

(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 *****