Nuclear Regulatory Commission

material identified in paragraphs (b)(3) and (b)(12) of this section;

(5) Details of construction and design of the device 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 device;

(6) Maximum external radiation levels at 5 and 30 centimeters from any external surface of the device, averaged over an area not to exceed 10 square centimeters, and the method of measurement;

(7) Degree of access of human beings to the device during normal handling and use;

(8) Total quantity of byproduct material expected to be distributed in the devices annually;

(9) The expected useful life of the device;

(10) The proposed methods of labeling or marking the device and its point-of-sale package to satisfy the requirements of §32.32(b);

(11) Procedures for prototype testing of the device 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 device;

(12) Results of the prototype testing of the device, including any change in the form of the byproduct material contained in the device, 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 committed doses resulting from the intake of byproduct material in any one year relevant to the safety criteria in §32.31 and the basis for these estimates;

(14) A determination that the probabilities with respect to the doses referred to in §32.31(a)(4) meet the criteria of that paragraph;

(15) Quality control procedures to be followed in the fabrication of production lots of the devices and the quality control standards the devices 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 device meets the safety criteria in §32.31.

(2) The device is unlikely to be routinely used by members of the general public in a non-occupational environment.

(3) The device has been registered in the Sealed Source and Device Registry.

[77 FR 43691, July 25, 2012]
§ 32.32

Each item has a durable, legible, readily visible label or marking on the external surface of the device containing:

(i) The following statement: “CONTAINS RADIOACTIVE MATERIAL”;

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

(iii) An identification of the person licensed under §32.30 to transfer the device for use under §30.22 of this chapter or equivalent regulations of an Agreement State;

(iv) Instructions and precautions necessary to assure safe installation, operation, and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information).

(b) An applicant for a license under §32.30 shall demonstrate that, even in unlikely scenarios of misuse, including those resulting in direct exposure to the unshielded source removed from the device for 1,000 hours at an average distance of 1 meter and those resulting in dispersal and subsequent intake of $10^{-4}$ of the quantity of byproduct material (or in the case of tritium, an intake of 10 percent), a person will not receive an external radiation dose or committed dose in excess of 100 mSv (10 rem), and, if the unshielded source is small enough to fit in a pocket, that the dose to localized areas of skin averaged over areas no larger than 1 square centimeter from carrying the unshielded source in a pocket for 80 hours will not exceed 2 Sv (200 rem).

[77 FR 43692, July 25, 2012]

§ 32.32 Conditions of licenses issued under §32.30: Quality control, labeling, and reports of transfer.

Each person licensed under §32.30 shall:

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

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

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 that 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/incident per year for each 10,000 exempt units distributed.
- Negligible—not more than one such failure/incident per year for each one million exempt units distributed.