Kansas Administrative Regulations

Department of Health and Environment

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

28-35-178b. General license; certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere.

(a)(1) Subject to the provisions of subsections (b) and (c), each commercial and industrial firm, research, educational, and medical institution, individual in the conduct of the individual's business, and federal, state, or local government agency shall be deemed to have been issued a general license to acquire, receive, possess, use, or transfer radioactive material that is contained in any device designed, manufactured, and used for one or more of the following purposes:

(A) Detecting, measuring, gauging, or controlling thickness, density, level interface location, radiation leakage, or qualitative or quantitative chemical composition; or

(B) producing light or an ionized atmosphere.

(2) The general license specified in paragraph (1) of this subsection shall apply only to radioactive material contained in any device that has been manufactured and labeled by a manufacturer in accordance with the specifications of a specific license issued to that manufacturer by the secretary, the nuclear regulatory commission, or an agreement state.

(3) The general license specified in paragraph (1) of this subsection shall not apply to radioactive material in any 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 cobalt-60, 3.7 MBq (0.1 mCi) of radium-226, or 37 MBq (1 mCi) of americium-241 or any other transuranic element, based on the activity indicated on the label.

(4) Each device shall have been received from one of the specific licensees described in paragraph (a)(2) or through a transfer made under paragraph (b)(9).

(b) Each person who acquires, receives, possesses, uses, or transfers radioactive material in a device pursuant to the general license specified in subsection (a) shall comply with all of the following requirements:

(1) Each person subject to this subsection shall ensure that all labels affixed to the device at the time of receipt and bearing a statement that removal of the label is prohibited are maintained and shall comply with all instructions and precautions provided by these labels.

(2) Each person subject to this subsection shall ensure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six-month intervals or at any other intervals specified in any manufacturer's label affixed to the device, except as follows:

(A) The person shall not be required to test devices containing only krypton for leakage of radioactive material.

(B) The person shall not be required to test, for any purpose, any device containing only tritium, not more than 100 microcuries of other beta-emitting or gamma-emitting material, or 10 microcuries of alpha-emitting material or any device held in storage in the original shipping container before initial installation.

(3) Each person subject to this subsection shall ensure that the tests required by paragraph (b)(2) and other operations involving testing, installation, servicing, and removal from installation of the radioactive material, its shielding, or containment are performed in compliance with one of the following:

(A) In accordance with instructions provided on labels affixed to the device; or

(B) by a person holding a specific license issued under this part or equivalent regulations of NRC or an agreement state to perform the tests and other operations.

(4)(A) Each person subject to this subsection shall maintain records showing compliance with the requirements of paragraphs (b)(2) and (b)(3). The records shall show the results of each test. The records also shall show the dates of the testing, installation, servicing, or removal from installation of the radioactive material, its shielding, or containment and the name of each person performing one or more of these tests and other operations.

(B) Each person shall maintain records of tests for leakage of radioactive material required by paragraph (b)(2) for three years after the next required leak test is performed or until the sealed source is transferred or disposed of. Each person shall maintain records of tests of the on-off mechanism and indicator, as required by

paragraph (b)(2), for three years after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed of. Each person shall maintain the records required by paragraph (b)(3) for three years from the date of the recorded event or until the device is transferred or disposed of.

(5) Upon a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 0.005 microcurie or more removable radioactive material, each person subject to this subsection shall take the following actions:

(A) Immediately suspend operation of the device until either of the following conditions is met:

(i) The device has been repaired by the manufacturer or other person holding a specific license issued under this part or equivalent regulations of NRC or an agreement state to repair the device; or

(ii) the device is transferred to a person authorized by a specific license to receive the radioactive material contained in the device;

(B) within 30 days, furnish to the secretary a report containing a brief description of the event and the remedial action taken; and

(C) within 30 days, if contamination of the premises or the environs is likely, furnish to the secretary a plan for ensuring that the premises and environs are acceptable for unrestricted use. The criteria for unrestricted use specified in K.A.R. 28-35-205 may be applicable, as determined by the secretary.

(6) A person subject to this subsection shall not abandon the device.

(7) A person shall not export any device containing radioactive material except in accordance with 10 CFR part 110.

(8) (A) Each person shall transfer or dispose of any device containing radioactive material only by export as provided in paragraph (b)(7), by transfer to another general licensee as authorized in paragraph (b)(9), or to a person authorized to receive the device by a specific license issued under this part or equivalent regulations of NRC or an agreement state.

(B) Each person shall furnish a report to the department within 30 days after the export of the device or the transfer of the device to a specific licensee. The report shall contain the following information:

(i) The identification of the device by manufacturer's name, model number, and serial number;

(ii) the name, address, and license number of the person receiving the device; and

(iii) the date of the transfer.

(C) Each person shall obtain written department approval before transferring the device to any other specific licensee not specifically identified in paragraph (b)(8)(A). The holder of a specific license may transfer a device for possession and use under its own specific license without approval, if the holder performs the following:

(i) Either verifies that the specific license authorizes the possession and use or applies for and obtains an amendment to the license authorizing the possession and use;

(ii) ensures that the device is labeled in compliance with these regulations. The label shall retain the name of the manufacturer, the model number, and the serial number;

(iii) obtains the manufacturer's or initial transferor's information concerning maintenance, including leak testing procedures that are applicable under the specific license; and

(iv) reports the transfer as required by paragraph (b)(8)(B).

(9) Any person subject to this subsection may transfer the device to another general licensee only if either of the following conditions is met:

(A) The device remains in use at a particular location. In this case, the transferor shall give the transferee a copy of this regulation and any safety documents identified in any label affixed to the device and, within 30 days of the transfer, provide a written report to the secretary containing identification of the device by manufacturer's name, model number, and serial number; the name and address of the transferee; and the name, telephone number, and position of an individual who can be contacted by the secretary concerning the device.

(B) The device is held in storage in the original shipping container at its intended location of use before initial use by a general licensee.

(10) Each person subject to this subsection shall comply with the provisions of K.A.R. 28-35-228a and K.A.R. 28-35-229a relating to reports of radiation incidents, theft, or loss of licensed material, but shall be exempt from the other requirements of parts 4 and 10 of these regulations.

(11) Each person shall respond to all written requests from the department to provide information relating to the general license within 30 calendar days of the date of the request or on or before any other deadline specified in the request. If the person cannot provide the requested information within the allotted time, the person, within that same time period, shall request a longer period to supply the information by submitting a letter to the department and shall provide written justification as to why the person cannot comply.

(12) Each general licensee shall appoint an individual responsible for having knowledge of the appropriate regulations and requirements and the authority for taking required actions to comply with appropriate regulations and requirements. The general licensee, through this individual, shall ensure day-to-day compliance with the appropriate regulations and requirements. This appointment shall not relieve the general licensee of any of the licensee's responsibility in this regard.

(13)(A) Each person shall register, in accordance with paragraph (b)(13)(B), each device generally licensed as required by this regulation. Each address for a location of use, as described in paragraph (b)(13)(B)(iv), shall represent a separate general licensee and shall require a separate registration and fee.

(B) In registering each device, the general licensee shall furnish the following information and any other information specifically requested by the department:

(i) The name and mailing address of the general licensee;

(ii) information about each device as indicated on the label, including the manufacturer's name, the model number, the serial number, and the radioisotope and activity;

(iii) the name, title, and telephone number of the responsible person appointed as a representative of the general licensee under paragraph (b)(12)

(iv) the address or location at which each device is used or stored, or both. For each portable device, the general licensee shall provide the address of the primary place of storage;

(v) certification by the responsible representative of the general licensee that the information concerning each device has been verified through a physical inventory and a check of the label information; and

(vi) certification by the responsible representative of the general licensee that the person is aware of the requirements of the general license.

(14) Each person shall report any change in the mailing address for the location of use, including any change in the name of the general licensee, to the department within 30 days of the effective date of the change. For a portable device, a report of address change shall be required only for a change in the primary place of storage of the device.

(15) No person may store a device that is not in use for longer than two years. If any device with shutters is not being used, the shutters shall be locked in the closed position. The testing required by paragraph (b)(2) shall not be required to be performed during the period of storage only. If the device is put back into service or transferred to another person and was not tested at the required test interval, the device shall be tested for leakage before use or transfer, and all shutters shall be tested before use. Each device kept in storage for future use shall be excluded from the two-year time limit if the general licensee performs quarterly physical inventories of the device while the device is in storage.

(c) Nothing in this regulation shall be deemed to authorize the manufacture or import of any device containing radioactive material.

(d) The general license specified in subsection (a) shall be subject to the provisions of K.A.R. 28-35-184a and K.A.R. 28-35-184b.

(Authorized by and implementing K.S.A. 48-1607; effective, T-86-37, Dec. 11, 1985; effective May 1, 1986; amended Nov. 1, 1996; amended March 24, 2006; amended July 27, 2007; amended March 18, 2011.)

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