4731.3380 SPECIFIC LICENSE; ICE DETECTION DEVICES; MANUFACTURE OR INITIAL TRANSFER.

Subpart 1. **Approval criteria.** An application for a specific license to manufacture or initially transfer ice detection devices containing strontium-90 for distribution to persons generally licensed under part 4731.3240 shall be approved if:

A. the applicant satisfies the general requirements of part 4731.3070;

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; and

(8) any additional information, including experimental studies and tests, required by the commissioner 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 that includes:

(1) the radiation caution symbol prescribed by part 4731.2300;

(2) a statement that the device contains strontium-90 and the quantity thereof;

(3) instructions for disposal;

(4) a statement that the device may be possessed pursuant to a general license;

(5) a statement that the manufacturer or civil authorities should be notified if the device is found;

(6) a statement that removal of the labeling is prohibited; and

(7) a statement that disassembly and repair of the device may be performed only by a person holding a specific license to manufacture or service such devices; and

E. the commissioner 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 that 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 the individual's 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 under item F; and

(5) quality control procedures have been established to satisfy the requirements of subpart 2;

F. the applicant subjects 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 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 subitem (3); and

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

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

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

(c) any other evidence of physical damage; and

G. the device has been registered in the Sealed Source and Device Registry.

Subp. 2. **Quality assurance; transfer prohibition.**

A. A person licensed under this part must visually inspect each device and must reject any that has an observable physical defect that could affect containment of the strontium-90.

B. A person licensed under this part must 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 wiping the entire surface area if it is less than 100 square centimeters. Detection on the filter paper of more than 2,200 disintegrations per minute of radioactive material per 100 square centimeters of surface wiped must be cause for rejection of the tested device.

C. A person licensed under this part must:

(1) maintain quality assurance systems in the manufacture of the ice detection device containing strontium-90 in a manner sufficient to provide reasonable 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 item D and in the license issued under this part, 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 this part must 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; and

(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 this part.

E. No person licensed under this part shall transfer to persons generally licensed under part 4731.3240, or under an equivalent general license of the NRC or an agreement state:

(1) any ice detection device containing strontium-90 tested and found defective under the criteria specified in a license issued under this part, 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 item C, subitem (2), unless:

(a) a procedure for defining sub-lot size, independence, and additional testing procedures is contained in the license issued under this part; and

(b) each individual sub-lot is sampled, tested, and accepted in accordance with unit (a) and item C, subitem (2), and any other criteria as may be required as a condition of the license issued under this part.

Statutory Authority: *MS s 144.1201; 144.1202; 144.1203; 144.1204; 144.1205*

History: *29 SR 755; 40 SR 145*

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