Kansas Administrative Regulations

Department of Health and Environment

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

28-35-178h. General license for use of by-product material for certain in vitro clinical or laboratory testing.

(a) A general license is hereby issued to any physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital to acquire, possess, use and transfer in accordance with the provisions of subsections (b), (c), (d), (e), and (f) of this section, the following radioactive materials in prepackaged units for use in any of the following stated tests:

(1) Iodine-125, in units not exceeding 10 microcuries each, for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(2) Iodine-131, in units not exceeding 10 microcuries each, for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(3) Carbon-14, in units not exceeding 10 microcuries each, for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(4) Hydrogen-3 (tritium), in units not exceeding 50 microcuries each, for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(5) Iron-59, in units not exceeding 20 microcuries each, for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(6) Selenium-75, in units not exceeding 10 microcuries each, for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(7) Mock Iodine-125 reference or calibration sources, in units not exceeding 0.05 microcuries of Iodine-129 and 0.005 microcurie of americium-241 each, for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(8) Cobalt-57, in units not exceeding 10 microcuries each, for use in in vitro clinical or labratory tests not involving internal or external administration of radioactive material or the radiation therefrom, to human beings or animals.

(b)(1) A person shall not acquire, possess, use or transfer radioactive material pursuant to the general license issued in subsection (a) of this section until the person has filed form RH-31, "Registration Certificate—In Vitro Testing with Radioactive Material Under General License," with the secretary and has received from the secretary a validated copy of the form, with a registration number assigned, or until the person has been authorized pursuant to K.A.R. 28-35-181d(d) to use radioactive material under the general license issued in subsection (a) of this regulation.

(2) Each person who files a form RH-31 shall provide all the information requested by that form.

(c) Each person who acquires, possesses, or uses radioactive material pursuant to the general license issued in subsection (a) of this section:

(1) Shall not possess, at any one time, at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, cobalt-57 or iron-59 in excess of 200 microcuries;

(2) shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection;

(3) shall use the radioactive material only for the uses authorized in subsection (a) of this section;

(4) shall not transfer the radioactive material except by transfer to a person authorized to receive it under a license issued by the secretary, the U.S. nuclear regulatory commission or an agreement state, and shall not transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from a supplier; and

(5) shall dispose of mock iodine-125 reference or calibration sources in accordance with the requirements of K.A.R. 28-35-223a.

(d) Each general licensee shall not receive, acquire, possess, or use radioactive material pursuant to subsection (a) of this section:

(1) Except as prepackaged units which are labeled in accordance with the provisions of a specific license issued by the secretary, the U.S. nuclear regulatory commission, or an agreement state; and

(2) Unless the following statement, or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

"This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, 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 U.S. 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)"

(e) Each person possessing or using radioactive materials under the general license issued in subsection (a) of this section shall file a written report with the secretary of any

change in the information furnished on form RH-31. The report shall be filed within 30 days after the effective date of any change.

(f) Any person using radioactive material pursuant to the general license issued in paragraph (1) of subsection (a) shall be exempt from the requirements of parts 4 and 10 of these regulations with respect to radioactive materials covered by that general license, except that any person using Mock Iodine-125 shall comply with the provisions of K.A.R. 28-35-223a, 28-35-228a and 28-35-229a.

(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 *****