

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) any quality control procedures proposed as alternatives to those prescribed in 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; and
- 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) the device has been subjected to and has satisfactorily passed the prototype tests under part 4731.3405.

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 affect containment of the tritium or promethium-147.

B. A person licensed under this part must take a random sample of the size required under 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 under items C to E.

C. Each device must be immersed in 30 inches of water for 24 hours and must show no visible evidence of water entry. 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 bubbles emanating from within the device or water entering the device must be considered a defective unit.

D. The immersion test water from the test in item C must be measured for tritium or promethium-147 content by an apparatus that has been calibrated to measure tritium or promethium-147, as appropriate. If more than 0.1 percent of the original amount of tritium or promethium-147 in any device is found to have leaked into the immersion test water, the leaking device must be considered a defective unit.

E. The levels of radiation from each device containing promethium-147 must be measured. Any device that has a radiation level in excess of 0.5 millirad per hour at ten centimeters from any surface when measured through 50 milligrams per square centimeter of absorber must be considered a defective unit.

F. An application for a license or for amendment of a license may include a description of procedures proposed as alternatives to those under items B 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 tritium or promethium-147 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 4731.3225:

(1) any luminous safety device that has been tested and found defective under the criteria and procedures in this subpart unless the defective units have been repaired or reworked and have then met the tests in items B 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 under items B to E.

Subp. 5. **Transfer reports.** A person licensed under this part must file an annual report with the commissioner that:

A. states the total quantity of tritium or promethium-147 transferred to persons generally licensed under part 4731.3225;

B. identifies each general licensee by name;

C. states the kinds and numbers of luminous devices transferred;

D. specifies the quantity of tritium or promethium-147 in each kind of device;
and

E. covers the year ending June 30 and is filed within 30 days thereafter.

Statutory Authority: *MS s 144.1202; 144.1203*

History: *29 SR 755*

Published Electronically: *March 12, 2009*