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[Human Resources] 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. [The purpose of]This administrative regulation establishes the[is to provide special] requirements for the possession, use and operation of intraoral[intra-oral] dental radiographic x-ray systems.

Section 1. Applicability. This administrative regulation shall apply to dental intraoral[intra-oral] 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[intra-oral] image receptor shall be provided with a means to limit the source to skin distance to not less than[:]
[(1)] eighteen (18) centimeters[if operable above fifty (50) kilovolts peak; or]
[(2)] [Ten (10) centimeters if not operable above fifty (50) kilovolts peak].

Section 3. Field Limitation. Each radiographic x-ray system designed for use with an intraoral[intra-oral] image receptor shall be equipped[provided] with a means to limit the x-ray beam.
(1) If the minimum source to skin distance [(SSD)]is eighteen (18) centimeters or more, the x-ray field[, at the minimum SSD,] shall be containable in a circle having a diameter of no more than seven (7) centimeters.[; or]
(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 [If the minimum SSD is less than eighteen (18) centimeters, the x-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than six (6) centimeters].

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[, in the judgment of the cabinet,] at least six (6) feet[one and eight tenths (1.8) meters] 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 ~~[if the exposure to the operator is within the limits provided by 902 KAR 100:020, Section 20]~~.

Section 5. Operating Procedures. In performing intraoral~~[intra-oral]~~ 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 ~~[Neither the tube housing assembly nor the position indicating device shall be hand-held during an exposure;]~~

~~[(3)] [The x-ray system shall be arranged and operated in a manner that the useful beam at the patient's skin does not exceed the dimensions specified in Section 3 of this administrative regulation.]~~

~~[(4)] [Each patient undergoing dental radiography shall be draped with a protective apron of not less than 0.25 mm lead equivalent to cover the gonadal area;]~~

~~[(5)] [Film of a USASI (USA) speed group rating of "D" or faster shall be used;]~~

~~[(6)] [All dental radiographic x-ray systems registered after March 2, 1977, shall be provided with electronic timers; and]~~

~~[(7)] [If patients are immobilized during an x-ray exposure mechanical restraints shall be used if technique permits]~~.

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. ~~[Filtration. In addition to the requirements of 902 KAR 100:115, Section 6, all~~

~~intra-oral dental radiographic systems manufactured on and after December 1, 1980, shall have a minimum half-value layer not less than one and five- tenths (1.5) millimeters aluminum equivalent filtration permanently installed in the useful beam.]~~

~~[Section 7.] [Linearity. On dental intra-oral radiographic systems certified under the federal performance standard, if the equipment allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer in accordance with the requirements of applicable federal standards, for any fixed x-ray tube potential within the range of forty (40) to 100 percent of the maximum rating, the average ratios of exposure to the indicated milliampere-seconds product obtained at any two (2) consecutive tube current settings shall not differ by more than one-tenth (0.1) times their sum.]~~

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.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person:Julie Brooks and Krista Quarles

Subject Headings:Public Health, Dentistry, Health and Medical Services

(1) Provide a brief summary of:

(a) What this administrative regulation does:
This administrative regulation establishes the standards for the possession, use and operation of intraoral dental radiographic x-ray systems.

(b) The necessity of this administrative regulation:
This administrative regulation is necessary to protect the dental office staff who use intraoral dental radiographic x-ray systems, the patients, and members of the general public from accidental exposure.

(c) How this administrative regulation conforms to the content of the authorizing statutes:
KRS 194A.050 authorizes the secretary of the cabinet to promulgate, administer, and enforce those administrative regulations necessary to implement programs mandated by federal law. KRS 211.844 authorizes the Cabinet for Health and Family Services to provide by administrative regulation for the registration and licensing of the possession or use of any source of ionizing or electronic product radiation, and to protect the public from unnecessary radiation exposure.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:
This administrative regulation ensures that all intraoral dental radiographic x-ray systems are operated in a safe manner that protects the patient, members of the general public, and the staff of the dental office engaged in taking the x-ray.

(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:
The amendment to this administrative regulation revises the requirements for shielding the patient during x-ray procedures, adds requirements for the use of hand-held x-ray devices, adds procedures to protect members of the general public from exposure, adds the option for a dental office to engage with a qualified expert for guidance, and cites to the applicable federal code of regulation for additional safety requirements.

(b) The necessity of the amendment to this administrative regulation:
The amendment to this administrative regulation is necessary to address updates to the technology used for intraoral dental radiographic x-ray systems, and to ensure these systems are operated in a safe manner.

(c) How the amendment conforms to the content of the authorizing statutes:
KRS 211.844 authorizes the cabinet to promulgate administrative regulations for the registration and licensing related to the possession and use of any source of ionizing or electronic product radiation, and to protect the public from unnecessary radiation exposure.

(d) How the amendment will assist in the effective administration of the statutes:
The amendment to this administrative regulation will continue to ensure intraoral dental radiographic x-ray systems meet all required safety standards.

(3) Does this administrative regulation or amendment implement legislation from the previous five years?No.

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

There are currently 1,550 registered dental offices that will be affected by this administrative regulation.

(5) Provide an analysis of how the entities identified in question (4) 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 (4) will have to take to comply with this administrative regulation or amendment:

Dental offices will need to ensure the intraoral dental radiographic x-ray systems are in compliance with the requirements of this administrative regulation and will need to make any necessary adjustments for compliance.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (4):

The costs associated with compliance can vary. Dental x-ray shielding supplies to protect from radiographic exposure can range in prices from $150 up to $300, depending on the product. New radiographic machines can range in price from $3,500 up to $10,000 or more. This administrative regulation does not require dental offices to purchase new machines, and most offices will have shielding products available.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (4):

Dental office staff, patients, and members of the general public will be protected from unnecessary radiation exposure.

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

(a) Initially:

This is an ongoing program, there are no initial cost.

(b) On a continuing basis:

This administrative regulation does not add to the cost to implement the radiation producing machine program.

(7) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation or this amendment:

The Radiation Health Branch is funded through a mix of state general fund dollars and revenue from licensing fees.

(8) 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 necessary to implement the requirements of this administrative regulation.

(9) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees:

There are no fees contained in this administrative regulation.

(10) TIERING: Is tiering applied?

Tiering is not applied as the provisions of this administrative regulation are applicable to all dental offices that have intraoral dental radiographic x-ray systems.

FISCAL IMPACT STATEMENT

(1) Identify each state statute, federal statute, or federal regulation that requires or authorizes the action taken by the administrative regulation.

KRS 194A.050 and 211.844.

(2) Identify the promulgating agency and any other affected state units, parts, or divisions:

The Department for Public Health, Radiation Health Branch is the promulgating agency.

(a) Estimate the following for the first year:

Expenditures:There will be no impact on program expenditures. The Radiation Health Branch currently issues licenses for the use of intraoral dental radiographic systems. Staff also regularly conduct inspections of these machines. These functions will not be impacted by the amendment to this administrative regulation.

Revenues:This administrative regulation will not generate revenue.

Cost Savings:This administrative regulation will not result in cost savings.

(b) How will expenditures, revenues, or cost savings differ in subsequent years?

There will be no change to expenditures, revenues, or cost savings in subsequent years.

(3) Identify affected local entities (for example: cities, counties, fire departments, school districts):

There are no affected local entities.

(a) Estimate the following for the first year:

Expenditures:Not applicable.

Revenues:Not applicable.

Cost Savings:Not applicable.

(b) How will expenditures, revenues, or cost savings differ in subsequent years?

Not applicable.

(4) Identify additional regulated entities not listed in questions (2) or (3):

Dental offices that utilize an intraoral dental radiographic x-ray system are additional regulated entities.

(a) Estimate the following for the first year:

Expenditures:This administrative regulation should not result in increased expenditures for the additional regulated entities in the first year. If funds are expended for compliance with this administrative regulation, the range can be between $150 to purchase new shielding materials up to $10,000 to purchase new intraoral radiographic x-ray systems. This would be a one-time expense. These expenditures would be considered part of the cost of doing business and not additional expenditures.

Revenues:This administrative regulation does not generate revenue for the additional regulated entities.

Cost Savings:This administrative regulation does not result in overall cost savings for the additional regulated entities.

(b) How will expenditures, revenues, or cost savings differ in subsequent years?
There will be no change in expenditures, revenues, or cost saving in subsequent years.

(5) Provide a narrative to explain the:

(a) Fiscal impact of this administrative regulation:
The fiscal impact of this administrative regulation will be minimal. Most registered dental offices utilize intraoral radiographic x-ray systems that are in compliance with the requirements of this administrative regulation. They may have minimal cost associated with purchasing new shielding equipment. Those items can cost between $150 and $300 depending on the style purchased. New intraoral radiographic x-ray systems can cost between $3,500 and $10,000, depending on the model purchased.

(b) Methodology and resources used to determine the fiscal impact:
The cost of the shielding items and radiographic x-ray systems was obtained through an internet search for the cost of dental x-ray supplies.

(6) Explain:

(a) Whether this administrative regulation will have an overall negative or adverse major economic impact to the entities identified in questions (2) - (4). ($500,000 or more, in aggregate)
This administrative regulation does not have an overall negative or adverse major economic impact. If a dental office were to purchase new intraoral radiographic x-ray system, the cost would not exceed $500,000. Most new systems cost between $3,500 and $10,000.

(b) The methodology and resources used to reach this conclusion:
The internet search returned several suggestions for the purchase of dental x-ray supplies, including x-ray systems. No single item was listed in excess of $10,000.

FEDERAL MANDATE ANALYSIS COMPARISON

(1) Federal statute or regulation constituting the federal mandate.

The requirements under 21 C.F.R. 1020.30 are applicable to all diagnostic x-ray systems and their major components.

(2) State compliance standards.

KRS 194A.050 authorizes the secretary of the cabinet to promulgate, administer, and enforce those administrative regulations necessary to implement programs mandated by federal law. KRS 211.844 authorizes the Cabinet for Health and Family Services to provide by administrative regulation for the registration and licensing of the possession or use of any source of ionizing or electronic product radiation, and to protect the public from unnecessary radiation exposure.

(3) Minimum or uniform standards contained in the federal mandate.

21 C.F.R. 1020.30(m) establishes the beam quality, including those for specified systems, and 21 C.F.R. 1020.30(k) establishes the threshold for leakage radiation from the diagnostic source assembly.

(4) Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate?

No, this administrative regulation does not impose any stricter requirements, or additional or different responsibilities or requirements.

(5) Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements.

Not applicable.