

**Nuclear Regulatory Commission**

**§ 32.29**

**§ 32.27 Same: Safety criteria.**

An applicant for a license under § 32.26 shall demonstrate that the product is designed and will be manufactured so that:

(a) In normal use and disposal of a single exempt unit, and in normal handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, it is unlikely that the external radiation dose in any one year, or the dose commitment resulting from the intake of radioactive material in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the product will exceed the dose to the appropriate organ as specified in Column I of the table in § 32.28.

(b) It is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding, or other safety features of the product from wear and abuse likely to occur in normal handling and use of the product during its useful life.

(c) In use and disposal of a single exempt unit and in handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, the probability is low that the containment, shielding, or other safety features of the product would fail under such circumstances that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column II of the table in § 32.28, and the probability is negligible that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column III of the table in § 32.28.<sup>1</sup>

[34 FR 6654, Apr. 18, 1969]

<sup>1</sup>It is the intent of this paragraph that as the magnitude of the potential dose increases above that permitted under normal conditions, the probability that any individual will receive such a dose must decrease. The probabilities have been expressed in general terms to emphasize the approximate nature of the estimates which are to be

**§ 32.28 Same: Table of organ doses.**

Part of body	Column I (rem)	Column II (rem)	Column III (rem)
Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye .....	0.005	0.5	15
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter ..	0.075	7.5	200
Other organs .....	0.015	1.5	50

[34 FR 6654, Apr. 18, 1969]

**§ 32.29 Conditions of licenses issued under § 32.26: Quality control, labeling, and reports of transfer.**

Each person licensed under § 32.26 shall:

(a) Carry out adequate control procedures in the manufacture of the product to assure that each production lot meets the quality control standards approved by the Commission;

(b) Label or mark each detector and its point-of-sale package so that:

(1) Each detector has a durable, legible, readily visible label or marking on the external surface of the detector containing:

(i) The following statement: "CONTAINS RADIOACTIVE MATERIAL";

(ii) The name of the radionuclide and quantity of activity; and

(iii) An identification of the person licensed under § 32.26 to transfer the detector for use pursuant to § 30.20 of this chapter or equivalent regulations of an Agreement State.

(2) The labeling or marking specified in paragraph (b)(1) of this section is located where its will be readily visible when the detector is removed from its mounting.

(3) The external surface of the point-of-sale package has a legible, readily visible label or marking containing:

(i) The name of the radionuclide and quantity of activity;

made. The following values may be used as guides in estimating compliance with the criteria:

Low—not more than one such failure per year for each 10,000 exempt units distributed.

Negligible—not more than one such failure per year for each one million exempt units distributed.

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(ii) An identification of the person licensed under §32.26 to transfer the detector for use pursuant to §30.20 of this chapter or equivalent regulations of an Agreement State; and

(iii) The following or a substantially similar statement:

THIS DETECTOR CONTAINS RADIO-ACTIVE MATERIAL AND HAS BEEN MANUFACTURED IN COMPLIANCE WITH U.S. NRC SAFETY CRITERIA IN 10 CFR 32.27. THE PURCHASER IS EXEMPT FROM ANY REGULATORY REQUIREMENTS.

(4) Each detector and point-of-sale package is provided with such other information as may be required by the Commission; and

(c) Maintain records of all transfers and file a report with the Director of the Office of Federal and State Materials and Environmental Management Programs by an appropriate method listed in §30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/Exempt Distribution.

(1) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(2) The report must indicate that the products are transferred for use under §30.20 of this chapter or equivalent regulations of an Agreement State.

(3) The report must include the following information on products transferred to other persons for use under §30.20 or equivalent regulations of an Agreement State:

(i) A description or identification of the type of each product and the model number(s);

(ii) For each radionuclide in each type of product and each model number, the total quantity of the radionuclide;

(iii) The number of units of each type of product transferred during the reporting period by model number.

(4)(i) The licensee shall file the report, covering the preceding calendar year, on or before January 31 of each year. In its first report after December 17, 2007, the licensee shall separately include data for transfers in prior years not previously reported to the Commission.

(ii) Licensees who permanently discontinue activities authorized by the license issued under §32.26 shall file a

report for the current calendar year within 30 days after ceasing distribution.

(5) If no transfers of byproduct material have been made under §32.26 during the reporting period, the report must so indicate.

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

[34 FR 6654, Apr. 18, 1969, as amended at 43 FR 6923, Feb. 17, 1978; 45 FR 38342, June 9, 1980; 48 FR 12334, Mar. 24, 1983; 72 FR 58488, Oct. 16, 2007; 73 FR 5719, Jan. 31, 2008; 73 FR 42673, July 23, 2008]

**§32.30 Certain industrial devices containing byproduct material: Requirements for license to manufacture, process, produce, or initially transfer.**

An application for a specific license to manufacture, process, produce, or initially transfer for sale or distribution devices containing byproduct material for use under §30.22 of this chapter or equivalent regulations of an Agreement State will be approved if:

(a) The applicant satisfies the general requirements of §30.33 of this chapter: However, the requirements of §30.33(a)(2) and (3) do not apply to an application for a license to transfer byproduct material in such industrial devices manufactured, processed, or produced under a license issued by an Agreement State;

(b) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, and conditions of handling, storage, use, and disposal of the industrial devices to demonstrate that the device will meet the safety criteria set forth in §32.31. The information should include:

(1) A description of the device and its intended use or uses;

(2) The type and quantity of byproduct material in each unit;

(3) Chemical and physical form of the byproduct material in the device and changes in chemical and physical form that may occur during the useful life of the device;

(4) Solubility in water and body fluids of the forms of the byproduct