

4731.3365 SPECIFIC LICENSE; CALIBRATION OR REFERENCE SOURCES; MANUFACTURE OR INITIAL TRANSFER.

Subpart 1. **Approval criteria.** An application for a specific license to manufacture or initially transfer calibration and reference sources containing americium-241 or radium-226 for distribution to persons generally licensed under part 4731.3230 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 calibration or reference source pertinent to evaluation of the potential radiation exposure, including:
 - (1) chemical and physical form and maximum quantity of americium-241 or radium-226 in the source;
 - (2) details of construction and design;
 - (3) details of the method of incorporation and binding of the americium-241 or radium-226 in the source;
 - (4) procedures for and results of prototype testing of sources that are designed to contain more than 0.005 microcurie (185 Bq) of americium-241 or radium-226, to demonstrate that the americium-241 or radium-226, respectively, contained in each source will not be released or be removed from the source under normal conditions of use;
 - (5) details of quality control procedures to be followed in manufacture of the source;
 - (6) a description of labeling to be affixed to the source or the storage container for the source; and
 - (7) any additional information, including experimental studies and tests, required by the commissioner to facilitate a determination of the safety of the source;
- C. each source will contain no more than five microcuries (185 kBq) of americium-241 or radium-226; and
- D. the commissioner determines, with respect to any type of source containing more than 0.005 microcurie (185 Bq) of americium-241 or radium-226, that:
 - (1) the method of incorporation and binding of the americium-241 or radium-226 in the source is such that the americium-241 or radium-226 will not be released or be removed from the source under normal conditions of use and handling of the source; and
 - (2) the source has been subjected to and has satisfactorily passed the prototype tests under part 4731.3410.

Subp. 2. **Labeling requirements.** A person licensed under this part must affix to each source or storage container for the source a label that:

A. contains sufficient information relative to safe use and storage of the source; and

B. includes the following statement or a substantially similar statement that contains the information called for:

"The receipt, possession, use, and transfer of this source, Model ..., Serial No. ..., are subject to a general license 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 – THIS SOURCE CONTAINS

AMERICIUM-241 [or RADIUM-226, as appropriate]. DO NOT TOUCH

RADIOACTIVE PORTION OF THIS SOURCE.

(Name of manufacturer or initial transferor)"

Sources licensed under Code of Federal Regulations, title 10, before January 19, 1975, may bear labels authorized by the regulations in effect on January 1, 1975.

Subp. 3. **Leak testing.**

A. A person licensed under this part must perform a dry wipe test upon each source containing more than 0.1 microcurie (3.7 kBq) of americium-241 or radium-226 before transferring the source to a general licensee under part 4731.3230.

B. The test must be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure.

C. The radioactivity on the paper must be measured by using radiation detection instrumentation capable of detecting 0.005 microcurie (0.185 kBq) of americium-241 or radium-226.

D. If the test discloses more than 0.005 microcurie (0.185kBq) of radioactive material, the source must be deemed to be leaking or losing americium-241 or radium-226 and must not be transferred to a general licensee under part 4731.3230.

Statutory Authority: *MS s 144.1202; 144.1203*

History: *29 SR 755; 33 SR 1440*

Published Electronically: *March 12, 2009*