Kansas Administrative Regulations

Department of Health and Environment

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

28-35-181u. Registration of sealed source information.

(a) Each manufacturer or initial distributor of a sealed source or device containing a sealed source shall submit a request for a certificate of registration and shall complete an evaluation of radiation safety information about each manufacturer's or initial distributor's sealed source or device containing a sealed source.

(b) Each request for a certificate of registration of a sealed source or device containing a sealed source shall be submitted to the department and shall include information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses, and leak testing.

Each request for a certificate of registration of a device containing a sealed source shall also include information about installation, service and maintenance, operating and safety instructions, potential health hazards, and minimization of danger to life and property.

(c) Each sealed source or device containing a sealed source shall be designed according to accepted industry standards or otherwise designed according to standards and criteria proposed by the manufacturer or distributor and accepted by the department.

(d) Each person submitting a request for review of safety information about the sealed source or device containing a sealed source shall manufacture and distribute the sealed source or device containing a sealed source in accordance with the following:

(1) The statements and representations, including quality control program, contained in the request for review; and

(2) the provisions of the certificate of registration.

(e) The authority to manufacture or initially distribute a sealed source or device containing a sealed source to specific licensees may be provided in the license without the issuance of a certificate of registration under either of the following conditions:

(1) The sources being manufactured or initially distributed are calibration and reference sources containing no more than either of the following:

(A) 37 MBq (1 mCi), for beta- or gamma-emitting radionuclides; or

(B) 0.37 MBq (10μCi), for alpha-emitting radionuclides.

(2) Each intended recipient of the sealed source or device containing a sealed source meets all of the following conditions:

(A) For unregistered sources, the intended recipient is qualified by training and experience and has sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in any form.

(B) For registered sealed sources contained in unregistered devices, the intended recipient is qualified by training and experience and has sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in unshielded form, as specified in the intended recipient's license.

(C) At least one of the following conditions is met:

(i) Each intended recipient is licensed pursuant to K.A.R. 28-35-182a through 28-35-182d or comparable provisions of the NRC or agreement state.

(ii) Each intended recipient is authorized for research and development.

(iii) The sealed sources and devices containing sealed sources are to be built to the unique specifications of the particular recipient and contain no more than 740 GBq (20 Ci) of tritium or 7.4 GBq (200 mCi) of any other radionuclide.

(f) Each holder of a certificate of registration shall provide the secretary or the secretary's designee with the opportunity to conduct additional reviews in accordance with this regulation as the secretary deems necessary to ensure compliance with these regulations. Any additional clarifying information necessary to conduct a review may be requested by the secretary. Each holder of a certificate of registration shall provide this information within 30 days of service of written notification from the secretary. (Authorized by and implementing K.S.A. 48-1607; effective April 1, 2022.)

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