

## Nuclear Regulatory Commission

## § 32.61

equivalent regulations of an Agreement State. This test must 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 filter paper must be measured using methods capable of detecting 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226. If a source has been shown to be leaking or losing more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 by the methods described in this section, the source must be rejected and must not be transferred to a general licensee under §31.8 of this chapter, or equivalent regulations of an Agreement State.

[77 FR 43694, July 25, 2012]

### § 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 radiation 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) Prototypes of the device have been subjected to and have satisfactorily passed the tests required by paragraph (f) of this section.

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

(f) The applicant shall subject at least five prototypes of the device to tests as follows:

(1) The devices are subjected to tests that adequately take into account the individual, aggregate, and cumulative

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effects of environmental conditions expected in service that could adversely affect the effective containment of strontium-90, such as temperature, moisture, absolute pressure, water immersion, vibration, shock, and weathering.

(2) The devices are inspected for evidence of physical damage and for loss of strontium-90 after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in paragraph (f)(3) of this section.

(3) Device designs are rejected for which the following has been detected for any unit:

(i) A leak resulting in a loss of 0.1 percent or more of the original amount of strontium-90 from the device; or

(ii) Surface contamination of strontium-90 on the device of more than 2,200 disintegrations per minute per 100 square centimeters of surface area; or

(iii) Any other evidence of physical damage.

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

[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; 77 FR 43694, July 25, 2012]

**§ 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 2,200 disintegrations per minute of radioactive material per 100 square centimeters of surface wiped shall be cause for rejection of the tested device.

(c) Each person licensed under § 32.61 shall:

(1) Maintain quality assurance systems in the manufacture of the ice detection device containing strontium-90 in a manner sufficient to provide rea-

sonable assurance that the safety-related components of the distributed devices are capable of performing their intended functions; and

(2) Subject inspection lots to acceptance sampling procedures, by procedures specified in paragraph (d) of this section and in the license issued under § 32.61, to provide at least 95 percent confidence that the Lot Tolerance Percent Defective of 5.0 percent will not be exceeded.

(d) Each person licensed under § 32.61 shall subject each inspection lot to:

(1) Tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could possibly affect the effective containment of strontium-90, such as absolute pressure and water immersion.

(2) Inspection for evidence of physical damage, containment failure, or for loss of strontium-90 after each stage of testing, using methods of inspection adequate to determine compliance with the following criteria for defective: A leak resulting in a loss of 0.1 percent or more of the original amount of strontium-90 from the device and any other criteria specified in the license issued under § 32.61.

(e) No person licensed under § 32.61 shall transfer to persons generally licensed under § 31.10 of this chapter, or under an equivalent general license of an Agreement State:

(1) Any ice detection device containing strontium-90 tested and found defective under the criteria specified in a license issued under § 32.61, unless the defective ice detection device has been repaired or reworked, retested, and determined by an independent inspector to meet the applicable acceptance criteria; or

(2) Any ice detection device containing strontium-90 contained within any lot that has been sampled and rejected as a result of the procedures in paragraph (c)(2) of this section, unless:

(i) A procedure for defining sub-lot size, independence, and additional testing procedures is contained in the license issued under § 32.61; and

(ii) Each individual sub-lot is sampled, tested, and accepted in accordance with paragraphs (c)(2) and (e)(2)(i) of this section and any other criteria