

**3701:1-46-37 Calibration or reference sources containing americium-241 or radium-226: requirements for license to manufacture or initially transfer.**

An application for a specific license to manufacture or initially transfer calibration or reference sources containing americium-241 or radium-226, for distribution to persons generally licensed under rule 3701:1-46-08 of the Administrative Code, will be approved if:

- (A) The applicant satisfies the general requirements of rule 3701:1-40-15 of the Administrative Code;
- (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, which are designed to contain more than one hundred eighty-five becquerels (0.005 microcurie) of americium-241 or radium-226, to demonstrate that the americium-241 or radium-226 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) Description of labeling to be affixed to the source or the storage container for the source;
  - (7) Any additional information, including experimental studies and tests, required by the director to facilitate a determination of the safety of the source.
- (C) Each source will contain no more than one hundred eighty-five kilobecquerels (five microcuries) of americium-241 or radium-226.
- (D) The director determines, with respect to any type of source containing more than one hundred eighty-five becquerels (0.005 microcurie) 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 prescribed in paragraph (E) of this rule.

- (E) The applicant shall subject at least five prototypes of each source that is designed to contain more than one hundred eighty-five becquerels (0.005 microcurie) 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 paragraph (E)(4) of this rule.
  - (4) Source designs are rejected for which the following has been detected for any unit: removal of more than one hundred eighty-five becquerels (0.005 microcurie) of americium-241 or radium-226 from the source or any other evidence of physical damage.

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CERTIFIED ELECTRONICALLY

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Certification

10/29/2015

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Date

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