Kansas Administrative Regulations

Department of Health and Environment

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

28-35-181n. Specific licenses to manufacture and distribute generators or reagent kits for preparation of radiopharmaceuticals containing radioactive material.

Each application for a specific license to manufacture and distribute generators or reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons licensed as specified in K.A.R. 28-35-181d for the uses listed in group III shall meet the requirements of subsections (a), (b), (c), and (d).

(a) Each applicant shall meet the general requirements specified in K.A.R. 28-35-180a.

(b) Each applicant shall submit documentation of one of the following:

(1) The generator or reagent kit is subject to the federal food, drug and cosmetic act or the public health service act and will be manufactured, labeled, and packaged in accordance with a new drug application (NDA) approved by the food and drug administration (FDA), a biologic product license issued by FDA, or a "notice of claimed investigational exemption for a new drug" (IND) accepted by FDA.

(2) The manufacture and distribution of the generator or reagent kit is not subject to the federal food, drug, and cosmetic act and the public health service act.

(c) Each applicant shall submit information on the following:

(1) The radionuclide;

(2) the chemical and physical form of the material;

(3) packaging, including maximum activity per package; and

(4) shielding provided by the packaging of the radioactive material contained in the generator or reagent kit.

(d) The label affixed to the generator or reagent kit shall contain information on the radionuclide, quantity, and date of assay.

(e) The label affixed to the generator or reagent kit, or the leaflet or brochure that accompanies the generator or reagent kit, shall contain the following:

(1) Adequate information, from a radiation safety standpoint, on the procedures to be followed and the equipment and shielding to be used in eluting the generator or processing radioactive material with the reagent kit; and

(2) a statement that "this generator or reagent kit, as appropriate, is approved for use by persons licensed by the department according to K.A.R. 28-35-181d for group III uses, or under equivalent licenses of the United States nuclear regulatory commission or another agreement state." The labels, leaflets, or brochures required by this paragraph shall be in addition to the labeling required by the FDA. The labels, leaflets, or brochures may be separate from FDA labeling, or with the approval of FDA, the labeling may be combined with the labeling required by the FDA.

(Authorized by and implementing K.S.A. 48-1607; effective, T-86-37, Dec. 11, 1985; effective May 1, 1986; amended July 27, 2007.)

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