

902 KAR 100:040. General provisions for specific licenses.

RELATES TO: KRS 211.842-211.852, 211.990(4), 10 C.F.R. 30.31-30.34, 30.36-30.39, 30.41, 30.50, 30.51, 30.61, 11 U.S.C. 101(2), (14)

STATUTORY AUTHORITY: KRS 194A.050, 211.090(3), 211.844

NECESSITY, FUNCTION, AND CONFORMITY: KRS 211.844 requires the Cabinet for Health and Family Services to promulgate administrative regulations for regulating and licensing the possession or use of sources of ionizing or electronic product radiation and the handling and disposal of radioactive waste. This administrative regulation establishes general provisions for the issuance of specific licenses to possess, use, or transfer radioactive material within Kentucky.

Section 1. License Requirement. Except for persons exempted by 902 KAR 100:015 and 100:045, a person shall not manufacture, produce, receive, possess, use, transfer, own, or acquire radioactive material except as authorized in a specific or general license issued in accordance with 902 KAR Chapter 100. Authority to transfer possession or control by the manufacturer; processor; or producer of equipment, devices, commodity, or other products containing radioactive material whose subsequent possession, use, transfer, or disposal by other persons are exempted from regulatory requirements, may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D. C., 20555.

Section 2. Types of Licenses. (1) Licenses for radioactive material shall be of two (2) types:

(a) General; or

(b) Specific.

(2) Except as specified in 902 KAR 100:050, general licenses shall be:

(a) Effective without the filing of an application with the cabinet or the issuance of licensing documents to the licensee; and

(b) Subject to other applicable requirements of 902 KAR Chapter 100 and limitations of 902 KAR 100:050.

(3) Specific licenses shall require:

(a) The submission of an application to the cabinet; and

(b) The issuance of a licensing document by the cabinet.

(4) Each license shall be subject to applicable requirements of 902 KAR Chapter 100 and to limitations specified in the licensing document.

Section 3. Filing of Application for a Specific License. (1) An application for specific license shall be filed with the Cabinet for Health and Family Services on Form RPS-7, incorporated by reference.

(2)(a) After the filing of the original application, or before the expiration of the license if the applicant has already been granted, the Cabinet may require additional information in order to determine if:

1. The application is to be granted or denied; or

2. A license is to be modified or revoked.

(b) Prelicensing visits may be made to the applicant's facility for the purpose of obtaining information in addition to that furnished in the original application.

(c) If the applicant or licensee fails to respond within thirty (30) days of receipt to a written request, for additional information, the cabinet shall suspend, modify, or revoke the license in accordance with 902 KAR 100:170, or shall deny the application.

(3) The application shall be signed by the applicant or licensee or a person duly authorized

to act for and on his behalf.

(4) An application for a license may include a request for a license authorizing one (1) or more activities if the application specifies the additional activities and complies with the provisions of 902 KAR Chapter 100 relating to specific licenses.

(5)(a) The applicant may incorporate in the application, by reference, information contained in previous applications, statements, or reports filed with the cabinet, if references are clear and specific.

(b) Information provided to the cabinet by an applicant or licensee, or information required to be maintained by statute, by 902 KAR Chapter 100, cabinet orders, or license conditions, shall be complete and accurate in all aspects.

(6) An application for a specific license to use radioactive material in the form of a sealed source or in a device that contains the sealed source shall:

(a) Identify the source or device by manufacture and model number as registered with:

1. The cabinet;
2. The U.S. Nuclear Regulatory Commission; or
3. An agreement state; and

(b) Contain the information identified in 902 KAR 100:058, Section 1.

(7) An application for a specific license shall contain, if required by the administrative regulation referenced:

(a) 1. A proposed decommissioning funding plan; or

2. A certification of financial assurance for decommissioning in accordance with 902 KAR 100:042; and

(b) An emergency plan for responding to a release in accordance with 902 KAR 100:041.

Section 4. General Requirements for the Issuance of a Specific License. (1) A license application shall be approved if the cabinet determines:

(a) The applicant is qualified by reason of training and experience to use the radioactive material in question for the purpose requested, in accordance with 902 KAR Chapter 100, and in a manner that minimizes danger to public health and safety or property;

(b) The applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety or property;

(c) The issuance of the license will not be adverse to the health and safety of the public; and

(d) The applicant satisfies applicable special requirements in 902 KAR Chapter 100.

(2) For an application for a license to receive and possess radioactive material that the cabinet determines will significantly affect the quality of the environment, the following shall apply:

(a) The secretary of the cabinet or his designee shall, before commencement of construction of the plant or facility in which the activity is to be conducted, weigh the environmental, economic, technical, and other benefits against environmental costs and shall consider available alternatives.

(b) The secretary shall, if appropriate, approve a license modified by conditions designed to protect environmental values.

(c) Commencement of construction prior to cabinet determination shall be grounds for denial of a license to receive and possess radioactive material in the plant or facility. As used in this subsection, "commencement of construction" shall include clearing of land, excavation, or other substantial action that would adversely affect the environment of a site, but shall not include site exploration, necessary roads for site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values.

(3)(a) The licensee shall notify the cabinet in writing, immediately following the filing of a

voluntary or involuntary petition for bankruptcy under Title 11 of the United States Code by or against:

1. The licensee;
 2. An entity, as defined in 11 U.S.C. 101(14) or (15), controlling the licensee or listing the license or licensee as property of the estate; or
 3. An affiliate, as defined in 11 U.S.C. 101(2), of the licensee.
- (b) The notification shall indicate:
1. The bankruptcy court in which the petition for bankruptcy was filed; and
 2. The date and case number of the filing of the petition.

Section 5. Issuance of Specific Licenses. (1) Upon a determination that an application meets the requirements of KRS 211.842 to 211.852 and 902 KAR Chapter 100, the cabinet shall issue a specific license authorizing the proposed activity in a form containing necessary and appropriate conditions and limitations.

(2) The cabinet may incorporate in a license when issued, or thereafter by appropriate rule, 902 KAR Chapter 100, or order, or as specified in Section 13 of this administrative regulation, additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of radioactive material subject to 902 KAR Chapter 100 as it deems appropriate or necessary in order to:

- (a) Minimize danger to public health and safety or property;
- (b) Require reports are maintained and the keeping of records, and provide for inspections of activities under the license as may be appropriate or necessary; and
- (c) Prevent loss or theft of licensed material.

Section 6. Specific Terms and Conditions of Licenses. (1) A license issued pursuant to this administrative regulation shall be subject to the provisions of KRS 211.842 to 211.852, 902 KAR Chapter 100, and orders of the cabinet.

(2) Neither the license nor a right under the license shall be assigned or otherwise transferred in violation of the provisions of KRS 211.842 to 211.852.

(3) A licensee under 902 KAR Chapter 100 shall confine use and possession of the licensed radioactive material to the locations and purposes authorized in the license.

(4) A portable gauge licensee shall use a minimum of two (2) independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, if portable gauges are not under the control and constant surveillance of the licensee.

Section 7. Expiration and Termination of Licenses. (1) Except as specified in subsection (4) of this section and in Section 8 of this administrative regulation, a specific license shall expire at midnight on the day, month, and year stated in the license.

(2) A licensee shall promptly notify the cabinet, in writing, and request termination of the license, if the licensee decides to terminate activities involving licensed materials. This notification and request for termination of the license shall include:

- (a) The reports and information specified in subsection (3)(d) and (e) of this section; and
- (b) A plan for completion of decommissioning, if required by 902 KAR 100:042 or by license condition.

(3) If a licensee does not submit an application for license renewal under Section 8 of this administrative regulation, the licensee, on or before the expiration date specified in the license, shall:

- (a) Terminate use of radioactive material;
- (b) Remove radioactive contamination to the extent practicable except for those procedures

covered by subsection (4) of this section;

(c) Properly dispose of radioactive material;

(d) File the Disposition of Radioactive Material, "Form RPS-10", with the Cabinet for Health and Family Services; and

(e) If licensed to possess radioactive material with a half-life greater than 120 days in an unsealed form, forward to the cabinet:

1. Records of disposal of radioactive material made pursuant to 902 KAR 100:021, Sections 3-6, including burials authorized before January 28, 1981; and

2. Records required by 902 KAR 100:019, Section 31(2)(d).

(f) If licensed activities are transferred or assigned in accordance with 902 KAR 100:040, Section 6, a licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, shall transfer the following records to the new licensee. The new licensee shall be responsible for maintaining these records until the license is terminated:

1. Records of disposal of licensed material made pursuant to 902 KAR 100:021, Sections 3 through 6 of this administrative regulation, including burials authorized before January 28, 1981; and

2. Records required by 902 KAR 100:019, Section 31(2)(d).

(g) Prior to license termination, a licensee shall forward the records required by 902 KAR 100:042, Section 15(3), to the cabinet.

(4) A specific license continues in effect, beyond the expiration date if necessary, with respect to possession of radioactive material until the cabinet notifies the licensee in writing that the license shall be terminated. During this time, the licensee shall:

(a) Limit actions involving radioactive material to those related to decommissioning; and

(b) Continue to control entry to restricted areas until they are suitable for release for unrestricted use and the cabinet notifies the licensee in writing that the license shall be terminated.

Section 8. Renewal of License. If a licensee has filed, an application in proper form for renewal or for a new license authorizing the same activities more than thirty (30) days prior to expiration of an existing license, the existing license shall not expire until the application has been finally determined by the cabinet.

Section 9. Amendment of Licenses. (1) An application for amendment of a license at the request of the licensee shall specify the respects in which the licensee desires the license to be amended and the grounds for the amendment.

(2) Every five (5) years or at the request of the cabinet, the licensee shall be required to amend the license in its entirety by submitting a complete application.

Section 10. Cabinet Action on Applications to Renew or Amend. In considering an application by a licensee to renew or amend his license, the cabinet shall apply the requirements of 902 KAR Chapter 100.

Section 11. Inalienability of Licenses. A license issued or granted under 902 KAR Chapter 100 or right to possess or utilize radioactive material granted by a license issued under 902 KAR Chapter 100 shall not be transferred, assigned, or otherwise disposed of, through transfer of control of a license to a person unless the cabinet, after securing full information, finds that the transfer is in accordance with the requirements of 902 KAR Chapter 100 and gives its consent in writing.

Section 12. Transfer of Material. (1) A licensee shall not transfer radioactive material except

as authorized by this administrative regulation.

(2) Except as stated in the license and subject to the provisions of subsections (3) and (4) of this section, a licensee may transfer radioactive material subject to the acceptance of the transferee to a person:

(a) Exempt from the requirements for a license as specified in this administrative regulation to the extent permitted under the exemption;

(b) Authorized to receive radioactive material under terms of a general license as specified in 902 KAR 100:050, or its equivalent, or a specific license or equivalent licensing document, issued by the cabinet, the U.S. Nuclear Regulatory Commission, or an agreement state;

(c) Otherwise authorized to receive radioactive material by the federal government or an agency thereof, the cabinet, or an agreement state; or

(d) As otherwise authorized by the cabinet in writing.

(3) Before transferring radioactive material to a specific licensee of the cabinet, U.S. Nuclear Regulatory Commission, or an agreement state or to a general licensee who is required to register with the cabinet, U.S. Nuclear Regulatory Commission, or an agreement state prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

(4) The following methods for the verification required by this administrative regulation shall be acceptable:

(a) The transferor may have in his possession, and read, a current copy of the transferee's specific license or registration certificate;

(b) The transferor may have in his possession a written certificate by the transferee that he is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date;

(c) For emergency shipments, the transferor may accept oral certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date, if the oral certification is confirmed in writing within ten (10) days of the shipment.

(d) The transferor may obtain other sources of information compiled by a reporting service from official records of the cabinet, the U.S. Nuclear Regulatory Commission, or the licensing agency of an agreement state as to the identity of licensees and the scope and expiration dates of licenses and registration; or

(e) If none of the methods of verification described in paragraphs (a) through (d) of this subsection are readily available or if a transferor desires to verify that information received by one (1) of the methods is correct or up-to-date, the transferor may obtain and record confirmation from the cabinet, U.S. Nuclear Regulatory Commission, or the licensing agency of an agreement state that the transferee is licensed to receive the radioactive material.

(5) Shipment and transport of radioactive material shall meet the requirements of 902 KAR Chapter 100.

Section 13. Modification, Revocation, and Suspension of Licenses. (1) The terms and conditions of a license shall be subject to amendment, revision, or modification, or the license may be suspended or revoked by reason of amendments to or violation of KRS 211.842 to 211.852, 902 KAR Chapter 100, or orders issued by the cabinet.

(2) A license may be revoked, suspended, or modified, in whole or in part, for:

(a) A material false statement in the application or in a statement of fact required under pro-

visions of KRS 211.842 to 211.852;

(b) A condition revealed by application or statement of fact;

(c) A report, record, or inspection, or other means that would warrant the cabinet to refuse to grant a license on an original application; or

(d) A violation of, or failure to observe the terms and conditions of KRS 211.842 to 211.852, the license, 902 KAR Chapter 100, or orders of the cabinet.

(3) Except in a case of willful violation or in which the public health, interest, or safety requires otherwise, a license shall not be modified, suspended, or revoked unless, prior to the institution of proceedings.

(a) The cabinet shall notify the licensee in writing, according to 902 KAR 1:400, Section 1, of the fact or conduct that may warrant cabinet action on the license.

(b) The cabinet shall provide the licensee with the opportunity for a conference and conference report according to 902 KAR 1:400, Sections 1 through 3.

(c) If no conference is requested within the timeframe, the Cabinet shall notify the licensee in writing according to 902 KAR 1:400 Section 2(a)-(c) and Section 3(2) of its final action and the licensee's right to appeal.

(4) A licensee whose license is suspended or revoked, shall have a right to a hearing under 902 KAR 1:400, Section 4 by, by making a written request as described in that Section.

Section 14. Retention of Records. (1) A person who receives radioactive material in accordance with a license issued under 902 KAR Chapter 100 shall keep records showing the receipt, transfer, and disposal of radioactive material.

(2)(a) Records of receipt of radioactive material that are required by subsection (1) of this section shall be maintained as long as the licensee retains possession of the radioactive material and for two (2) years following transfer or disposal of the radioactive material.

(b) Records of transfer of radioactive material shall be maintained by the licensee who transferred the material for five (5) years after the transfer.

(c) Records of disposal of radioactive material shall be maintained in accordance with 902 KAR 100:021.

(3) Other records required by 902 KAR Chapter 100 or by a license condition shall be maintained for the period specified in 902 KAR Chapter 100. If the retention period is not specified by 902 KAR Chapter 100 or a license condition, the records shall be permanently maintained unless the cabinet authorizes disposition upon proper application for destruction.

(4) Records required to be maintained by 902 KAR Chapter 100 shall be:

(a) The original, a reproduced copy, or a microform if duly authenticated by authorized personnel and capable of producing a clear and legible copy after storage for the period specified by 902 KAR Chapter 100; or

(b) In electronic media with the capability for producing legible, accurate, and complete records during the required retention period.

(5) Records, including letters, drawings, and specifications, shall include pertinent authentication stamps, initials, or signatures. The licensee shall maintain adequate safeguards against tampering with, and loss of, records.

Section 15. Reporting Requirements. (1) Immediate report. A licensee shall notify the Cabinet for Health and Family Services, Radiation Health Branch, no later than four (4) hours, after the discovery of an event that prevents or overcomes immediate protective actions necessary to avoid exposure to radiation or radioactive materials or a release of radioactive materials that may exceed regulatory limits. An event includes a fire, explosion, or toxic gas release.

(2) Twenty-four (24) hour report. A licensee shall notify the Cabinet for Health and Family

Services, Radiation Health Branch within twenty-four (24) hours after the discovery of an event involving radioactive material, as follows:

(a) An unplanned contamination event that:

1. Requires access to the contaminated area, by workers or the public, to be restricted for more than twenty-four (24) hours by imposing additional radiological controls or by prohibiting entry into the area;

2. Involves a quantity of material greater than five (5) times the lowest annual limit on intake specified in 10 C.F.R. 20, Appendix B, for the material; and

3. Requires access to the area restricted for a reason other than to allow isotopes with a half-life of less than twenty-four (24) hours to decay prior to decontamination;

(b) An event in which equipment is disabled or fails to function as designed, if:

1. The equipment is required by administrative regulation or license condition to prevent a release exceeding regulatory limits, to prevent an exposure to radiation or radioactive material exceeding regulatory limits, or to mitigate the consequences of an accident;

2. The equipment is required to be available and operable if it is disabled or fails to function; and

3. Redundant equipment is not available and operable to perform the required safety function;

(c) An event that requires unplanned medical treatment, at a medical facility, of an individual with spreadable radioactive contamination on the individual's clothing or body; or

(d) An unplanned fire or explosion damaging radioactive material or a device, container, or equipment containing radioactive material, if:

1. The quantity of material involved is greater than five (5) times the lowest annual limit on intake specified in 10 C.F.R. 20, Appendix B, for the radioactive material; and

2. The damage affects the integrity of the radioactive material or its container.

(3) A report by a licensee in response to the requirements of this section shall be made as follows:

(a) A licensee shall make a report as required by subsections (1) and (2) of this section by telephone to the Cabinet for Health and Family Services, Radiation Health Branch at (502) 564-3700 from 8 a.m.-4:30 p.m. Eastern Time Monday through Friday, or at (800) 255-2587 at other hours. To the extent that the information is available at the time of notification, the information provided in these reports shall include:

1. The caller's name and call back telephone number;

2. A description of the event, including date and time;

3. The exact location of the event;

4. The isotopes, quantities, and chemical and physical form of the radioactive material involved; and

5. Available personnel radiation exposure data.

(b) A licensee who makes a telephone report shall submit a written follow-up report within thirty (30) days of the initial report. A written report prepared pursuant to another administrative regulation of 902 KAR Chapter 100 may be submitted to fulfill this requirement, if the report contains the necessary information and the appropriate distribution is made. The report shall be sent to the Manager, Radiation Health Branch, 275 East Main Street, Frankfort, Kentucky 40621. The report shall include the following:

1. A description of the event, including the probable cause and the manufacturer and model number, if applicable, of equipment that failed or malfunctioned;

2. The exact location of the event;

3. The isotopes, quantities, and chemical and physical form of the radioactive material involved;

4. Date and time of the event;
5. Corrective actions taken or planned and results of evaluations or assessments; and
6. The extent of every exposure of every individual to radiation or to a radioactive material, without identification of any individual by name.

Section 16. Material Incorporated by Reference. (1) The following material is incorporated by reference:

(a) Cabinet for Health and Family Services Form RPS-7 "Application for Radioactive Material License", 6/2011;

(b) Cabinet for Health and Family Services Form RPS-10 "Disposition of Radioactive Material" 3/2011; and

(c) "Annual Low Level Radioactive Waste (LLRW) Report", 3/2011.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Office of the Commissioner of Public Health, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m.902 KAR 100:040 General provisions for specific licenses. (1 Ky.R. 394; eff. 2-5-75; Am. 3 Ky.R. 413; eff. 12-1-76; 12 Ky.R. 1017; eff. 1-3-86; 16 Ky.R. 2542; eff. 6-27-90; 19 Ky.R. 1916; 2437; eff. 4-21-93; 21 Ky.R. 2298; eff. 4-19-95; 22 Ky.R. 2483; eff. 8-1-96; 23 Ky.R. 3988; eff. 8-20-97; 26 Ky.R. 2382; 27 Ky.R. 793; eff. 9-11-2000; 38 Ky.R. 372; 949; eff. 11-16-11.)