CABINET FOR HEALTH AND FAMILY SERVICES
Department for Public Health
Division of Public Health Protection and Safety
(Amended After Comments)

902 KAR 100:050. General licenses.

RELATES TO: KRS 194A.005, 211.842-211.852, 211.990(4), 10 C.F.R. Part 31, 42 U.S.C. 2021

STATUTORY AUTHORITY: KRS 194A.050(1), ~~[211.090,]~~211.844

NECESSITY, FUNCTION, AND CONFORMITY: KRS 194A.050(1) requires the secretary to promulgate, administrative regulations necessary to implement programs mandated by federal law, to qualify for the receipt of federal funds, and to cooperate with other state and federal agencies. KRS 211.844 authorizes the cabinet ~~[for Human Resources is empowered by KRS 211.844]~~to provide by regulation for the registration and licensing of the possession or use of any source of ionizing or electronic product radiation and the handling and disposal of radioactive waste. ~~[The purpose of]~~This administrative regulation establishes~~[is to provide for]~~ the general licensing requirements for~~[of]~~ certain uses of radioactive material and specific devices containing radioactive material.

Section 1. Definitions.

(1) "Agreement state" means a state that the United States Nuclear Regulatory Commission (NRC) or the United States Atomic Energy Commission has entered into an effective agreement under subsection 274 b. of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2021(b) et seq.).

(2) "Cabinet" is defined by KRS 194A.005(1).

(3) "Licensee" means a person who holds:

(a) A specific license issued by the cabinet pursuant to 902 KAR 100:040 and this administrative regulation;

(b) A specific license issued by the U.S. Nuclear Regulatory Commission or an agreement state; or

(c) A general license pursuant to this administrative regulation or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state.

Section 2. Applicability. ~~[The provisions of]~~This administrative regulation establishes the requirements for licensees~~[apply to persons]~~ who manufacture or use radioactive material under a general license. Except as established in subsections (1) through (4) of this section, the licensee shall comply with 10 C.F.R. Part 31.

(1) The licensee shall not be subject to:

(a) 10 C.F.R. 31.4;

(b) 10 C.F.R. 31.22; or

(c) 10 C.F.R. 31. 23.

(2) Application for specific license. Each application for a specific license shall be filed pursuant to 902 KAR 100:040.

(3)

(a) Reference to the NRC, Commission, or an agreement state shall be deemed to reference the Cabinet for Health and Family Services, Department for Public Health, Radiation Health Branch ~~**[ ], the NRC, or an agreement state]**~~ **.**

(b) In 10 C.F.R. 31.5(b)(1)(ii), 31.5(c)(3)(ii), 31.5(c)(8)(i), 31.6, 31.7(a), 31.10(a), 31.10(b)(1), and 31.12(c)(4), reference to "an agreement state", shall be deemed to be a reference to "the NRC, or an agreement state".

(c) In 10 C.F.R. 31.6, reference to "any non-agreement state" or "offshore waters" shall be deemed a reference to the "Commonwealth of Kentucky".

(4) Notifications and reports required by 10 C.F.R. Part 31 shall be directed to the manager, Radiation Health Branch at:

(a) 275 East Main Street, Mailstop HS1-C-A, Frankfort, Kentucky 40621;

(b) (502) 564-1492: Facsimile;

(c) (502) 564-3700: Telephone, Monday through Friday, 8 a.m. to 4:30 p.m.; or

(d) (800) 225-2587: Telephone, for hours except those established in paragraph (c) of this subsection. ~~[as provided under this administrative regulation.]~~

~~[Section 2.] [General Licenses; Source Material.]~~

~~[(1)] [A general license is hereby issued authorizing commercial and industrial firms, research, educational and medical institutions, and state and local government agencies to use and transfer not more than fifteen (15) pounds of source material at any time for research, development, educational, commercial, or operational purposes. A person authorized to use or transfer source material pursuant to this general license may not receive more than a total of 150 pounds of source material in any one (1) calendar year:]~~

~~[(2)] [Persons who receive, possess, use or transfer source material pursuant to the general license issued in subsection (1) of this section are exempt from the provisions of these administrative regulations to the extent that such receipt, possession, use, or transfer is within the terms of such general license; provided, however, that this exemption shall not be deemed to apply to any person who is also in possession of source material under a specific license issued pursuant to these administrative regulations.]~~

~~[(3)] [A general license is hereby issued authorizing the receipt of title of source material without regard to quantity. The general license under this subsection does not authorize any person to receive, possess, use, or transfer source material.]~~

~~[(4)] [Depleted uranium in industrial products and devices.]~~

~~[(a)] [A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of this subsection, depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.]~~

~~[(b)] [The general license applies only to industrial products or devices which have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to 902 KAR 100:058 or in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission or an Agreement State which authorizes manufacture of the products or devices for distribution to persons generally licensed by the U.S. Nuclear Regulatory Commission or an Agreement State.]~~

~~[(c)]~~

~~[1.] [Persons who receive, acquire, possess, or use depleted uranium pursuant to this general license shall notify the cabinet. The notification shall be submitted within thirty (30) days after the first receipt or acquisition of such depleted uranium. The general licensee shall furnish the following information and such other information as may be required:]~~

~~[a.] [Name and address of the general licensee;]~~

~~[b.] [A statement that the general licensee has developed and will maintain procedures designed to establish physical control over the depleted uranium and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and]~~

~~[c.] [Name and/or title, address, and telephone number of the individual duly authorized to act for and on behalf of the general licensee in supervising the procedures.]~~

[2.] [The general licensee possessing or using depleted uranium under this general license shall report in writing to the cabinet any changes in information furnished by the notification. The report shall be submitted within thirty (30) days after the effective date of such change.]

[(d)] [A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by paragraph (a) of this subsection;]

[1.] [Shall not introduce such depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium;]

[2.] [Shall not abandon such depleted uranium;]

[3.] [Shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of 902 KAR 100:040. In the case where the transferee receives the depleted uranium pursuant to the general license established by this subsection, the transferor shall furnish the transferee a copy of this administrative regulation. In the case where the transferee receives the depleted uranium pursuant to a general license contained in the U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent, the transferor shall furnish the transferee a copy of this administrative regulation accompanied by an note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or Agreement State under requirements substantially the same as those in this administrative regulation;]

[4.] [Within thirty (30) days of any transfer, shall report in writing to the cabinet the name and address of the person receiving the depleted uranium pursuant to such transfer; and]

[5.] [Shall not export such depleted uranium except in accordance with a license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 110.]

[(e)] [Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by this subsection is exempt from the requirements of 902 KAR 100:020 and 902 KAR 100:165 of these administrative regulations with respect to the depleted uranium covered by that general license.]

[Section 3.] [General Licenses; Radioactive Material Other than Source Material.]

[(1)] [A general license is hereby issued to transfer, receive, acquire, own, possess, and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission for use pursuant to 10 CFR Part 31.3;]

[(a)] [Static elimination device. Devices designed for use as static eliminators which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries of polonium-210 per device; and]

[(b)] [Ion generating tube. Devices designed for ionization of air which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries of polonium-210 per device or a total of not more than fifty (50) millicuries of hydrogen-3 (tritium) per device.]

[(2)] [The general license provided in subsection (1) of this section is subject to all applicable provisions of these administrative regulations including provisions relating to the labeling of containers.]

[(3)] [Certain measuring, gauging or controlling devices.]

[(a)] [A general license is hereby issued to commercial, and industrial firms and to research, educational and medical institutions, individuals in the conduct of their business, and state or local government agencies to own, receive, acquire, possess, use or transfer in accordance with the provisions of this subsection, radioactive material,

~~excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.]~~

~~[(b)] [The general license in this subsection applies only to radioactive material contained in devices which have been manufactured and labeled in accordance with the specifications contained in a specific license issued by the cabinet pursuant to 902 KAR 100:058 or in accordance with the specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement State which authorizes distribution of devices to persons generally licensed by the U.S. Nuclear Regulatory Commission or an Agreement State. Regulations under the Federal Food, Drug, and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling thereon which is found in 21 CFR Part 179.21.]~~

~~[(c)] [Any person who owns, receive, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general license in this subsection:]~~

~~[1.] [Shall assure 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 thereon and shall comply with all instructions and precautions provided by such labels;]~~

~~[2.] [Shall assure 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 (6) month intervals or at such other intervals as are specified in the label; however,]~~

~~[a.] [Devices containing only krypton need not be tested for leakage of radioactive material, and]~~

~~[b.] [Devices containing only tritium or not more than 100 microcuries of other beta and/or gamma-emitting material or ten (10) microcuries of alpha-emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;]~~

~~[3.] [Shall assure that other testing, installation, servicing, and removal from installation involving the radioactive material, its shielding or containment, are performed:]~~

~~[a.] [In accordance with the instructions provided by the labels; or]~~

~~[b.] [By a person holding an applicable specific license from the cabinet, the U.S. Nuclear Regulatory Commission or an Agreement State to perform such activities;]~~

~~[4.] [Shall maintain records showing compliance with the requirements of this subsection. The records shall show the results of tests. The records also shall show the names of persons and dates of performance of testing, installation, servicing, and removal from installation concerning the radioactive material, its shielding or containment. Records of tests for leakage of radioactive material shall be maintained for one (1) year after the next required leak test is performed or until the sealed source is transferred or disposed. Records of tests of the "on-off" mechanism and indicator shall be maintained for one (1) year after the next required test of the "on-off" mechanism and indicator is performed or until the sealed source is transferred or disposed. Records which are required by subparagraph 3 of this paragraph shall be maintained for a period of two (2) years from the date of the recorded event or until the device is transferred or disposed;]~~

~~[5.] [Upon the occurrence of 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, shall immediately suspend operation of the device~~

~~until it has been repaired by the manufacturer or other person holding an applicable specific license from the cabinet, the U.S. Nuclear Regulatory Commission or an Agreement State to repair such devices, or disposed of by transfer to a person authorized by an applicable specific license to receive the radioactive material contained in the device and, within thirty (30) days, furnish to the cabinet a report containing a brief description of the event and the remedial action taken;]~~

~~[6.] [Shall not abandon the device containing radioactive material;]~~

~~[7.] [Except as provided in subparagraph 8 of this paragraph, shall transfer or dispose of the device containing radioactive material only by transfer to a specific licensee of the cabinet, the U.S. Nuclear Regulatory Commission or an Agreement State whose specific license authorizes him to receive the device and within thirty (30) days after transfer of a device to a specific licensee shall furnish to the cabinet a report containing identification of the device by manufacturer's name and model number and the name and address of the person receiving the device. No report is required if the device is transferred to the specific licensee in order to obtain a replacement device;]~~

~~[8.] [Shall transfer the device to another general licensee only:]~~

~~[a.] [Where the device remains in use at a particular location. In such case the transferor shall give the transferee a copy of this administrative regulation and any safety documents identified in the label on the device and within thirty (30) days of the transfer, report to the cabinet the manufacturer's name and model number of device transferred, the name and address of the transferee, and the name and/or position of an individual who may constitute a point of contact between the cabinet and the transferee; or]~~

~~[b.] [Where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee; and]~~

~~[9.] [Shall comply with the provisions of 902 KAR 100:020 for reporting radiation incidents, theft, or loss of licensed material, but shall be exempt from the other requirements of 902 KAR 100:020 and 902 KAR 100:165.]~~

~~[(d)] [The general license in this subsection does not authorize the manufacture of devices containing radioactive material.]~~

~~[(e)] [The general license provided in this subsection is subject to the provisions of 902 KAR 100:012, 902 KAR 100:015, 902 KAR 100:040, Sections 7, 13 and 14 and 902 KAR 100:070.]~~

~~[(f)] [A general license is hereby issued to any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement State authorizing the holder to manufacture, install, or service a device described in this subsection to install and service such device provided:]~~

~~[1.] [The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the U.S. Nuclear Regulatory Commission or an Agreement State; and]~~

~~[2.] [Such person assures that any labels required to be affixed to the device under regulations of U.S. Nuclear Regulatory Commission or an Agreement State which licensed manufacture of the device bear a statement that removal of the label is prohibited.]~~

~~[(4)] [Luminous safety devices for aircraft.]~~

~~[(a)] [A general license is hereby issued to own, receive, acquire, possess, and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided:]~~

~~[1.] [Each device contains not more than ten (10) curies of tritium or 300 millicuries of promethium-147; and]~~

[2.] [Each device has been manufactured, assembled, or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the cabinet or any Agreement State to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in Section 32.53 of 10 CFR, Part 32, of the regulations of the U.S. Nuclear Regulatory Commission.]

[(b)] [Persons who own, receive, acquire, possess, or use luminous safety devices pursuant to the general license in paragraph (a) of this subsection are exempt from the requirements of 902 KAR 100:020 and 902 KAR 100:165 except that they shall comply with the provisions relating to reports of theft or loss of sources of radiation and the provisions relating to notification of incidents.]

[(c)] [This general license does not authorize the manufacture, assembly, or repair of luminous safety devices containing tritium or promethium-147.]

[(d)] [This general license does not authorize the ownership, receipt, acquisition, possession or use of promethium-147 contained in instrument dials.]

[(e)] [This general license is subject to the provisions of 902 KAR 100:015, 902 KAR 100:040, Sections 7, 13, and 14 and 902 KAR 100:070.]

[(5)] [Calibration and reference sources.]

[(a)] [A general license is hereby issued to those persons listed below to own, receive, acquire, possess, use, and transfer, in accordance with the provisions of paragraphs (d) and (e) of this subsection, americium-241 in the form of calibration or reference sources:]

[1.] [Any person who holds a specific license issued by the cabinet which authorizes him to receive, possess, use, and transfer radioactive material; and]

[2.] [Any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission which authorizes him to receive, possess, use, and transfer special nuclear material.]

[(b)] [A general license is hereby issued to receive, possess, use, and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of paragraphs (d) and (e) of this subsection to any person who holds a specific license issued by the cabinet which authorizes him to receive, possess, use, and transfer radioactive material.]

[(c)] [A general license is hereby issued to own, receive, possess, use, and transfer radium-226 in the form of calibration or reference sources in accordance with the provisions of paragraphs (d) and (e) of this subsection to any person who holds a specific license issued by the cabinet which authorizes him to receive, possess, use, and transfer radioactive material.]

[(d)] [The general license in paragraphs (a), (b) and (c) of this subsection apply only to calibration or reference sources which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the U.S. Nuclear Regulatory Commission pursuant to Section 32.57 of 10 CFR, Part 32, or Section 70.39 of 10 CFR, Part 70, or which may have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the cabinet or any Agreement State pursuant to licensing requirements equivalent to those contained in 902 KAR 100:058.]

[(e)] [Persons who own, receive, acquire, possess, use, and transfer one (1) or more calibration or reference sources pursuant to these general licenses:]

[1.] [Shall not possess at any one (1) time, at any one (1) location of storage or use, more than five (5) microcuries of americium 241, five (5) microcuries of plutonium or five (5) microcuries of radium-226 in such sources;]

[2.] [Shall not receive, possess, use, or transfer such source unless the source, or the storage container, bears a label which includes the following statement or a substantially similar statement which contains the information called for in the following statement: "The receipt, possession, use and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of the U.S. Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label. CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS (AMERICIUM-241). (PLUTONIUM) (RADIUM-226)*. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE. Name of Manufacturer or Importer" *Showing only the name of the appropriate material.]

[3.] [Shall not transfer, abandon, or dispose of such source except by transfer to a person authorized by a license from the cabinet, U.S. Nuclear Regulatory Commission, or an Agreement State to receive the source;]

[4.] [Shall store such source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241, plutonium or radium-226 which might otherwise escape during storage; and]

[5.] [Shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.]

[(f)] [The general licenses provided in paragraphs (a), (b) and (c) of this subsection are subject to the provisions of 902 KAR 100:015, 902 KAR 100:020, 902 KAR 100:040, Sections 7, 13, and 14, 902 KAR 100:070, and 902 KAR 100:165.]

[(g)] [These general licenses do not authorize the manufacture of calibration or reference sources containing americium-241, plutonium, or radium-226.]

[(6)] [A general license is hereby issued to own radioactive material without regard to quantity. The general license under this subsection does not authorize the licensee to manufacture, produce, transfer, receive, possess, or use radioactive material.]

[(7)] [Ice detection devices.]

[(a)] [A general license is hereby issued to own, receive, acquire, possess, use, and transfer strontium-90 contained in ice detection devices, provided each device contains not more than fifty (50) microcuries of strontium-90 and each device has been manufactured or imported in accordance with a specific license, issued by the U.S. Nuclear Regulatory Commission or each device has been manufactured in accordance with the specifications contained in a specific license issued by the cabinet or any Agreement State to the manufacturer of such device pursuant to licensing requirements equivalent to those in 902 KAR 100:058.]

[(b)] [Persons who own, receive, acquire, possess, use, or transfer strontium-90 contained in ice detection devices pursuant to the general license in paragraph (a) of this subsection:]

[1.] [Shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating to the device, discontinue use of the device until it has been inspected, tested for leakage, and repaired by a person holding a specific license from the cabinet, U.S. Nuclear Regulatory Commission or an Agreement State to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of these administrative regulations;]

[2.] [Shall assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon;]

[3.] [Are exempt from the other requirements of these administrative regulations except that such persons shall comply with 902 KAR 100:015, 902 KAR 100:020, Sections 16 and 17, 902 KAR 100:021, 902 KAR 100:040, Sections 7, 13, and 14 and 902 KAR 100:070.]

[(c)] [This general license does not authorize the manufacture, assembly, disassembly or repair of strontium-90 sources in ice detection devices.]

[Section 4.] [General License for use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing.]

[(1)] [A general license is hereby issued to any physician, veterinarian, clinical laboratory, or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of subsections (2), (3), (4), (5), and (6) of this section, the following radioactive materials in prepackaged units for use in In Vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:]

[(a)] [Iodine-125, in units not exceeding ten (10) microcuries each.]

[(b)] [Iodine-131, in units not exceeding ten (10) microcuries each.]

[(c)] [Carbon-14, in units not exceeding ten (10) microcuries each.]

[(d)] [Hydrogen-3 (Tritium), in units not exceeding fifty (50) microcuries each.]

[(e)] [Iron-59, in units not exceeding twenty (20) microcuries each.]

[(f)] [Cobalt-57, in units not exceeding ten (10) microcuries each.]

[(g)] [Mock iodine-125 reference or calibration sources, in units not exceeding 0.05 microcurie of iodine-29 and 0.005 microcurie of americium-241 each.]

[(h)] [Selenium-75, in units not exceeding ten (10) microcuries each.]

[(2)] [No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by subsection (1) of this section until he has filed form KR-251, "Registration Certificate – In Vitro Testing" with the cabinet and received from the cabinet a validated copy of form KR-251 with certification number assigned. The physician, veterinarian, clinical laboratory, or hospital shall furnish on form KR-251, the following information and such other information as may be required by that form:]

[(a)] [Name and address of the physician, veterinarian, clinical laboratory, or hospital;]

[(b)] [The location of use; and]

[(c)] [A statement that the physician, veterinarian, clinical laboratory, or hospital has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive materials as authorized under the general license in subsection (1) of this section and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.]

[(3)] [A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by subsection (1) of this section shall comply with the following:]

[(a)] [The general licensee shall not possess at any one (1) time, pursuant to the general license in subsection (1) of this section, at any one (1) location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, cobalt-57 and/or iron-59 in excess of 200 microcuries.]

[(b)] [The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.]

[(c)] [The general licensee shall use the radioactive material only for the uses authorized by subsection (1) of this section.]

[(d)] [The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the cabinet, the U.S. Nuclear Regulatory Commission, or any Agreement State, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.]

[(e)] [The general licensee shall dispose of the Mock iodine-125 reference or calibration sources as required by 902 KAR 100:021, Section 2.]

[(4)] [The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to subsection (1) of this section:]

[(a)] [Except as prepackaged units which are labeled in accordance with the provisions of a specific license issued under these administrative regulations or in accordance with the provisions of an applicable specific license issued pursuant to 902 KAR 100:058 or in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission, or any Agreement State which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), selenium-75, cobalt-57, Mock iodine-125 or iron-59 to persons generally licensed under subsection (1) of this section or its equivalent;]

[(b)] [Unless the following statement, or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package: "This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a state with which the commission has entered into an agreement for the exercise of regulatory authority. Name of Manufacturer]

[(5)] [The physician, veterinarian, clinical laboratory, or hospital possessing or using radioactive material under the general license of subsection (1) of this section shall report in writing to the cabinet, any changes in the information furnished by him in the "Registration Certificate - In Vitro Testing," form KR-251. The report shall be furnished within thirty (30) days after the effective date of such change.]

[(6)] [Any person using radioactive material pursuant to the general license of subsection (1) of this section is exempt from the requirements 902 KAR 100:020, 902 KAR 100:021, and 902 KAR 100:165, except that such person using the Mock-iodine 125 shall comply with the provisions of 902 KAR 100:020, Sections 16 and 17 and 902 KAR 100:021.]

[(7)] [Any licensee who is licensed pursuant to 902 KAR 100:073 for medical use of radioactive material also is authorized to use radioactive material under the general license in this section for the specified in vitro uses without filing form KR-251 as required; provided, that the licensee is subject to the other provisions of this section.]

[Section 5.] [General License for Medical Diagnostic Uses.]

[(1)] [A general license is hereby issued to any physician to receive, possess, transfer, or use radioactive material set forth below for the stated diagnostic uses, provided, however, that the use is in accordance with the provisions of subsections (2), (3), and (4) of this section, the radioactive material is in the form of capsules, disposable syringes, or other prepackaged individual doses; and the radioactive material has been manufactured in accordance with a specific license issued by the cabinet pursuant to 902 KAR 100:058, or by the U.S. Nuclear Regulatory Commission or any Agreement State pursuant to equivalent regulations authorizing distribution to persons generally licensed pursuant to this subsection or its equivalent:]

[(a)] [Iodine-131 as sodium iodide for measurement of thyroid uptake;]

[(b)] [Iodine-131 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume;]

[(c)] [Iodine-125 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume;]

[(d)] [Cobalt-57 for the measurement of intestinal absorption of cyanocobalamin;]

[(e)] [Cobalt-58 for the measurement of intestinal absorption of cyanocobalamin;]

[(f)] [Cobalt-60 for the measurement of intestinal absorption of cyanocobalamin;]

[(g)] [Chromium-51 as sodium radiochromate for determination of red blood cell volumes and studies of red blood cell survival time.]

[(2)] [Manufacturers of radiopharmaceuticals which are under a general license shall affix a certain identifying label to the container or in the leaflet or brochure which accompanies the radiopharmaceutical as otherwise provided in these administrative regulations.]

[(3)] [No physician shall receive, possess, use, or transfer radioactive material pursuant to the general license established by subsection (1) of this section until he has filed form KR-252, "Registration Certificate - Medical Use of Radioactive Material" with the cabinet and received from the cabinet a validated copy of the form KR-252 with certification number assigned. The generally licensed physician shall furnish on form KR-252 the following information and such other information as may be required by that form:]

[(a)] [Name and address of the generally licensed physician;]

[(b)] [A statement that the generally licensed physician is a duly licensed physician authorized to dispense drugs in the practice of medicine in the state of Kentucky and specifying the license number; and]

[(c)] [A statement that the generally licensed physician has appropriate radiation measuring instruments to carry out the diagnostic procedures for which he proposes to use the radioactive material under the general license of this section and that he is competent in the use of such instruments.]

[(4)] [A physician who receives, possesses or uses a pharmaceutical containing radioactive material pursuant to the general license established by subsection (1) of this section shall comply with the following:]

[(a)] [He shall not possess at any one time pursuant to the general license in subsection (1) of this section more than:]

[1.] [200 microcuries of iodine-131;]

[2.] [200 microcuries of iodine-125;]

[3.] [Five (5) microcuries of cobalt-57;]

[4.] [Five (5) microcuries of cobalt-60;]

[5.] [Five (5) microcuries of cobalt-58; and]

[6.] [200 microcuries of chromium-51.]

[(b)] [He shall store the pharmaceutical, until administered, in the original shipping container or a container providing the equivalent radiation protection.]

[(c)] [He shall use the pharmaceutical only for the uses authorized by subsection (1) of this section.]

[(d)] [He shall not administer the pharmaceutical to a woman with confirmed pregnancy or to a person under eighteen (18) years of age.]

[(e)] [He shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the cabinet, the U.S. Nuclear Regulatory Commission or any Agreement State, or in any manner other than in the unopened, labeled shipping container as received from the supplier, except by administering it to a patient.]

[(5)] [The generally licensed physician possessing or using radioactive material under the general license of subsection (1) of this section shall report to the cabinet, any changes in the information furnished by him in the "Registration Certificate - Medical Use of Radioactive Material," form KR-252. The report shall be submitted within thirty (30) days after the effective date of change.]

[(6)] [Any person using radioactive material pursuant to the general license of subsection (1) of this section is exempt from the requirements of 902 KAR 100:020, 902 KAR

~~100:021 and 902 KAR 100:165.]~~
(1 Ky.R. 397; eff. 2-5-1975; 12 Ky.R. 1023; eff. 1-3-1986; 16 Ky.R. 2546; eff. 6-27-1990; Crt eff. 8-16-2019; 50 Ky.R. 199, 1141; eff, 12-13-2023.)

STEVEN J. STACK, Commissioner
ERIC C. FRIEDLANDER, Secretary

APPROVED BY AGENCY: October 11, 2023
FILED WITH LRC: October 12, 2023 at 9:30 a.m.
CONTACT PERSON: Krista Quarles, Policy Analyst, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; phone 502-564-6746; fax 502-564-7091; email CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person:Krista Quarles

(1) Provide a brief summary of:

(a) What this administrative regulation does:
This administrative regulation establishes the general licensing requirements for certain uses of radioactive material and specific devices containing radioactive material.

(b) The necessity of this administrative regulation:
This administrative regulation identifies alternate licensing criteria for lower activities and specific uses of radioactive materials.

(c) How this administrative regulation conforms to the content of the authorizing statutes:
KRS 211.844 requires the cabinet to provide by administrative regulation the requirements for the licensing, use, and disposal of radioactive materials.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:
This administrative regulation ensures all those engaged in the licensing, use, transfer, and disposal of radioactive source material meet the regulatory requirements.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation:
The amendment to this administrative regulation adopts by reference the requirements of 10 C.F.R. Part 31. The amended after comments version amends section 2 for clarification of the notification requirements.

(b) The necessity of the amendment to this administrative regulation:
As an agreement state with the Nuclear Regulatory Commission (NRC), Kentucky is required to have state regulations compatible with the regulations promulgated by NRC. This change will make the Radiation Health Branch (RHB) compatible with applicable requirements of 10 C.F.R. Part 31.

(c) How the amendment conforms to the content of the authorizing statutes:
KRS 211.842(1) and (2) establish the cabinet as the radiation control agency of the state of Kentucky and authorize the cabinet to issue licenses pertaining to radioactive materials and require registration of other sources of ionizing radiation.

(d) How the amendment will assist in the effective administration of the statutes:
The amendment to this administrative regulation ensures all licensees who have a general license for certain uses of radioactive material and specific devices containing radioactive material are in full compliance with state and federal requirements.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation:
There are currently 118 licenses issued for certain uses of radioactive material and specific devices containing radioactive material.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment:

No additional actions will be needed by the licensee to comply with this administrative regulation.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3):

There is a minimal cost to the cabinet associated with updating references.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3):

Adopting 10 C.F.R. Part 31 by reference will reduce the redundancy between state and federal requirements. This will reduce the time needed to research applicable regulations and make it easier for the licensee to review existing guidance documents.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially:

This is an ongoing program there are no initial costs.

(b) On a continuing basis:

This administrative regulation does not impact costs for the agency.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation:

The Radiation Health Branch is funded through a mix of state general fund dollars and the various fees associated with issuing licenses.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment:

An increase in fees or funding is not needed to implement the amendment to this administrative regulation.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees:

There are no fees associated with this administrative regulation.

(9) TIERING: Is tiering applied?

Tiering is not applied. The requirements of this administrative regulation are applied equally to all licensees.

FISCAL NOTE

(1) What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation?

The Radiation Health Branch within the Department for Public Health will be impacted by this administrative regulation.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation.

KRS 194A.050(1) and 211.844.

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year?

This administrative regulation does not generate revenue.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years?

This administrative regulation does not generate revenue.

(c) How much will it cost to administer this program for the first year?

There is no impact on cost to the agency.

(d) How much will it cost to administer this program for subsequent years?

There is no impact to cost to the agency.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation:

(4) Estimate the effect of this administrative regulation on the expenditures and cost savings of regulated entities for the first full year the administrative regulation is to be in effect.

(a) How much cost savings will this administrative regulation generate for the regulated entities for the first year?

This administrative regulation may result in minimal cost savings for the regulated entities. The amendment to this administrative regulation reduces the administrative burden of having to research and follow duplicative state and federal requirements.

(b) How much cost savings will this administrative regulation generate for the regulated entities for subsequent years?

This administrative regulation may result in minimal cost savings for the regulated entities. The amendment to this administrative regulation reduces the administrative burden of having to research and follow duplicative state and federal requirements.

(c) How much will it cost the regulated entities for the first year?

This administrative regulation will have no impact on cost for the regulated entities.

(d) How much will it cost the regulated entities for subsequent years?

This administrative regulation will have no impact on cost for the regulated entities.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Cost Savings (+/-):

Expenditures (+/-):

Other Explanation:

(5) Explain whether this administrative regulation will have a major economic impact, as defined below.

"Major economic impact" means an overall negative or adverse economic impact from an administrative regulation of five hundred thousand dollars ($500,000) or more on state or local government or regulated entities, in aggregate, as determined by the promulgating administrative bodies. [KRS 13A.010(13)] This administrative regulation does not have a major economic impact.

FEDERAL MANDATE ANALYSIS COMPARISON

(1) Federal statute or regulation constituting the federal mandate.

Atomic Energy Act of 1954, 42 U.S.C. 2021, as amended, and 10 C.F.R. Part 31.

(2) State compliance standards.

As an agreement state with the Nuclear Regulatory Commission the state is required to have a program for the control of radiation hazards adequate to protect the public health and safety with respect to the materials within the state covered by the proposed agreement. The state is required to adopt compliance standards for the protection of the public health, safety, and the environment from hazards associated with such material which are equivalent, to the extent practicable, or more stringent than, standards adopted and enforced by the Commission for the same purpose.

(3) Minimum or uniform standards contained in the federal mandate.

In accordance with 42 U.S.C. 2021(g), the commission is authorized and directed to cooperate with the states in the formulation of standards for protection against hazards of radiation to assure that state and commission programs for protection against hazards of radiation will be coordinated and compatible. Pursuant to 42 U.S.C. 2021(a)(3) the purpose of this standard is to promote orderly regulatory pattern between the commission and state governments with respect to nuclear development and use and regulation of byproduct, source, and special nuclear materials.

(4) Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate?

No

(5) Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements.

Not applicable as there are no stricter standards, or additional or different responsibilities or requirements.