

§32.16 Certain items containing by-product material: Records and reports of transfer.

(a) Each person licensed under §32.14 or §32.17 shall maintain records of all transfers of nuclear material and file a report 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.

(b) The report must include the following information on items transferred to other persons for use under §30.15 or §30.16 of this chapter or equivalent regulations of an Agreement State:

(1) A description or identification of the type of each product;

(2) For each radionuclide in each type of product, the total quantity of the radionuclide; and

(3) The number of units of each type of product transferred during the reporting period.

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

(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 permanently discontinue activities authorized under the license issued under §32.14 or §32.17.

(d) The report must cover the period between the filing of the preceding report and the occurrence specified in paragraphs (c) (1), (2), or (3) of this section. If no transfers of byproduct material have been made under §32.14 or §32.17 during the reporting period, the report must so indicate.

(e) The licensee shall maintain the record of a transfer for a period of one year after the event is included in a report to the Commission.

[48 FR 12333, Mar. 24, 1983; 48 FR 23383, May 25, 1983, as amended at 68 FR 58804, Oct. 10, 2003]

§32.17 Resins containing scandium-46 and designed for sand-consolidation in oil wells: Requirements for license to manufacture, or initially transfer for sale or distribution.

An application for a specific license to manufacture, or initially transfer for sale or distribution, synthetic plastic resins containing scandium-46 for use pursuant to §30.16 of this chapter will be approved if:

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

(b) The product is designed to be used only for sand-consolidation in oil wells;

(c) The applicant submits the following information:

(1) The general description of the product to be manufactured or initially transferred.

(2) A description of control procedures to be used to assure that the concentration of scandium-46 in the final product at the time of distribution will not exceed 1.4×10^{-3} microcurie/milliliter.

(d) Each container of such product will bear a durable, legible label approved by the Commission, which contains the following information:

(1) The product name;

(2) A statement that the product contains radioactive scandium and is designed and manufactured only for sand-consolidation in oil wells;

(3) Instructions necessary for proper use; and

(4) The manufacturer's name.

[32 FR 4241, Mar. 18, 1967, as amended by 38 FR 29314, Oct. 24, 1973; 43 FR 6922, Feb. 17, 1978]

§32.18 Manufacture, distribution and transfer of exempt quantities of by-product material: Requirements for license.

An application for a specific license to manufacture, process, produce, package, repack, or transfer quantities of byproduct material for commercial distribution to persons exempt pursuant to §30.18 of this chapter or the equivalent regulations of an Agreement State will be approved if:

(a) The applicant satisfies the general requirements specified in §30.33 of this chapter: *Provided, however,* That the requirements of §30.33(a) (2) and (3)

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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

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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