

CABINET FOR HEALTH AND FAMILY SERVICES

Department for Public Health

Division of Public Health Protection and Safety

(New Administrative Regulation)

902 KAR 100:185. Standards for protection against radiation from radioactive materials.

RELATES TO: KRS 194A.005(1), 211.180(1), 211.842-211.852, 211.990(4), 216B.015(22), 10 C.F.R. Part 20, 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 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(1) requires cabinet to provide by administrative regulation for the licensing of the possession or use of sources of ionizing and the handling and disposal of radioactive waste. This administrative regulation establishes the standards for protection of the user and general public against radiation exposure, the standards for protection against ionizing radiation resulting from activities conducted by persons issued licenses or registrations by the cabinet, and the standards to control the receipt, possession, use, transfer, and disposal of sources of radiation by a person, or licensee. The total dose to an individual, including doses resulting from licensed and unlicensed radioactive material and radiation sources other than background radiation, shall not exceed the standards for protection against radiation established in this administrative regulation.

Section 1. Definitions.

- (1) "Agreement state" means a state with which 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.
- (4) "Person" is defined by KRS 216B.015(22).

Section 2. Applicability. This administrative regulation shall apply to a licensee. The licensee shall comply with 10 C.F.R. Part 20 except as established in subsections (1) through (5) of this section.

- (1) The licensee shall not be subject to:
 - (a) 10 C.F.R. 20.1003, Definition for licensee;
 - (b) 10 C.F.R. 20.1007;
 - (c) 10 C.F.R. 20.1009;
 - (d) 10 C.F.R. 20.1405;
 - (e) 10 C.F.R. 20.1406(b);
 - (f) 10 C.F.R. 20.1905(g);
 - (g) 10 C.F.R. 20.2203(c);

- (h) 10 C.F.R. 20.2206(a)(1), (a)(3), (a)(4), and (a)(5);
- (i) 10 C.F.R. 20.2401; and
- (j) 10 C.F.R. 20.2402.

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

(3) Reference to "NRC Form 313, Application for Material License" shall be deemed to be a reference to "Application for Radioactive Material License" RPS-7, incorporated by reference in 902 KAR 100:040.

(4) Reference to the violations under 10 C.F.R. 20.2401 shall be deemed to be a reference to 902 KAR 100:170.

(5) Reference to the criminal penalties under 10 C.F.R. 20.2402 shall be deemed to be a reference to KRS 211.990.

Section 3. Annual Report of Waste Generated.

(1) A licensee issued a specific license, pursuant to 902 KAR 100:040, shall file an Annual Low Level Radioactive Waste (LLRW) Report with the cabinet.

(2) The report shall be filed if the licensee was, or was not, a waste generator during the reporting period, except for a licensee that is authorized for only sealed radioactive sources and has leak test results indicating no leakage or damaged sources.

(3) The report shall:

- (a) Contain information regarding low-level radioactive waste associated with activities authorized by the license for a period of one (1) calendar year;
- (b) Contain the types and amounts of generated waste, and estimates of future wastes to be generated; and
- (c) Be filed no later than January 15 of the following year.

Section 4. Reporting of Events and Notifications. The reporting of events and notifications required by 10 C.F.R. Part 20 shall be directed to the manager, Radiation Health Branch, at:

- (1) 275 East Main Street, Mailstop HS1-C-A, Frankfort, Kentucky 40621;
- (2) (502) 564-1492: Facsimile;
- (3) (502) 564-3700: Telephone, Monday through Friday from 8 a.m. to 4:30 p.m.; or
- (4) (800) 255-2587: Telephone, for hours outside of those in subsection (3) of this section.

Section 5. Incorporation by Reference.

(1) "Annual Low Level Radioactive Waste (LLRW) Report", 05/2023, is incorporated by reference.

(2) This material may be inspected, copied, or obtained, subject to applicable copy right law, at Department for Public Health, Radiation Health Branch, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m.

(3) This material is available on the agency's Web site at <https://www.chfs.ky.gov/agencies/dph/dphps/rhb/Documents/LLRWReportForm1.pdf>.

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 receipt, possession, use, transfer, and disposal of licensed material by any licensee in such a manner that the total dose to an individual, including doses resulting from licensed and unlicensed radioactive material and from radiation sources other than background radiation, does not exceed the standards for protection against radiation.

(b) The necessity of this administrative regulation:

This new administrative regulation is necessary to protect radiation workers and the public from exposure to excessive radiation and sets safety limits.

(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:

There are approximately 350 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 new 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 20 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 new administrative regulation will not impact cost to the agency.

(b) On a continuing basis:

There will be no ongoing costs to the agency to implement this new administrative regulation.

(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?

No. 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 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 to the agency.

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

This new administrative regulation does not impact 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. 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 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 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 20.

(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.