

CABINET FOR HEALTH AND FAMILY SERVICES
Department for Public Health
Division of Public Health Protection and Safety
(New Administrative Regulation)

902 KAR 100:200. Licenses and radiation safety requirements for irradiators.

RELATES TO: KRS 194A.005(1), 211.180(1), 211.842-211.852, 211.990(4), 10 C.F.R. Part 36, 42 U.S.C. 2021(b)

STATUTORY AUTHORITY: KRS 194A.050(1), 211.844(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 194A.050(1) requires the secretary of the Cabinet for Health and Family Services to promulgate administrative regulations 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 the handling and disposal of radioactive waste. This administrative regulation establishes procedures, criteria, terms, and conditions upon which the cabinet issues licenses for special nuclear 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 902 KAR 100:050 or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state.

Section 2. Applicability. This administrative regulation shall apply to a licensee. Except as established in subsections (1) through (4) of this section, the licensee shall comply with 10 C.F.R. Part 36.

- (1) The licensee shall not be subject to:
 - (a) 10 C.F.R. 36.2, Definitions:
 1. Commencement of Construction (2); and
 2. Construction (9)(ii);
 - (b) 10 C.F.R. 36.8;
 - (c) 10 C.F.R. 36.91; and
 - (d) 10 C.F.R. 36.93.
- (2) Reference to the NRC, the 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.
- (3) Each application for a specific license shall be filed pursuant to this administrative regulation.
- (4) Notifications, reports, and correspondence required by 10 C.F.R. 36 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) 255-2587: Telephone, for hours except those established in paragraph (c) of this subsection.

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

APPROVED BY AGENCY: May 26, 2023

FILED WITH LRC: June 7, 2023 at 2:35 p.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on August 21, 2023, at 9:00 a.m. using the CHFS Office of Legislative and Regulatory Affairs Zoom meeting room. The Zoom invitation will be emailed to each requestor the week prior to the scheduled hearing. Individuals interested in attending this virtual hearing shall notify this agency in writing by August 14, 2023, 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 virtually 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, 2023. 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: 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 new administrative regulation establishes the requirements for the issuance of a license authorizing the use of sealed sources containing radioactive materials in irradiators used to irradiate objects or materials using gamma radiation. This part also contains radiation safety requirements for operating irradiators.

(b) The necessity of this administrative regulation:

This new administrative regulation is necessary to protect the public from improper use and disposal of radioactive source material.

(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 new 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:

This is a new administrative regulation.

(b) The necessity of the amendment to this administrative regulation:

This is a new administrative regulation.

(c) How the amendment conforms to the content of the authorizing statutes:

This is a new administrative regulation.

(d) How the amendment will assist in the effective administration of the statutes:

This is a new administrative regulation.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation:

The Radiation Health Branch within the Department for Public Health is the only entity affected by this new administrative regulation. There are no irradiators in Kentucky at this time, so no licensees will be affected.

(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:

There will be no new actions required for compliance with this new administrative regulation. Adopting 10 C.F.R. Part 36 by reference will expedite the process if a company desires to site an irradiator in Kentucky. There will be no impact to existing radioactive materials licensees.

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

There is no anticipated change in cost for existing regulated entities.

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

Adopting 10 C.F.R. Part 36 by reference will expedite the application process a new company will have to follow to perform irradiator work in Kentucky.

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

(a) Initially:

This new administrative regulation will not add cost to the agency.

(b) On a continuing basis:

This new administrative regulation will not impact ongoing costs to 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 this new 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 new administrative regulation.

(9) TIERING: Is tiering applied?

Tiering is not applied. The requirements of this new 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 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 new 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 new administrative regulation does not generate revenue.

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

This new administrative regulation does not impact cost for the agency.

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

This new administrative regulation does not impact cost for 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 new administrative regulation may result in minimal cost savings for the regulated entities. This new 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 new administrative regulation may result in minimal cost savings for the regulated entities. This new 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 new 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 new 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 new 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 36.

(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 standard, or additional or different responsibilities or requirements in this administrative regulation.