

§ 32.19

of this chapter do not apply to an application for a license to transfer byproduct material manufactured, processed, produced, packaged, or repackaged pursuant to a license issued by an Agreement State;

(b) 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;

(c) 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

(d) The applicant submits copies of prototype labels and brochures and the Commission approves such labels and brochures.

[35 FR 6428, Apr. 22, 1970, as amended at 43 FR 6922, Feb. 17, 1978]

§ 32.19 Same: Conditions of licenses.

Each license issued under § 32.18 is subject to the following conditions:

(a) No more than 10 exempt quantities set forth in § 30.71, Schedule B of this chapter shall be sold or transferred in any single transaction. For purposes of this requirement, an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in § 30.71, Schedule B of this chapter, provided that the sum of such fractions shall not exceed unity.

(b) Each quantity of byproduct material set forth in § 30.71, Schedule B of this chapter shall be separately and individually packaged. No more than 10 such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to § 30.18 of this chapter. 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.

(c) The immediate container of each quantity or separately packaged fractional quantity of byproduct material shall bear a durable, legible label which (1) identifies the radioisotope

10 CFR Ch. I (1-1-06 Edition)

and the quantity of radioactivity, and (2) bears the words "Radioactive Material."

(d) In addition to the labeling information required by paragraph (c) of this section, the label affixed to the immediate container, or an accompanying brochure, shall also (1) state that the contents are exempt from NRC or Agreement State licensing requirements; (2) bear the words "Radioactive Material—Not for Human Use—Introduction Into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or Into Products Manufactured for Commercial Distribution is Prohibited—Exempt Quantities Should Not be Combined"; and (3) set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material.

[35 FR 6428, Apr. 22, 1970]

§ 32.20 Same: Records and material transfer reports.

(a) Each person licensed under § 32.18 of this part shall maintain records of transfer of material identifying, by name and address, each person to whom byproduct material is transferred for use under § 30.18 of this chapter or the equivalent regulations of an Agreement State and stating the kinds and quantities of byproduct material transferred. The licensee shall maintain the record of a transfer for a period of one year after the event is included in a summary report to the Commission.

(b) The licensee shall file a summary report stating the total quantity of each isotope transferred under the specific license with the Director of Nuclear Material Safety and Safeguards by an appropriate method listed in § 30.6(a) of this chapter, with a copy to the appropriate NRC Regional Office listed in appendix D to part 20 of this chapter.

(c) The licensee shall file the summary report within 30 days following:

(1) Five years after filing the preceding report; or

(2) Filing an application for renewal of the license under § 30.37; or

(3) Notifying the Commission under § 30.34(f) of the licensee's decision to

Nuclear Regulatory Commission

§ 32.22

permanently discontinue activities authorized under the license issued under § 32.18.

(d) The report must cover the period between the filing of the preceding report and the occurrences specified in paragraph (c) (1), (2), or (3) of this section. If no transfers of byproduct material have been made under § 32.18 during the reporting period, the report must so indicate.

[48 FR 12333, Mar. 24, 1983, as amended at 68 FR 58804, Oct. 10, 2003]

§ 32.21 Radioactive drug: Manufacture, preparation, or transfer for commercial distribution of capsules containing carbon-14 urea each for “in vivo” diagnostic use for humans to persons exempt from licensing; Requirements for a license.

(a) An application for a specific license to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution capsules containing 37 kBq (1 μ Ci) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each for “in vivo” diagnostic use, to persons exempt from licensing under § 30.21 of this chapter or the equivalent regulations of an Agreement State will be approved if:

(1) The applicant satisfies the general requirements specified in § 30.33 of this chapter, provided that the requirements of § 30.33(a) (2) and (3) of this chapter do not apply to an application for a license to transfer byproduct material manufactured, prepared, processed, produced, packaged, or repackaged pursuant to a license issued by an Agreement State;

(2) The applicant meets the requirements under § 32.72(a)(2) of this part;

(3) The applicant provides evidence that each capsule contains 37 kBq (1 μ Ci) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process);

(4) The carbon-14 urea is not contained in any food, beverage, cosmetic, drug (except as described in this section) or other commodity designed for ingestion or inhalation by, or topical application to, a human being;

(5) The carbon-14 urea is in the form of a capsule, identified as radioactive, and to be used for its radioactive prop-

erties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and

(6) The applicant submits copies of prototype labels and brochures and the NRC approves these labels and brochures.

(b) Nothing in this section relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing drugs.

[62 FR 63640, Dec. 2, 1997, as amended at 66 FR 64738, Dec. 14, 2001]

§ 32.21a Same: Conditions of license.

Each license issued under § 32.21 of this part is subject to the following conditions:

(a) The immediate container of the capsule(s) must bear a durable, legible label which:

(1) Identifies the radioisotope, the physical and chemical form, the quantity of radioactivity of each capsule at a specific date; and

(2) Bears the words “Radioactive Material.”

(b) In addition to the labeling information required by paragraph (a) of this section, the label affixed to the immediate container, or an accompanying brochure also must:

(1) State that the contents are exempt from NRC or Agreement State licensing requirements; and

(2) Bears the words “Radioactive Material. For ‘In Vivo’ Diagnostic Use Only. This Material Is Not To Be Used for Research Involving Human Subjects and Must Not Be Introduced into Foods, Beverages, Cosmetics, or Other Drugs or Medicinals, or into Products Manufactured for Commercial Distribution. This Material May Be Disposed of in Ordinary Trash.”

[62 FR 63640, Dec. 2, 1997]

§ 32.22 Self-luminous products containing tritium, krypton-85 or promethium-147: Requirements for license to manufacture, process, produce, or initially transfer.

(a) An application for a specific license to manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147, or to initially transfer such products for use pursuant to § 30.19