

**4731.3345 SPECIFIC LICENSE; LUMINOUS SAFETY DEVICES; MANUFACTURE, ASSEMBLE, REPAIR, OR INITIALLY TRANSFER.**

Subpart 1. **Approval criteria.** An application for a specific license to manufacture, assemble, repair, or initially transfer luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under part 4731.3225, shall be approved if:

- A. the applicant satisfies the general requirements of part 4731.3070;
- B. the applicant submits sufficient information regarding each device pertinent to evaluation of the potential radiation exposure, including:
  - (1) chemical and physical form and maximum quantity of tritium or promethium-147 in each device;
  - (2) details of construction and design;
  - (3) details of the method of binding or containing the tritium or promethium-147;
  - (4) procedures for and results of prototype testing to demonstrate that the tritium or promethium-147 will not be released to the environment under the most severe conditions likely to be encountered in normal use;
  - (5) quality assurance procedures to be followed that are sufficient to ensure compliance with subpart 4; and
  - (6) 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 ten curies of tritium or 300 millicuries of promethium-147. The levels of radiation from each device containing promethium-147 will not exceed 0.5 millirad per hour at ten centimeters from any surface when measured through 50 milligrams per square centimeter of absorber;
- D. the commissioner determines that:
  - (1) the method of incorporation and binding of the tritium or promethium-147 in the device is such that the tritium or promethium-147 will not be released under the most severe conditions that are likely to be encountered in normal use and handling of the device;
  - (2) the tritium or promethium-147 is incorporated or enclosed so as to preclude direct physical contact by any person with it;
  - (3) the device is so designed that it cannot easily be disassembled; and

(4) prototypes of the device have been subjected to and have satisfactorily passed the tests under item E;

E. the applicant must 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 tritium or promethium-147, 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 tritium or promethium-147, 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 tritium or promethium-147 from the device;

(b) surface contamination of tritium or promethium-147 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

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

Subp. 2. **Labeling requirements.** A person licensed under this part to manufacture, assemble, or initially transfer devices containing tritium or promethium-147 for distribution to persons generally licensed under part 4731.3225 must, except as provided in subpart 3, affix to each device a label containing:

A. the radiation symbol prescribed by part 4731.2300;

B. such other information as may be required by the commissioner, including disposal instructions when appropriate; and

C. the following or a substantially similar statement that contains all of the information called for:

"The receipt, possession, use, and transfer of this device, Model ..., Serial No. ..., containing ... (identity and quantity of radioactive material) are subject to a general license or the equivalent and the regulations of the Minnesota commissioner of health, the Nuclear Regulatory Commission, or a state with which the Nuclear Regulatory

Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION – RADIOACTIVE MATERIAL

(Name of manufacturer, assembler, or initial transferor)"

The model, serial number, and name of manufacturer, assembler, or initial transferor may be omitted from the label if they are elsewhere specified in the labeling affixed to the device.

Subp. 3. **Alternative labeling.** If the commissioner determines that it is not feasible to affix a label to the device containing all the information required under subpart 2, the commissioner may waive those requirements and require in lieu thereof that:

A. a label be affixed to the device identifying:

- (1) the manufacturer, assembler, or initial transferor; and
- (2) the type of radioactive material; and

B. a leaflet bearing the following information be enclosed in or accompany the container in which the device is shipped:

- (1) the name of the manufacturer, assembler, or initial transferor;
- (2) the type and quantity of radioactive material;
- (3) the model number;
- (4) a statement that the receipt, possession, use, and transfer of the device are subject to a general license or the equivalent and the rules of the commissioner, the NRC, or an agreement state; and
- (5) such other information as may be required by the commissioner, including disposal instructions when appropriate.

Subp. 4. **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 adversely affect containment of the tritium or promethium-147.

B. A person licensed under this part must:

- (1) maintain quality assurance systems in the manufacture of the luminous safety device 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 C 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.

C. The licensee 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 adversely affect the effective containment of tritium or promethium-147, such as absolute pressure and water immersion; and

(2) inspection for evidence of physical damage, containment failure, or for loss of tritium or promethium-147 after each stage of testing, using methods of inspection adequate for applying the following criteria for defective:

(a) a leak resulting in a loss of 0.1 percent or more of the original amount of tritium or promethium-147 from the device;

(b) levels of radiation in excess of 0.5 millirad (5 microgray) per hour at ten centimeters from any surface when measured through 50 milligrams per square centimeter of absorber, if the device contains promethium-147; and

(c) any other criteria specified in the license issued under this part.

D. No person licensed under this part shall transfer to persons generally licensed under part 4731.3225 or under an equivalent general license of the NRC or an agreement state:

(1) any luminous safety device that has been tested and found defective under a condition of a license issued under this part, unless the defective luminous safety device has been repaired or reworked, retested, and determined by an independent inspector to meet the applicable acceptance criteria; or

(2) any luminous safety device contained within any lot that has been sampled and rejected as a result of the procedures in item B, 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 items B, subitem (2), and D, subitem (2), unit (a), and any other criteria that may be required as a condition of the license issued under this part.

**Subp. 5. Transfer reports.**

A. A person licensed under this part must file an annual report with the commissioner that covers the year ending June 30 and is filed within 30 days thereafter. If

no transfers have been made to persons generally licensed under part 4731.3225 during the reporting period, the report must so indicate. The report must:

- (1) state the total quantity of tritium or promethium-147 transferred to persons generally licensed under part 4731.3225;
- (2) identify each general licensee by name;
- (3) state the kinds and numbers of luminous devices transferred; and
- (4) specify the quantity of tritium or promethium-147 in each kind of device.

B. A person licensed under this part must report annually all transfers of devices to persons for use under a general license in the NRC's or an agreement state's regulations that are equivalent to part 4731.3225 to the NRC or responsible agreement state agency. If no transfers have been made to the NRC or a particular agreement state during the reporting period, this information must be reported to the NRC or responsible agreement state agency upon request of the agency. The report must:

- (1) state the total quantity of tritium or promethium-147 transferred;
- (2) identify each general licensee by name;
- (3) state the kinds and numbers of luminous devices transferred; and
- (4) specify the quantity of tritium or promethium-147 in each kind of device.

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

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