Nuclear Regulatory Commission

§ 32.26 Gas and aerosol detectors containing byproduct material: Requirements for license to manufacture, process, produce, or initially transfer.

An application for a specific license to manufacture, process, or produce gas and aerosol detectors containing byproduct material and designed to protect health, safety, or property, or to initially transfer such products for use under § 30.20 of this chapter or 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) do not apply to an application for a license to transfer byproduct material in

§ 32.24 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>
<th>Column IV (rem)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole body; head and trunk: active blood-forming organs; gonads; or lens of eye</td>
<td>0.001</td>
<td>0.01</td>
<td>0.5</td>
<td>15</td>
</tr>
<tr>
<td>Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter</td>
<td>0.015</td>
<td>0.15</td>
<td>7.5</td>
<td>200</td>
</tr>
<tr>
<td>Other organs</td>
<td>0.003</td>
<td>0.03</td>
<td>1.5</td>
<td>50</td>
</tr>
</tbody>
</table>

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gas and aerosol detectors manufactured, processed or produced pursuant to 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 gas and aerosol detector to demonstrate that the product will meet the safety criteria set forth in §32.27. The information should include:

1. A description of the product 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 product and changes in chemical and physical form that may occur during the useful life of the product;
4. Solubility in water and body fluids of the forms of the byproduct material identified in paragraphs (b) (3) and (12) of this section;
5. Details of construction and design of the product as related to containment and shielding of the byproduct material and other safety features under normal and severe conditions of handling, storage, use, and disposal of the product;
6. Maximum external radiation levels at 5 and 25 centimeters from any external surface of the product, averaged over an area not to exceed 10 square centimeters, and the method of measurement;
7. Degree of access of human beings to the product during normal handling and use;
8. Total quantity of byproduct material expected to be distributed in the product annually;
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.

(c)1 The Commission determines that the product meets the safety criteria in §32.27; and
2 The product has been evaluated by the NRC and registered in the Sealed Source and Device Registry.


§ 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 §32.26.

(b) It is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding, or