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

902 KAR 100:147. Diagnostic radiation machine and therapeutic radiation machine medical events.

RELATES TO: KRS 211.842-211.852, 211.990(4)
STATUTORY AUTHORITY: KRS 194A.050, 211.025, 211.844
CERTIFICATION STATEMENT:
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 211.025 requires the cabinet to administer all provisions of law related to public health and do all other things reasonably necessary to protect and improve the health of the people. KRS 211.844 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 the medical event reporting standards for human use diagnostic mobile and stationary radiography, fluoroscopy, computed tomography (CT) radiation-generating equipment, and therapeutic machines.

Section 1. Definition. "Unintended dose" means a diagnostic or interventional x-ray patient radiation dose resulting from a human error or equipment malfunction during the procedure.

Section 2. Applicability. This regulation shall apply to all diagnostic and therapeutic radiation producing machines used in the healing arts for human use, and to persons, equipment and materials used in connection with the possession and use or operation of these systems.

Section 3. Medical Event Reporting.
(1) Upon discovery of a diagnostic or therapeutic radiation producing machine medical event the registrant shall contact the cabinet regarding the medical event within one business day.
(2)
(a) Contact may be made via phone 502-564-3700; or
(b) By email to rpm@ky.gov.
(3) Emailed notification shall include:
(a) Medical Event Report as the subject line;
(b) The Kentucky registration number of the person making the report and name of registered facility; and
(c) A brief synopsis of the medical event including:
1. The date of discovery;
2. Nature of the event;
3. Number of patients affected; and
4. Severity, stated as mild, moderate, or severe.
(4) The following forms shall be submitted to the cabinet within thirty (30) days:
(a) Diagnostic Radiation Machine Medical Event Reporting Form (RPS 425) for diagnostic machine medical events; or
(b) Therapeutic Radiation Machine Medical Event Reporting Form (RPS 450) for therapeutic machine medical events.

(5) The forms required by subsection (4) of this section shall include a statement of corrective actions to prevent reoccurrence.

Section 4. Radiation Producing Machine Events Criteria. Other than events that result from intervention by a patient or human research subject, any medical event that meets any of the following criteria shall be reported in which the administration of ionizing radiation from a:

(1) Therapeutic radiation producing machine:

(a) Involves the wrong patient, wrong treatment modality, or wrong treatment site;

(b) When the weekly administered dose differs from the weekly prescribed dose by thirty (30) percent or more;

(c) When the total administered dose differs from the total prescribed dose by twenty (20) percent or more of the total prescribed dose;

(d) When the dose differs by fifty (50) percent or greater for any single fraction of a multi-fraction treatment; or

(e) Any equipment failure, software issue, personnel error, accident, mishap or other unusual occurrence that causes or is likely to cause significant physical harm to the patients.

(2) For diagnostic radiation producing machine:

(a) Results in an unintended dose to the skin greater than 2 Gy (200 rads) to the same area for a procedure or series;

(b) Results in an unintended dose greater than five (5) times the facility's established protocol for a procedure or exceeds 0.5 Gy (50 rads) to an organ or 0.05 Gy (5 rads) total effective dose for the procedure;

(c) Involves the wrong patient or wrong site for the entire diagnostic exam (procedure or service) and exceeds 0.5 Gy (50 rads) to an organ or 0.05 Gy (5 rads) total effective dose for the procedure; or

(d) Involves any equipment failure, personnel error, accident, mishap or other unusual occurrence with the administration of ionizing radiation that exceeds 0.05 Gy (5 rads) total effective dose for the procedure.

(3) For diagnostic radiation machines any wrong patient or wrong site imaged regardless of dose received shall be reported, documented, and addressed internally within the facility.

Section 5. Material Incorporated by Reference.

(1) The following material is incorporated by reference:

(a) "Diagnostic Radiation Machine Medical Event Reporting Form", RPS 425; and

(b) "Therapeutic Radiation Machine Medical Event Reporting Form", RPS 450.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Radiation Health Branch, Division of Public Health Protection and Safety, Department for Public Health, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m. Eastern Time or 7 a.m. to 3:30 p.m. Central Time.

(3) This material is available online at https://www.chfs.ky.gov/agencies/dph/dphps/rhb/Pages/rpmp.aspx.

COMPILER'S NOTE: 2025 RS HB 6, enacted by the General Assembly on March 27, 2025, altered the information to be provided at the time an administrative regulation is filed. Aside from formatting changes necessary to upload the regulation into the LRC's publication application, this regulation has been published as submitted by the agency.

JOHN R. LANGEFELD, MD, Commissioner
STEVEN J. STACK, MD, MBA, Secretary

APPROVED BY AGENCY: November 3, 2026

FILED WITH LRC: November 5, 2026 at 1:40 p.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on January 25, 2027, at 9:00 a.m. Eastern Time, 8 a.m. Central Time 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 January 15, 2027, 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 through January 31, 2027. 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: 502-564-7476; Fax: 502-564-7091; CHFSregs@ky.gov.