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(9) The expected useful life of the product;

(10) The proposed methods of labeling or marking the detector and its point-of-sale package to satisfy the requirements of § 32.29(b);

(11) Procedures for prototype testing of the product to demonstrate the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage, use, and disposal of the product;

(12) Results of the prototype testing of the product, including any change in the form of the byproduct material contained in the product, the extent to which the byproduct material may be released to the environment, any increase in external radiation levels, and any other changes in safety features;

(13) The estimated external radiation doses and dose commitments relevant to the safety criteria in § 32.27 and the basis for such estimates;

(14) A determination that the probabilities with respect to the doses referred to in § 32.27(c) meet the criteria of that paragraph;

(15) 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; and

(16) Any additional information, including experimental studies and tests, required by the Commission.


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Same: Table of organ doses.

<table>
<thead>
<tr>
<th>Part of body</th>
<th>Column I (rem)</th>
<th>Column II (rem)</th>
<th>Column III (rem)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye</td>
<td>0.005</td>
<td>0.5</td>
<td>15</td>
</tr>
<tr>
<td>Hands and forearms; feet and ankles; localized areas of skin averaged over an area no larger than 1 square centimeter</td>
<td>0.075</td>
<td>7.5</td>
<td>200</td>
</tr>
</tbody>
</table>

1 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 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.
§ 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 it 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;

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

(iii) The following or a substantially similar statement:

THIS DETECTOR CONTAINS RADIOACTIVE 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 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.