Kansas Administrative Regulations

Department of Health and Environment

Article 35.—Radiation—Part 3. Licensing of Sources of Radiation.

28-35-181j. Specific licenses to manufacture and distribute calibration sources containing americium-241 or radium-226.

(a) 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 K.A.R. 28-35-178e shall not be approved unless the following requirements are met:

(1) The applicant shall satisfy the general requirements of part 3 of these regulations.

(2) The applicant shall submit sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including the following:

(A) Chemical and physical form and maximum quantity of americium-241 or radium-226 in the source;

(B) details of construction and design;

(C) details of the method of incorporation and binding of the americium-241 or radium-226 in the source;

(D) procedures for and results of prototype testing of sources that are designed to contain more than 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;

(E) details of quality control procedures to be followed in manufacture of the source;

(F) description of labeling to be affixed to the source or the storage container for the source; and

(G) any additional information, including experimental studies and tests, required by the department to facilitate a determination of the safety of the source.

(3) Each source shall contain no more than 5 microcuries of americium-241 or radium-226. With respect to any type of source containing more than 0.005 microcurie of americium-241 or radium-226, it shall be determined by the secretary that the method of incorporation and binding of more than 0.005 microcuries of the americium-241 or radium-226 in the source prevents the release or removal of americium-241 or radium-226 from the source under normal conditions of use and handling of the source.

(4) The applicant shall subject at least five prototypes of each source that is designed to contain more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 to the following tests:

(A) Initial measurement. The quantity of radioactive material deposited on the source shall be measured by direct counting of the source.

(B) Weathering test. Each source shall be subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions, including physical handling, moisture, and water immersion, expected in service that could adversely affect the effective containment or binding of americium-241 or radium-226. Each source shall be 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 specified in subsection (b).

(C) Wet wipe test. The entire radioactive surface of the source shall be wiped with filter paper moistened with water, with the application of moderate finger pressure. Removal of radioactive material from the source shall be determined by measuring the radioactivity on the filter paper after the paper has dried or by direct measurement of the radioactivity on the source following the wet wipe.

(D) Water soak test. The source shall be immersed in water at room temperature for 24 consecutive hours. The source shall then be removed from the water. Removal of radioactive material from the source shall be determined by direct measurement of the radioactivity on the source after the source has dried or by measuring the radioactivity in the residue obtained by evaporation of the water in which the source was immersed.

(E) Dry wipe test. A dry wipe test shall be performed on each source containing more than 3.7 kilobecquerels (0.1 microcurie) of americium-241 or radium-226 before

transferring the source to a general licensee under K.A.R. 28-35-178e or under equivalent regulations of an agreement state. The dry wipe test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure. The radioactivity on the filter paper shall be measured using a method capable of detecting 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226. If a source has been shown to be leaking or losing more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 by any of the methods described in this subsection, the source shall be rejected and shall not be transferred to a general licensee under K.A.R. 28-35-178e or equivalent regulations of an agreement state.

(F) Observations. Removal of more than 0.005 microcurie of radioactivity in any test prescribed by paragraph (a)(4) shall be cause for rejection of the source design. Results of prototype tests submitted to the nuclear regulatory commission shall be given in terms of radioactivity in microcuries and percent of removal from the total amount of radioactive material deposited on the source.

(6) Each source or storage container for the source shall have a label affixed that contains sufficient information about safe use and storage of the source and includes the following or an equivalent statement:

"The receipt, possession, use and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of the United States Nuclear Regulatory Commission or of a State with which the 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). DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____

(Name of manufacturer or initial transferor)."

(b) Each person licensed under this regulation shall perform a dry wipe test upon each source containing more than 3.7 kilobecquerels (0.1 microcurie) of americium-241 or radium-226 before transferring the source to a general licensee in accordance with

K.A.R. 28-35-178e or equivalent regulations of an agreement state or the nuclear regulatory commission. This test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure. The radioactivity on the paper shall be measured by using radiation detection instrumentation capable of detecting 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226. If this test discloses more than 0.185 kilobecquerel (0.005 microcurie) of radioactive material or if there is evidence of any physical damage, the source shall be deemed to be leaking or losing americium-241 or radium-226 and shall not be transferred to a general licensee in accordance with K.A.R. 28-35-178e or equivalent regulations of an agreement state or the nuclear regulatory commission. (Authorized by and implementing K.S.A. 48-1607; effective, T-86-37, Dec. 11, 1985; effective May 1, 1986; amended March 18, 2011; amended April 1, 2022.)

***** Authenticated Kansas Administrative Regulation *****