 1979, may be used until one year from September 27, 1979.

§ 32.72

10 CFR Ch. I (1–1–14 Edition)

waste disposal requirements set out in § 20.2001.

[33 FR 16553, Nov. 14, 1968, as amended at 38 FR 34110, Dec. 11, 1973; 39 FR 26148, July 17, 1974; 40 FR 8786, Mar. 3, 1975; 42 FR 21604, Apr. 28, 1977; 42 FR 26987, May 26, 1977; 44 FR 50325, Aug. 28, 1979; 56 FR 23472, May 21, 1991; 58 FR 67660, Dec. 22, 1993; 72 FR 55929, Oct. 1, 2007]

Subpart C—Specifically Licensed Items

§ 32.72 Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35.

(a) An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing byproduct material for use by persons authorized pursuant to part 35 of this chapter will be approved if:

(1) The applicant satisfies the general requirements specified in 10 CFR 30.33;

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

(i) 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);

(ii) Registered or licensed with a state agency as a drug manufacturer;

(iii) Licensed as a pharmacy by a State Board of Pharmacy;

(iv) Operating as a nuclear pharmacy within a Federal medical institution; or

(v) A Positron Emission Tomography (PET) drug production facility registered with a State agency.

(3) 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

(4) The applicant satisfies the following labeling requirements:

(i) 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.

(ii) 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 paragraph (a)(2)(iii) or (iv) of this section:

(1) May prepare radioactive drugs for medical use, as defined in 10 CFR 35.2, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in paragraphs (b)(2) and (b)(4) of this section, or an individual under the supervision of an authorized nuclear pharmacist as specified in 10 CFR 35.27.

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

(i) This individual qualifies as an authorized nuclear pharmacist as defined in 10 CFR 35.2,

(ii) This individual meets the requirements specified in § 35.55(b) and 35.59 of this chapter, and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

(iii) This individual is designated as an authorized nuclear pharmacist in accordance with paragraph (b)(4) of this section.

(3) The actions authorized in paragraphs (b)(1) and (b)(2) of this section are permitted in spite of more restrictive language in license conditions.