Kansas Administrative Regulations

Department of Health and Environment

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

28-35-181h. Specific licenses to manufacture and distribute the devices specified in <strong>K.

A.R. 28-35-178b. An application for a specific license to manufacture and distribute one or more of the devices specified in K.A.R. 28-35-178b shall not be approved unless the applicant meets the requirements of subsections (a) and (b) of this regulation in addition to meeting all of the additional applicable requirements specified in these regulations.

(a) Each applicant shall submit information about the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that the following conditions are met:

(1) The device can be safely operated by individuals not having training in radiological protection;

(2) under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any individual will receive a dose in excess of 10 percent of the limits specified in K.A.R. 28-35-212a; and

(3) under accident conditions, including fire and explosion, associated with handling, storage, and use of the device, it is unlikely that any individual will receive an external radiation dose or dose commitment in excess of the following organ doses:

(A) Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	15 rems
(B) Hands and forearms; feet and ankles; localized areas of skin averaged	200

over areas no larger than 1 square centimeter	rems
(C) Other organs	50 rems.

(b)(1) Each device shall bear a durable, legible, clearly visible label or labels that contain, in clearly identified and separate statements, the following information:

(A) Instructions and precautions necessary to ensure safe installation, operation, and servicing of the device. Operating and service manuals may be identified in the label and used to provide this information;

(B) specification of whether or not leak testing or testing of any on-off mechanism and indicator is required. The information shall include the maximum allowable time intervals between tests and shall identify the radioactive material by isotope, quantity of radioactivity, and date that the quantity was determined; and

(C) the information required in one of the following statements, as appropriate, in the same or a substantially similar form:

(i) "The receipt, possession, use, and transfer of this device, model_____, serial no. _____, are subject to a general license or the equivalent and the regulations of the U.S. nuclear regulatory commission or a state with which the U.S. nuclear regulatory commission has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION—
RADIOACTIVE
MATERIAL

_____

(Name of
manufacturer or
distributor)"; or

(ii) "The receipt, possession, use, and transfer of this device, model_____, serial no._____, are subject to a general license or the equivalent, and the regulations of a licensing state. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION—
RADIOACTIVE
MATERIAL

_____
(Name of
manufacturer or
distributor)"

(2) The model, serial number, and name of the manufacturer or distributor may be omitted from the requirements specified in paragraphs (b)(1)(C)(i) and (ii) if the information is elsewhere specified in labeling affixed to the device.

(3) Each device having a separate source housing that provides the primary shielding for the source shall also bear, on the source housing, a durable label containing the device model number and serial number, the isotope and quantity, the words "Caution — Radioactive Material," the radiation symbol described in part 4 of these regulations, and the name of the manufacturer or initial distributor.

(4) Each device containing at least 370 Mbq (10 mCi) of cesium-137, 3.7 Mbq (0.1 mCi) of strontium-90, 37 Mbq (1 mCi) of americium-241 or any other transuranic element based on the activity indicated on the label shall meet the following criteria:

(A)(i) Bear a permanent label affixed to the source housing if the source housing is separable, including the words "Caution — Radioactive Material"; or

(ii) bear a permanent label affixed to the device if the source housing is not separable, including the words "Caution — Radioactive Material"; and

(B) if practicable, bear the radiation symbol described in part 4 of these regulations.

(c) If the device is required to be tested at intervals longer than six months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material, or for both, the applicant shall include in the application sufficient

information to demonstrate that the longer interval is justified by the performance characteristics of the device or of similar devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the applicant shall address the following in the application:

(1) The primary containment of the source capsule;

(2) protection of the primary containment;

(3) the methods of sealing the primary containment;

(4) the containment construction materials;

(5) the form of contained radioactive material;

(6) the maximum temperature withstood during prototype tests;

(7) the maximum pressure withstood during prototype tests;

(8) the maximum quantity of contained radioactive material;

(9) the radiotoxicity of contained radioactive material; and

(10) any prior operating experience with identical devices or similarly designed and constructed devices.

(d) If the general licensee under K.A.R. 28-35-178b, or under equivalent regulations of an agreement state, is authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device, the applicant shall include in the application the written instructions to be followed by the general licensee, the estimated calendar-quarter doses associated with each operation, and the bases for the estimates. The submitted information shall demonstrate that performance of the specified operations by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a dose in excess of 10 percent of the annual limits specified in part 4 of these regulations.

(e) Each device shall be listed on the nuclear regulatory commission's sealed source and device registry.

(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 May 4, 2018.)

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