

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;
- 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 appropriate tests required by item E; and

E. the applicant subjects at least five prototypes of each source that is designed to contain more than 0.005 microcurie (0.185 kilobecquerel) of americium-241 or radium-226 to tests as follows:

(1) the initial quantity of radioactive material deposited on each source is measured by direct counting of the source;

(2) the sources 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 or binding of americium-241 or radium-226, such as physical handling, moisture, and water immersion;

(3) the sources are inspected for evidence of physical damage and for loss of americium-241 or radium-226, after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in subitem (4); and

(4) source designs are rejected for which the following has been detected for any unit: removal of more than 0.005 microcurie (0.185 kilobecquerel) of americium-241 or radium-226 from the source or any other evidence of physical damage.

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 or equivalent regulations of the NRC or an agreement state.

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 methods capable of detecting 0.005 microcurie (0.185 kBq) of americium-241 or radium-226.

D. If a source has been shown to be leaking or losing more than 0.005 microcurie (0.185kBq) of americium-241 or radium-226 by the methods described in this subpart, the source must be rejected and must not be transferred to a general licensee under part 4731.3230, or equivalent regulations of the NRC or an agreement state.

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

History: *29 SR 755; 33 SR 1440; 40 SR 145*

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