

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) the device has been subjected to and has satisfactorily passed the prototype tests under part 4731.3415; and

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

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 take a random sample of the size required by part 4731.3420 for lot tolerance percent defective of five percent from each inspection lot and must subject each unit in the sample to the tests in items D and E.

D. Each device must be immersed in 30 inches of water for 24 hours and must show no visible evidence of physical contact between the water and the strontium-90. Absolute pressure of the air above the water must then be reduced to one inch of mercury. Lowered pressure must be maintained for one minute or until air bubbles cease to be

given off by the water, whichever is longer. Pressure must then be increased to normal atmospheric pressure. Any device that leaks, as evidenced by physical contact between the water and the strontium-90, must be considered a defective unit.

E. The immersion test water from the test under item D must be measured for radioactive material. If the amount of radioactive material in the immersion test water is greater than 0.1 percent of the original amount of strontium-90 in any device, the device must be considered a defective unit.

F. An application for a license or for amendment to a license may include a description of procedures proposed as alternatives to those prescribed under items C to E and proposed criteria for acceptance under those procedures. The commissioner shall approve the proposed alternative procedures if the applicant demonstrates that:

(1) the procedures will consider defective any sampled device that has a leakage rate exceeding 0.1 percent of the original quantity of strontium-90 in any 24-hour period; and

(2) the operating characteristic curve or confidence interval estimate for the alternative procedures provides a lot tolerance percent defective of five percent at the consumer's risk of 0.10.

G. No person licensed under this part shall transfer to persons generally licensed under part 4731.3240:

(1) any device that has been tested and found defective under the criteria and procedures specified in this subpart, unless the defective units have been repaired or reworked and then met the tests required under items C to E; or

(2) any inspection lot that has been rejected as a result of the procedures under part 4731.3420, or alternative procedures under item F, unless the defective units have been sorted and removed or have been repaired or reworked and have then met the tests required under items C to E.

Statutory Authority: *MS s 144.1202; 144.1203*

History: *29 SR 755*

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