

1 CABINET FOR HEALTH AND FAMILY SERVICES

2 Department for Public Health

3 Division of Public Health Protection and Safety

4 (Amendment)

5 902 KAR 100:052. Specific domestic licenses of broad [Broad] scope for byproduct material
6 [licenses].

7 RELATES TO: KRS 211.842-211.852, 211.990(4), 10 C.F.R Part 33

8 STATUTORY AUTHORITY: KRS 194.050, 211.090, 211.844

9 NECESSITY, FUNCTION, AND CONFORMITY: The Cabinet for Health and Family
10 Services [~~Human Resources~~] is authorized by KRS 211.844 to provide by administrative
11 regulation for the registration and licensing of the possession or use of sources of ionizing
12 or electronic product radiation and the handling and disposal of radioactive waste. This
13 administrative regulation prescribes requirements for the issuance of specific licenses of
14 broad scope for byproduct [~~radioactive~~] material.

15 Section 1. Definitions. (1) “Cabinet” is defined by KRS 194A.005(1).

16 (2) “Licensee” means a person who holds:

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

19 (b) A specific license issued by the U.S. Nuclear Regulatory Commission or an
20 Agreement State; or

21 (c) A general license pursuant to 902 KAR 100:050 or equivalent regulations of the

1 U.S. Nuclear Regulatory Commission or an Agreement State.

2 Section 2. Applicability. This administrative regulation establishes requirements for
3 specific licensees to possess, use or transfer byproduct [radioactive] material for licenses
4 of broad scope. Except as established in subsections (1) through (3) of this section, the
5 licensee shall comply with 10 C.F.R. Part 33.

6 (1) The licensee shall not be subject to:

7 (a) 10 C.F.R. 33.8;

8 (b) 10 C.F.R. 33.21; and

9 (c) 10 C.F.R. 33.23.

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

12 (3) The "Cabinet for Health and Family Services, Department for Public Health, Radiation
13 Health Branch" shall be used in lieu of federal references to the "Commission" and the "NRC."

14 ~~[Section 2. Types of Specific Licenses of Broad Scope. (1) A "Type A specific license~~
15 ~~of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession,~~
16 ~~use and transfer of a chemical or physical form of the radioactive material specified in the~~
17 ~~license, but not exceeding quantities specified in the license, for any authorized purpose.~~
18 ~~The quantities specified are usually in the multicurie range.~~

19 ~~(2) A "Type B specific license of broad scope" is a specific license authorizing receipt,~~
20 ~~acquisition, ownership, possession, use and transfer of a chemical or physical form of~~
21 ~~radioactive material specified in 902 KAR 100:090, relating to broad license quantities, for~~
22 ~~any authorized purpose. The possession limit for a Type B broad license, if only one (1)~~
23 ~~radionuclide is possessed, is the quantity specified for that radionuclide in Column I of the~~

1 table in Section 2 of 902 KAR 100:090. If two (2) or more radionuclides are possessed, the
2 possession limit for each is determined as follows: for each radionuclide, determine the
3 ratio of the quantity possessed to the applicable quantity specified in Column I of the table
4 in Section 2 of 902 KAR 100:090 for that radionuclide. The sum of the ratios for all
5 radionuclides possessed under the license shall not exceed unity.

6 (3) A "Type C specific license of broad scope" is a specific license authorizing receipt,
7 acquisition, ownership, possession, use and transfer of a chemical or physical form of
8 radioactive material specified in 902 KAR 100:090, relating to broad licensed quantities, for
9 any authorized purpose. The possession limit for a Type C broad license, if only one (1)
10 radionuclide is possessed, is the quantity specified for that radionuclide in Column II of the
11 table in Section 2 of 902 KAR 100:090. If two (2) or more radionuclides are possessed, the
12 possession limit is determined for each as follows: for each radionuclide determine the ratio
13 of the quantity possessed to the applicable quantity specified in Column II of the table in
14 Section 2 of 902 KAR 100:090 for that radionuclide. The sum of the ratios for all
15 radionuclides possessed under the license shall not exceed unity.

16 Section 3. Requirements for the Issuance of a Type A Specific License of Broad Scope.

17 An application for a Type A specific license of broad scope will be approved if:

18 (1) The applicant satisfies the general requirements specified in 902 KAR 100:040;

19 (2) The applicant has engaged in a reasonable number of activities involving the use of
20 radioactive material; and

21 (3) The applicant has established administrative controls and requirements relating to
22 organization, management, procedures, recordkeeping, material control and accounting,
23 and management review that are necessary to assure safe operations, including:

1 ~~(a) The establishment of a radiation safety committee composed of persons, such as a~~
2 ~~radiation safety officer, a representative of management, and persons trained and~~
3 ~~experienced in the safe use of radioactive materials;~~

4 ~~(b) The appointment of a radiation safety officer who is qualified by training and~~
5 ~~experienced in radiation protection, who is available for advice and assistance on~~
6 ~~radiological safety matters; and~~

7 ~~(c) The establishment of appropriate administrative procedures to assure control of~~
8 ~~procurement and use of radioactive material; completion of safety evaluation of proposed~~
9 ~~uses of radioactive material which take into consideration matters, such as the adequacy~~
10 ~~of facilities and equipment, training and experience of the user, and the operating or~~
11 ~~handling procedures; and review, approval, and recording by the radiation safety committee~~
12 ~~of safety evaluations of proposed uses prepared in accordance with this subsection prior~~
13 ~~to use of the radioactive material.~~

14 ~~Section 4. Requirements for the Issuance of a Type B Specific License of Broad Scope.~~

15 ~~An application for a Type B specific license of broad scope will be approved if:~~

16 ~~(1) The applicant satisfies the general requirements specified in 902 KAR 100:040; and~~

17 ~~(2) The applicant has established administrative controls and provisions relating to~~
18 ~~organization, management, procedures, recordkeeping, material control and accounting,~~
19 ~~and management review that are necessary to assure safe operations, including:~~

20 ~~(a) The appointment of a radiation safety officer who is qualified by training and~~
21 ~~experience in radiation protection, who is available for advice and assistance on~~
22 ~~radiological safety matters; and~~

23 ~~(b) The establishment of appropriate administrative procedures to assure control of~~

1 procurement and use of radioactive material; completion of safety evaluations or proposed
2 uses of radioactive materials which take into consideration such matters as the adequacy
3 of facilities and equipment, training and experience of the user, the operating or handling
4 procedures; and review, approval and recording by the radiation safety officer of safety
5 evaluations of proposed uses prepared in accordance with this subsection prior to use of
6 the radioactive material.

7 ~~Section 5. Requirements for the Issuance of a Type C Specific License of Broad Scope.~~

8 An application for a Type C specific license of broad scope shall be approved if:

9 (1) The applicant satisfies the general requirements specified in 902 KAR 100:040;

10 (2) The applicant submits a statement that radioactive material will be used only by, or
11 under the direct supervision of, individuals who have received:

12 (a) A college degree at the bachelor level, or equivalent training and experience, in the
13 physical or biological sciences or in engineering;

14 (b) At least forty (40) hours of training and experience in the safe handling of radioactive
15 materials, characteristics of ionizing radiation, units of radiation dose and quantities,
16 radiation detection instrumentation, biological hazards of exposure to radiation appropriate
17 to the type and forms of radioactive material to be used; and

18 (3) The applicant has established administrative controls and provisions relating to
19 procurement of radioactive material, procedures, recordkeeping, material control and
20 accounting, and management review necessary to assure safe operations.

21 ~~Section 6. Prohibited Acts and Conditions for Specific Licenses of Broad Scope. (1)~~

22 Unless otherwise specifically authorized by these administrative regulations, persons
23 licensed under this administrative regulation shall not:

1 ~~(a) Conduct tracer studies in the environment involving direct release of radioactive~~
2 ~~material;~~

3 ~~(b) Receive, acquire, own, possess, use, or transfer, devices containing 100,000 curies~~
4 ~~or more of radioactive material in sealed sources used for irradiation of materials;~~

5 ~~(c) Conduct activities for which a specific license issued by the cabinet under 902 KAR~~
6 ~~100:051 or 902 KAR 100:058 is required; or~~

7 ~~(d) Add or cause the addition of radioactive material to a food, beverage, cosmetic,~~
8 ~~drug, or other product designed for ingestion or inhalation by, or application to, a human~~
9 ~~being.~~

10 ~~(2) Each Type A specific license of broad scope issued under this administrative~~
11 ~~regulation shall be subject to the condition that radioactive material possessed under the~~
12 ~~license may only be used by, or under the direct supervision of, individuals approved by~~
13 ~~the licensee's radiation safety committee.~~

14 ~~(3) Each Type B specific license of broad scope issued under this administrative~~
15 ~~regulation shall be subject to the condition that radioactive material possessed under the~~
16 ~~license may only be used by, or under the direct supervision of, individuals approved by~~
17 ~~the licensee's radiation safety officer.~~

18 ~~(4) Each Type C specific license of broad scope issued under this administrative~~
19 ~~regulation shall be subject to the condition that radioactive material possessed under this~~
20 ~~license may only be used by, or under the direct supervision of, individuals who satisfy the~~
21 ~~requirements of Section 5 of this administrative regulation.]~~

902 KAR 100:052

REVIEWED:

Jeffrey D. Howard, Jr., M.D. Date
Commissioner, Department for Public Health

APPROVED:

Adam Meier, Date
Secretary, Cabinet for Health and Family Services

PUBLIC HEARING AND PUBLIC COMMENT PERIOD

A public hearing on this administrative regulation shall, if requested, be held on August 27, 2018, at 9:00 a.m. in Suites A & B, Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky, 40621. Individuals interested in attending this hearing shall notify this agency in writing by August 20, 2018, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on this proposed administrative regulation until August 31, 2018. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to the contact person. Pursuant to KRS 13A.280(8), copies of the statement of consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

CONTACT PERSON: Laura Begin, Legislative and Regulatory Analyst, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, KY 40621, Phone: 502-564-6746, Fax: 502-564-2767; Laura.Begin@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Administrative Regulation: 902 KAR 100:052

Agency Contact: Julie Brooks
Phone Number: (502) 564-3970
Email: julied.brooks@ky.gov

Contact Person: Laura Begin
Phone Number: (502) 564-6746
Email: laura.begin@ky.gov

Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes the requirements for the issuance of specific licenses of broad scope for byproduct material.

(b) The necessity of this administrative regulation: As an Agreement State with the authority to operate its radiation program, the Department for Public Health, Radiation Health Branch, is required to maintain a compatible set of regulations to those of the U.S. Nuclear Regulatory Commission (NRC) which govern the receipt, transfer, possession, use, and distribution of radioactive material in the Commonwealth.

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 194A.050(1) requires the secretary of the Cabinet for Health and Family Services to adopt administrative regulations necessary to protect the health of the individual citizens of the Commonwealth and necessary to operate the programs and fulfill the responsibilities vested in the Cabinet. KRS 211.844(1) requires the Cabinet to provide by administrative regulation for the registration and licensing of the possession or use of sources of ionizing or electronic product radiation and to regulate the handling and disposal of radioactive waste. This administrative regulation regulates the issuance of specific licenses of broad scope for byproduct material.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation ensures all those who possess or use sources of ionizing or electronic product radiation are properly licensed. By referencing the federal standards for broad scope licenses, affected entities do not have inconsistent state and federal requirements during the time it takes the Cabinet to amend state regulations.

(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: This amendment adopts by reference the applicable NRC regulations for licenses and radiation safety requirements for broad scope licenses.

(b) The necessity of the amendment to this administrative regulation: This amendment is necessary as the agreement between NRC and the Commonwealth requires the Radiation Health Branch to promulgate regulations that are compatible with NRC regulations.

(c) How the amendment conforms to the content of the authorizing statutes: The amendment is consistent with the authorizing statutes, which require the secretary to adopt regulations for the registration and licensing of the possession of any source of ionizing or electronic product radiation necessary to protect the public from unnecessary radiation exposure.

(d) How the amendment will assist in the effective administration of the statutes: Once the amendment is effective, Kentucky regulation will reference the most up-to-date requirements for the issuance of specific licenses of broad scope for byproduct material.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: Four (4) specific licensees and all future applicants for a specific license of broad scope.

(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 questions (3) will have to take to comply with this administrative regulation or amendment: No action is required.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the identities identified in question (3): There is no cost of compliance.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Regulated entities will be in full compliance with NRC regulations.

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

(a) Initially: This program is already operating. There is no cost to implement this administrative regulation.

(b) On a continuing basis: This program is already operating. There is no cost to implement this administrative regulation.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: This amendment does not affect funding.

(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: No increase in fees or funding is associated with this administrative regulation.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees. This amendment does not establish or increase any fees.

(9) TIERING: Is tiering applied? (Explain why or why not.) No. This administrative regulation affects all radioactive materials licensees subject to 902 KAR Chapter 100 regulations.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Administrative Regulation: 902 KAR 100:052

Agency Contact: Julie Brooks
Phone Number: (502) 564-3970
Email: julied.brooks@ky.gov

Contact Person: Laura Begin
Phone Number: (502) 564-6746
Email: laura.begin@ky.gov

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? Only the Radiation Health Branch in the Department for Public Health will be impacted by this administrative regulation as it contains reference to the federal regulation. There are no new requirements.

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) requires the secretary of the Cabinet for Health and Family Services to adopt administrative regulations necessary to protect the health of the individual citizens of the Commonwealth and necessary to operate the programs and fulfill the responsibilities vested in the Cabinet. KRS 211.844(1) requires the Cabinet to provide by administrative regulation for the registration and licensing of the possession or use of sources of ionizing or electronic product radiation and to regulate the handling and disposal of radioactive waste. 10 C.F.R. Part 33 contains the federal requirements that Kentucky must be consistent with.

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 generates no 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 generates no revenue.

(c) How much will it cost to administer this program for the first year? This administrative regulation does not add cost to the agency.

(d) How much will it cost to administer this program for subsequent years? This administrative regulation does not add 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:

FEDERAL MANDATE ANALYSIS COMPARISON

Regulation: 902 KAR 100:052

Contact Person: Julie Brooks, 502-564-3970, ext. 4069

1. Federal statute or regulation constituting the federal mandate. The Atomic Energy Act of 1954 as amended, the Energy Policy Act of 2005 and 10 C.F.R. Part 33.
2. State compliance standards. This regulation adopts the federal standards for the issuance of specific licenses of broad scope for radioactive material.
3. Minimum or uniform standards contained in the federal mandate. The federal mandate requires state regulations to be compatible with the equivalent federal regulations.
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. There are no different, stricter, or additional responsibilities or requirements.