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

902 KAR 100:130. Dental.

RELATES TO: KRS 211.842-211.852, 211.990(4), 21 C.F.R. 1020.30
STATUTORY AUTHORITY: KRS 194A.050, 211.090, 211.844
CERTIFICATION STATEMENT:
NECESSITY, FUNCTION, AND CONFORMITY: The Cabinet for Health and Family Services is authorized by KRS 211.844 to provide by administrative regulation for the registration and licensing of the possession or use of any sources of ionizing or electronic product radiation and the handling and disposal of radioactive waste. This administrative regulation establishes the requirements for the possession, use and operation of intraoral dental radiographic x-ray systems.

Section 1. Applicability. This administrative regulation shall apply to dental intraoral radiographic x-ray systems and to persons, equipment and materials used in connection with the possession, use or operation of these systems.

Section 2. Source to Skin Distance. Each radiographic x-ray system designed for use with an intraoral image receptor shall be provided with a means to limit the source to skin distance to not less than eighteen (18) centimeters.

Section 3. Field Limitation. Each radiographic x-ray system designed for use with an intraoral image receptor shall be equipped with a means to limit the x-ray beam.

(1) If the minimum source to skin distance is eighteen (18) centimeters or more, the x-ray field shall be containable in a circle having a diameter of no more than seven (7) centimeters.

(2) Circular beams are permitted but the cabinet recommends the use of rectangular collimation.

(3) The useful beam shall be limited to the area of clinical interest.

Section 4. Operator and Public Protection.

(1) Except for hand-held x-ray systems with integral shields, each installation shall be provided with a protective barrier for the operator or shall be so arranged that the operator can conveniently stand at least six (6) feet from the patient, the tube housing assembly, and outside the path of the useful x-ray beam while making an exposure.

(2) If six (6) feet cannot be maintained, a barrier shall be provided, with the ability to view the patient, while making the exposure.

(3) The operator shall monitor and secure the area prior to making an exposure near public areas.

(4) In dental facilities using a large, multi-patient open-bay design, a patient in proximity to another patient being radiographed shall be treated as a member of the public.

(5) All public areas shall comply with the applicable requirements of 902 KAR 100:019.

Section 5. Operating Procedures. In performing intraoral dental radiography, the following rules shall apply:

(1) Patient and image receptor film holding devices shall be used if technique permits.

(2) Except for units designed to be hand-held, the tube housing and position indicating device shall not be hand-held during an exposure.

(3) No individual shall be used routinely to hold the image receptor or patient during a radiation exposure.

(4) The registrant shall restrict the presence of individuals in the area of the patient being radiographed. Parents or guardians may accompany a child or person with special needs. Those persons shall be positioned so that no part of their body is exposed to the primary beam and be protected from secondary radiation by protective lead shielding to not less than 0.25 millimeter lead equivalent material.

(5) A sufficient number of protective apparel (e.g., aprons, gloves, thyroid collars) and auxiliary shields shall be available to provide the necessary radiation protection for all patients and personnel who are involved with x-ray operations.

(a) All protective apparel and auxiliary shields shall be evaluated annually for integrity and clearly labeled with their lead equivalence.

(b) Shielding shall be provided for patients when it will not interfere with the examination.

(c) In accordance with guidance from a qualified expert, registrants implementing dose reduction technologies (e.g., position-indicating device 20-30 cm, rectangular collimation, fast digital image receptors) and procedures, may develop and submit to the cabinet for approval their own policies and procedures regarding human patient protection, exposure of pregnant patients, patient shielding, and patient education.

(6) The registrant shall annually review their radiation protection program in accordance with 902 KAR 100:019 Section 2.

(7) The registrant shall maintain and make available safe operating procedures to include written safety procedures and techniques required for the safe use of the x-ray system.

(8) Image receptors of speeds slower than ANSI speed group E/F or D speed shall not be used for intraoral radiography.

(9) Dental fluoroscopy without image intensification shall not be used.

(10) Technique factors and selection criteria shall be appropriate to the age and size of the patient.

(11) The registrant shall maintain a quality control program that complies with 902 KAR Chapter 100.

Section 6. Beam Quality. The half-value layer of the useful beam shall:

(1) Not be less than the value specified in 21 C.F.R. 1020.30(m), Table 1; and

(2) Meet requirements specified in 21 C.F.R. 1012.30(m)(1).

Section 7. Leakage Radiation. The leakage radiation from the diagnostic source assembly shall be measured in accordance with 21 C.F.R. 1020.30(k).

Section 8. kVp Accuracy. The kVp accuracy shall be within plus or minus ten (10) percent of its indicated value.

Section 9. Coefficient of Variation. The coefficient of variation for timing, radiation exposure and reproducibility shall not exceed 0.05 in four (4) consecutive exposures.

Section 10. Maintaining Compliance. Diagnostic x-ray systems and their associated components used on humans and certified pursuant to the Federal X-Ray Equipment Performance Standards for Ionizing Radiation Emitting Products, 21 C.F.R. Part 1020, shall be maintained in compliance with applicable requirements of that standard.

Section 11. Additional Requirements. In addition to the requirements of this administrative regulation, dental intraoral x-ray systems shall:

(1) Provide a visual and audible indication x-rays are being produced.

(2) Utilize a "dead-man" exposure switch.

(3) Provide a means to terminate the exposure at a preset:

(a) Time interval;

(b) Product of current and time;

(c) Number of pulses; or

(d) Radiation exposure to the image receptor.

(4) Display their technique factors prior to exposure:

(a) If automatic exposure controls are used, the technique factors, which are set prior, shall be indicated; or

(b) May be met by permanent display of markings on x-ray systems using fixed technique factors.

(5) Have tube housing assembly supports so that the tube housing assembly remains stable during the exposure unless tube housing movement is a designed function of the x-ray system.

(6) Not be operated at less than 50 kVp.

Section 12. Hand-held Devices. In addition to the standards in 902 KAR Chapter 100, the following applies specifically to intraoral hand-held devices.

(1) Any dental intraoral hand-held x-ray system used shall be cleared by the Federal Food and Drug Administration prior to use.

(2) The hand-held x-ray system shall be equipped with a backscatter shield of not less than .25 millimeter lead equivalent.

(3) The registrant shall maintain documentation that each operator has completed training as specified by the manufacturer, to ensure the operator is competent in the safe use of the x-ray system.

(4) The training required by subsection (3) of this section shall, at a minimum, contain:

(a) Basics of x-ray production and scatter,

(b) ALARA principle and basic protective measures to include time, distance, and shielding; and

(c) Proper positioning of the patient and operator, location and orientation of the handheld device, and operator's hand positioning on the device.

(5) When the hand-held x-ray system is not in use it shall be secured and stored so that it is not accessible to members of the public.

(6) The registrant shall provide personal dosimeters for all new hand-held x-ray system operators to determine if further monitoring is required pursuant to 902 KAR 100:19 Section.

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
STEPHEN J. STACK, M.D., MBA, Secretary

APPROVED BY AGENCY: August 1, 2025

FILED WITH LRC: September 9, 2025 at 10:09 a.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on November 24, 2025, 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 November 17, 2025, 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 November 30, 2025. 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; email CHFSregs@ky.gov.