Kansas Administrative Regulations

Department of Health and Environment

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

28-35-181d. Specific licenses for one or more groups of medical uses.

(a) Any institution, person, or group of persons meeting the requirements of K.A.R. 28-35-181a or 28-35-181b may file a written application with the secretary for a specific license to use radioactive material for any group or groups of medical uses. Each application shall meet the requirements of K.A.R. 28-35-179a and shall designate the intended group or groups of uses for the radioactive material.

(b) Each application for a specific license to use radioactive material for any group or groups of medical uses shall meet all of the following requirements:

(1) The applicant, or the physician or physicians designated in the application as the individual user or users, has adequate clinical experience in performing the medical use or uses for which application is made.

(2) The applicant's proposed radiation detection instrumentation is adequate for conducting the medical procedures specified in the group or groups of uses for which application is made.

(3) The applicant's radiation safety operating procedures are adequate for the proper handling and disposal of radioactive material involved in the group or groups of uses for which application is made.

(4) The applicant, or the physician or physicians designated in the application as the individual user or users, and all other personnel who will be involved in the preparation and use of the radioactive material have adequate training and experience in the handling of radioactive material. The training and experience shall be appropriate for the conduct of the uses included in the group or groups of uses for which application is made.

(c) Each licensee who is licensed under this regulation shall be subject to the following limitations:

(1) A licensee who has been issued a license for group I, II, IV, or V uses shall not receive, possess, or use radioactive material, except those radiopharmaceuticals manufactured in the form to be administered to the patient, and labeled, packaged, and distributed in accordance with a specific license issued by the secretary, or the nuclear regulatory commission or an agreement state.

(2) A licensee who has been issued a license for group III uses shall not receive, possess, or use generators or reagent kits containing radioactive material and shall not use reagent kits that do not contain radioactive material to prepare radiopharmaceuticals containing radioactive material, except for the following:

(A) Reagent kits not containing radioactive material that are approved by the secretary, the nuclear regulatory commission, or an agreement state for use by persons licensed pursuant to this regulation for group III medical uses; or

(B) generators or reagent kits containing radioactive material that are manufactured, labeled, packaged, and distributed in accordance with a specific license issued by the secretary, the nuclear regulatory commission, or an agreement state.

(3) Each licensee who has been issued a license for group III uses and who uses generators or reagent kits shall elute the generator or process radioactive material with the reagent kit in accordance with instructions that are approved by the secretary, the nuclear regulatory commission, or an agreement state and furnished by the manufacturer on the label attached to, or in the leaflet or brochure that accompanies, the generator or reagent kit.

(4) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99 or technetium-99m generators or rubidium-82 from strontium-82 or rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or for strontium-82 and strontium-85 contamination, respectively, in accordance with part 3 of these regulations. Each licensee shall record the results of each test and shall retain each record for three years after the record is made. Each licensee shall report to the department the results of each test that exceeds the permissible concentration in accordance with part 3 of these regulations at the time of generator elution.

(5) Each licensee who has been issued a license for group I, II, or III uses and who uses the radioactive material for clinical procedures other than those specified in the product labeling or package insert shall comply with the product labeling regarding the following:

(A) Chemical and physical form;

(B) route of administration; and

(C) dosage range.

(6) A licensee who has been issued a license for group IV uses shall not receive, possess, or use radioactive material unless contained in a source or device that has been manufactured, labeled, packaged, and distributed in accordance with a specific license issued by the secretary, the nuclear regulatory commission, or an agreement state.

(d) Each licensee who is licensed under this regulation shall be authorized to use radioactive material under the general license issued in K.A.R. 28-35-178h for the specified in vitro uses, without filing form RH-31 as otherwise required by that regulation. However, the licensee shall be subject to the other requirements of K.A.R. 28-35-178h.

(e) Each licensee who is licensed under this regulation shall be authorized, subject to the provisions of subsections (f) and (g), to receive, possess, and use the following for calibration and reference standards:

(1) Any radioactive material listed in group I, II, or III that has a half-life of 100 days or less, in amounts not exceeding 15 millicuries;

(2) any radioactive material listed in group I, II, or III that has a half-life of more than 100 days, in amounts not exceeding 200 microcuries;

(3) technetium-99m, in amounts not exceeding 30 millicuries; and

(4) any radioactive material, in amounts not exceeding three millicuries per source, contained in calibration or reference sources that have been manufactured, labeled, packaged, and distributed in accordance with a specific license issued by the secretary, the nuclear regulatory commission, or an agreement state.

(f)(1) Each licensee who possesses sealed sources as calibration or reference sources pursuant to subsection (e) shall cause each sealed source containing

radioactive material, other than hydrogen-3, that has a half-life of more than 30 days and that is in any form other than gas to be tested for leakage, contamination, or both at intervals not exceeding six months. In the absence of a certificate from a transferor indicating that a leak test has been made within six months before the transfer of a particular sealed source, that sealed source shall not be used until tested, unless one of the following conditions is met:

(A) The source contains 100 microcuries or less of beta-emitting, gamma-emitting, or beta-emitting and gamma-emitting material, or 10 microcuries or less of alpha-emitting material.

(B) The sealed source is stored and is not being used.

(2) Each leak test required by paragraph (f)(1) shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from sealed source or from the surfaces of the device in which the sealed source is permanently mounted or stored and on which contamination might be expected to accumulate. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the department.

(3) If the leak test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired, or to be disposed of in accordance with parts 3 and 4 of these regulations. A report shall be filed with the secretary within five days of the test, describing the equipment involved, the test results, and the corrective action taken.

(g) Each licensee who possesses and uses calibration and reference sources pursuant to subsection (e) shall perform the following:

(1) Follow radiation safety and handling instructions that are approved by the secretary, the nuclear regulatory commission, or an agreement state and furnished by the manufacturer on the label attached to the source, or permanent container, or in the leaflet or brochure that accompanies the source;

(2) maintain the instructions referenced in paragraph (g)(1) in a legible and conveniently available form; and

(3) conduct a quarterly physical inventory to account for all sources received and possessed. A record of each inventory shall be maintained for inspection by the department and shall include the quantities and kinds of radioactive material, location of sources, and the date of the inventory.

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

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