

Kansas Administrative Regulations

Department of Health and Environment

Article 35.—Radiation

28-35-181m. Specific licenses to manufacture, prepare, or distribute radiopharmaceuticals containing radioactive material for medical use.

An application for a specific license to manufacture, prepare, or distribute radiopharmaceuticals containing radioactive material and used by persons as specified in part 6 of these regulations shall not be approved unless the applicant meets the requirements of this regulation and all other applicable requirements of these regulations.

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

(b) Each applicant shall submit evidence of either of the following:

(1) The radiopharmaceutical containing radioactive material 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 U.S. food and drug administration (FDA), a biologic product license issued by the FDA, or a "notice of claimed investigational exemption for a new drug" (IND) accepted by the FDA.

(2) The manufacture and distribution of the radiopharmaceutical containing radioactive material is not subject to the federal food, drug, and cosmetic act or the public health service act.

(c) Each applicant shall submit evidence of at least one of the following:

(1) The applicant is registered or licensed with the FDA as a drug manufacturer.

(2) The applicant is registered or licensed with a state agency as a drug manufacturer.

(3) The applicant is licensed as a pharmacy by the state board of pharmacy.

(4) The applicant is operating as a nuclear pharmacy within a federal medical institution.

(5) The applicant is operating a positron emission tomography (PET) drug production facility.

(d) Each applicant shall submit the following information on the radionuclide:

(1) The chemical and physical form of the material;

(2) the packaging in which the radionuclide is shipped, including the maximum activity per package; and

(3) evidence that the shielding provided by the packaging of the radioactive material is appropriate for the safe handling and storage of radiopharmaceuticals by group licensees.

(e)(1) Each applicant shall comply with the following labeling requirements:

(A) A label that shall be affixed to each transport radiation shield, whether the shield is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label shall include the following:

(i) The radiation symbol and the words "CAUTION—RADIOACTIVE MATERIAL" or "DANGER—RADIOACTIVE MATERIAL";

(ii) the name of the radioactive drug and the abbreviation; and

(iii) the quantity of radioactivity at a specified date and time. For radioactive drugs with a half-life greater than 100 days, the time may be omitted; and

(B) a label that shall be affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label shall include the radiation symbol and the words "CAUTION—RADIOACTIVE MATERIAL" or "DANGER—RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

(2) The labels, leaflets, or brochures required by this regulation shall be made in addition to the labeling required by the FDA. The labels, leaflets, or brochures may be separate from the FDA labeling, or with the approval of the FDA, the labeling may be combined with the labeling required by the FDA.

(f) All of the following shall apply to each licensee described in paragraph (c)(3) or (c)(4), or both:

(1) The licensee may prepare radioactive drugs for medical use, if each radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in paragraphs (2) and (4) of this subsection, or an individual under the supervision of an authorized nuclear pharmacist.

(2) The licensee may allow a pharmacist to work as an authorized nuclear pharmacist if at least one of the following conditions is met:

(A) The pharmacist meets the requirements in 10 C.F.R. 35.55(b) and 35.59 as adopted by reference in K.A.R. 28-35-264, and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist.

(B) The pharmacist is designated as an authorized nuclear pharmacist in accordance with paragraph (4) of this subsection.

(C) The pharmacist qualifies as an authorized nuclear pharmacist as defined in 10 C.F.R. 35.2, as adopted by reference in K.A.R. 28-35-264.

(3) The actions authorized in paragraphs (1) and (2) of this subsection shall be permitted in spite of more restrictive language in license conditions.

(4) The licensee may designate a pharmacist as an authorized nuclear pharmacist if at least one of the following conditions is met:

(A) The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material.

(B) The individual practiced at a government agency or federally recognized Indian tribe pharmacy before November 30, 2007 or at any other pharmacy before August 8, 2009.

(5) Each licensee shall provide a copy of the state pharmacy license or registration, not later than 30 days after the date that the licensee allows an individual to work as an authorized nuclear pharmacist under paragraph (2) of this subsection, and one of the following documents to the department:

(A) The individual's certification by a specialty board whose certification process has been recognized as specified in 10 C.F.R. 35.55(a), as adopted by reference in K.A.R. 28-35-264;

(B) a department, NRC, or agreement state license listing the individual as an authorized nuclear pharmacist;

(C) an NRC master materials licensee permit listing the individual as an authorized nuclear pharmacist;

(D) a permit issued by a licensee of broad scope or an NRC master materials permittee or the authorization from a commercial nuclear pharmacy that is authorized to list its own authorized nuclear pharmacist; or

(E) documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a government agency or federally recognized Indian tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date noticed by the NRC as permitted by 10 C.F.R. 35.13(b)(5).

(g) Each application from a medical facility, an educational institution, or a federal facility to produce positron emission tomography (PET) radioactive drugs for noncommercial transfer to licensees within the applicant's consortium authorized for medical use under part 6 of these regulations or equivalent agreement state requirements shall include the following:

(1) A request for authorization for the production of PET radionuclides or evidence of an existing license issued under these regulations or equivalent NRC or agreement state requirements for a PET radionuclide production facility within the applicant's consortium from which the applicant receives PET radionuclides;

(2) evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting the requirements of subsection (c);

(3) the name of each individual authorized to prepare PET radioactive drugs if the applicant is a pharmacy and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in paragraphs (f)(2) and (f)(4); and

(4) the name of each PET radioactive drug for production and noncommercial distribution to the applicant's consortium, including the chemical and physical form of each drug.

(h) Each licensee licensed under subsection (g) for the production of positron emission tomography (PET) radioactive drugs for noncommercial transfer to licensees within the applicant's consortium authorized for medical use under part 6 of these regulations or equivalent agreement state requirements shall meet the following requirements:

(1) Comply with the labeling requirements specified in subsection (e);

(2) possess and use instrumentation to measure the radioactivity of PET radioactive drugs intended for noncommercial distribution to members of the licensee's consortium and have procedures for using the instrumentation;

(3) measure, by direct measurement or by a combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs before transfer for commercial distribution;

(4) perform tests before initial use, periodically, and following repair on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument, and make adjustments if necessary; and

(5) check each instrument for constancy and proper operation at the beginning of each day of use.

(i) Nothing in these regulations shall exempt the licensee from the requirement to comply with applicable FDA requirements and other federal and state requirements governing radioactive drugs.

(Authorized by and implementing K.S.A. 48-1607; effective, T-86-37, Dec. 11, 1985; effective May 1, 1986; amended Dec. 30, 2005; amended July 27, 2007; amended March 18, 2011; amended May 4, 2018; amended April 1, 2022.)

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