

## Nuclear Regulatory Commission

## § 32.15

### § 32.13 Same: Prohibition of introduction.

No person may introduce byproduct material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under § 30.14 of this chapter or equivalent regulations of an Agreement State, except in accordance with a license issued under § 32.11.

[72 FR 58487, Oct. 16, 2007]

### § 32.14 Certain items containing byproduct material; requirements for license to apply or initially transfer.

An application for a specific license to apply byproduct material to, or to incorporate byproduct material into, the products specified in § 30.15 of this chapter or to initially transfer for sale or distribution such products containing byproduct material for use pursuant to § 30.15 of this chapter will be approved if:

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

(b) The applicant submits sufficient information regarding the product pertinent to evaluation of the potential radiation exposure, including:

(1) Chemical and physical form and maximum quantity of byproduct material in each product;

(2) Details of construction and design of each product;

(3) The method of containment or binding of the byproduct material in the product;

(4) Procedures for and results of prototype testing to demonstrate that the material will not become detached from the product and that the byproduct material will not be released to the environment under the most severe conditions likely to be encountered in normal use of the product;

(5) Quality control procedures to be followed in the fabrication of production lots of the product and the quality control standards the product will be required to meet;

(6) The proposed method of labeling or marking each unit, except timepieces or hands or dials containing tritium or promethium-147, and its container with the identification of the manufacturer or initial transferor of

the product and the byproduct material in the product;

(7) For products for which limits on levels of radiation are specified in § 30.15 of this chapter, the radiation level and the method of measurement;

(8) Any additional information, including experimental studies and tests, required by the Commission to facilitate a determination of the safety of the product.

(c) Each product will contain no more than the quantity of byproduct material specified for that product in § 30.15 of this chapter. The levels of radiation from each product containing byproduct material will not exceed the limits specified for that product in § 30.15 of this chapter.

(d) The Commission determines that the byproduct material is properly contained in the product under the most severe conditions that are likely to be encountered in normal use and handling.

[31 FR 5316, Apr. 2, 1966, as amended at 34 FR 6652, Apr. 18, 1969; 43 FR 6922, Feb. 17, 1978; 63 FR 32971, June 17, 1998; 72 FR 58487, Oct. 16, 2007]

### § 32.15 Same: Quality assurance, prohibition of transfer, and labeling.

(a) Each person licensed under § 32.14 shall:

(1) Maintain quality assurance practices in the manufacture of the part or product, or the installation of the part into the product;

(2) Subject inspection lots to such testing as may be required as a condition of the license issued under § 32.14 taking a random sample of the size required by the tables in § 32.110, and for Lot Tolerance Percent Defective of 5.0 percent, accept or reject inspection lots in accordance with the directions of § 32.110; and

(3) Visually inspect each unit, except electron tubes containing byproduct material, in inspection lots. Any unit which has an observable physical defect that could affect containment of the byproduct material shall be considered as a defective unit.

(b) An application for a license or for amendment of a license may include a description of procedures proposed as alternatives to those prescribed by paragraph (a)(2) of this section, and