

§ 32.57

10 CFR Ch. I (1-1-01 Edition)

§ 32.57 Calibration or reference sources containing americium-241: Requirements for license to manufacture or initially transfer.

An application for a specific license to manufacture or initially transfer calibration or reference sources containing americium-241, for distribution to persons generally licensed under § 31.8 of this chapter, will be approved if:

- (a) The applicant satisfies the general requirements of § 30.33 of this chapter;
- (b) The applicant submits sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including:
 - (1) Chemical and physical form and maximum quantity of americium 241 in the source;
 - (2) Details of construction and design;
 - (3) Details of the method of incorporation and binding of the americium-241 in the source;
 - (4) Procedures for and results of prototype testing of sources, which are designed to contain more than 0.005 microcurie of americium-241, to demonstrate that the americium-241 contained in each source will not be released or be removed from the source under normal conditions of use;
 - (5) Details of quality control procedures to be followed in manufacture of the source;
 - (6) Description of labeling to be affixed to the source or the storage container for the source;
 - (7) Any additional information, including experimental studies and tests, required by the Commission to facilitate a determination of the safety of the source.
- (c) Each source will contain no more than 5 microcuries of americium-241.
- (d) The Commission determines, with respect to any type of source containing more than 0.005 microcurie of americium-241, that:
 - (1) The method of incorporation and binding of the americium-241 in the source is such that the americium-241 will not be released or be removed from the source under normal conditions of use and handling of the source; and

- (2) The source has been subjected to and has satisfactorily passed the prototype tests prescribed by § 32.102, Schedule C, of this part.

[30 FR 8192, June 26, 1965, as amended at 43 FR 6923, Feb. 17, 1978]

§ 32.58 Same: Labeling of devices.

Each person licensed under § 32.57 shall affix to each source, or storage container for the source, a label which shall contain sufficient information relative to safe use and storage of the source and shall include the following statement or a substantially similar statement which contains the information called for in the following statement:¹

The receipt, possession, use and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of the United States Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION—RADIOACTIVE MATERIAL—THIS SOURCE CONTAINS AMERICIUM-241. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

Name of manufacturer or initial transferor)
(Sec. 161, as amended, Pub. L. 83-703, 68 Stat. 948 (42 U.S.C. 2201); sec. 201, as amended, Pub. L. 93-438, 88 Stat. 1243 (42 U.S.C. 5841))

[30 FR 8192, June 26, 1965, as amended at 40 FR 8786, Mar. 3, 1975; 43 FR 6923, Feb. 17, 1978]

§ 32.59 Same: Leak testing of each source.

Each person licensed under § 32.57 shall perform a dry wipe test upon each source containing more than 0.1 microcurie of americium-241 prior to transferring the source to a general licensee under § 31.8 of this chapter. This test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure. The radioactivity on the paper shall be measured by using radiation detection instrumentation capable of detecting 0.005 microcurie of americium-241. If any such test discloses more than 0.005

¹Sources licensed under § 32.57 prior to January 19, 1975 may bear labels authorized by the regulations in effect on January 1, 1975.

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microcurie of radioactive material, the source shall be deemed to be leaking or losing americium-241 and shall not be transferred to a general licensee under § 31.8 of this chapter.

[30 FR 8192, June 26, 1965]

§ 32.60 [Reserved]

§ 32.61 Ice detection devices containing strontium-90; requirements for license to manufacture or initially transfer.

An application for a specific license to manufacture or initially transfer ice detection devices containing strontium-90 for distribution to persons generally licensed under § 31.10 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 each type of device pertinent to evaluation of the potential radiation exposure, including:

(1) Chemical and physical form and maximum quantity of strontium-90 in the device;

(2) Details of construction and design of the source of radiation and its shielding;

(3) Radiation profile of a prototype device;

(4) Procedures for and results of prototype testing of devices to demonstrate that the strontium-90 contained in each device will not be released or be removed from the device under the most severe conditions likely to be encountered in normal handling and use;

(5) Details of quality control procedures to be followed in manufacture of the device;

(6) Description of labeling to be affixed to the device;

(7) Instructions for handling and installation of the device;

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

(c) Each device will contain no more than 50 microcuries of strontium-90 in an insoluble form;

(d) Each device will bear durable, legible labeling which includes the radi-

ation caution symbol prescribed by § 20.1901(a) of this chapter, a statement that the device contains strontium-90 and the quantity thereof, instructions for disposal and statements that the device may be possessed pursuant to a general license, that the manufacturer or civil authorities should be notified if the device is found, that removal of the labeling is prohibited and that disassembly and repair of the device may be performed only by a person holding a specific license to manufacture or service such devices;

(e) The Commission determines that:

(1) The method of incorporation and binding of the strontium-90 in the device is such that the strontium-90 will not be released from the device under the most severe conditions which are likely to be encountered in normal use and handling of the device;

(2) The strontium-90 is incorporated or enclosed so as to preclude direct physical contact by any individual with it and is shielded so that no individual will receive a radiation exposure to a major portion of his body in excess of 0.5 rem in a year under ordinary circumstances of use;

(3) The device is so designed that it cannot be easily disassembled;

(4) The device has been subjected to and has satisfactorily passed the prototype tests prescribed by § 32.103; and

(5) Quality control procedures have been established to satisfy the requirements of § 32.62.

[30 FR 9905, Aug. 10, 1965, as amended at 43 FR 6923, Feb. 17, 1978; 56 FR 23472, May 21, 1991; 58 FR 67660, Dec. 22, 1993]

§ 32.62 Same: Quality assurance; prohibition of transfer.

(a) Each person licensed under § 32.61 shall visually inspect each device and shall reject any which has an observable physical defect that could affect containment of the strontium-90.

(b) Each person licensed under § 32.61 shall test each device for possible loss of strontium-90 or for contamination by wiping with filter paper an area of at least 100 square centimeters on the outside surface of the device, or by wiping the entire surface area if it is less than 100 square centimeters. The detection on the filter paper of more than