Kansas Administrative Regulations

Department of Health and Environment

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

28-35-181p. Specific license to manufacture or distribute radioactive material for use by persons generally licensed under <strong>K.

A.R. 28-35-178h. An application for a specific license to manufacture or distribute, or to manufacture and distribute radioactive material for use by persons generally licensed under K.A.R. 28-35-178h, shall not be approved unless the applicant meets the requirements of subsections (a), (b), (c) and (d) of this regulation.

(a) The radioactive material shall be prepared for distribution in prepackaged units of:

(1) iodine-125 in units not exceeding 10 microcuries each;

(2) iodine-131 in units not exceeding 10 microcuries each;

(3) carbon-14 in units not exceeding 10 microcuries each;

(4) hydrogen-3 (tritium) in units not exceeding 50 microcuries each;

(5) iron-59 in units not exceeding 20 microcuries each;

(6) selenium-75 in units not exceeding 10 microcuries each;

(7) mock iodine-125 in units not exceeding 0.05 microcuries of iodine-129 and 0.005 microcuries of americum-241; or

(8) cobalt-57 in units not exceeding 10 microcuries each.

(b) Each prepackaged unit shall bear a durable clearly visible label:

(1) identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed:

(A) 10 microcuries of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75;

(B) 50 microcuries of hydrogen-3 (tritium);

(C) 20 microcuries of iron-59; or

(D) 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each; and

(2) Displaying the radiation caution symbol described in K.A.R 28-35-219a and the words, "CAUTION—RADIOACTIVE MATERIAL", and "not for internal or external use in humans or animals".

(c) The following statement, or a substantially similar statement, shall appear on a label affixed to each prepackaged unit, or in a leaflet or brochure to accompany the package:

"The radioactive material may be received, acquired, possessed, and used only by physicians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license 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.

_____

Name of manufacturer"

(d) The label to be affixed to the unit, or a leaflet or brochure which is to accompany the package, shall contain information concerning the precautions to be observed in handling and storing the radioactive material and regarding the waste disposal requirements of K.A.R. 28-35-223a.

(Authorized by and implementing K.S.A. 1984 Supp. 48-1607; effective, T-86-37, Dec. 11, 1985; effective May 1, 1986.)

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