

3701:1-46-40 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 rule 3701:1-46-10 of the Administrative Code will be approved if:

- (A) The applicant satisfies the general requirements specified in rule 3701:1-40-15 of the Administrative Code;
- (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 director to facilitate a determination of the safety of the device;
- (C) Each device will contain no more than 1.85 megabecquerels (fifty microcuries) of strontium-90 in an insoluble form;
- (D) Each device will bear durable, legible labeling which includes the radiation symbol prescribed by paragraph (A) of rule 3701:1-38-18 of the Administrative Code, 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 director 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 five millisieverts (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 rule.
 - (5) Quality control procedures have been established to satisfy the requirements of rule 3701: 1-46-41 of the Administrative Code.
- (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 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 rule.
 - (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 per cent or more of the original amount of strontium-90 from the device;
 - (b) Surface contamination of strontium-90 on the device of more than two thousand two hundred disintegrations per minute per one hundred square centimeters of surface area; or
 - (c) Any other evidence of physical damage.
- (G) The device has been registered in the sealed source and device registry.

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CERTIFIED ELECTRONICALLY

Certification

10/29/2015

Date

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