

Kansas Department of Health and Environment Administrative Regulations
Article 35.—Radiation
Dental Facilities

*****Note: Throughout this document, KDHE refers to: Kansas Department of Health and Environment, Radiation Control Program.**

Part 1—Definitions

K.A.R. 28-35-135 through K.A.R. 28-35-135y. ***Definitions***

If you are unsure of the definition of anything in the regulations, here is where you go to find the majority of them.

K.A.R. 28-35-137. ***Records***

Each licensee or registrant shall keep records showing the receipt, transfer, and disposal of all sources of radiation, and any other records specifically required by these regulations.

What this means: Any time you purchase, sell, or dispose of/scrap an x-ray producing device, you should receive documentation from the vendor that these things occurred. You shall also inform KDHE within 30 days of any of these events occurring. State-specific forms can be found on our website.

What we expect from you: All documentation of x-ray equipment purchase, transfer and disposal (including copies of the forms sent to KDHE) need to be kept on file for the life of the practice.

Why: This helps KDHE track ownership of x-ray producing devices in order to ensure their safe and responsible use.

K.A.R. 28-35-138. ***Inspections***

(a) Each licensee or registrant shall afford, at all reasonable times, the secretary or the secretary's duly authorized representative the opportunity to inspect sources of radiation and the premises and installations in which such sources of radiation are used or stored.

(b) Each licensee or registrant, upon reasonable notice, shall make available, for inspection by the secretary or the secretary's duly authorized representative records maintained pursuant to these regulations.

What this means: KDHE is allowed to inspect any facility that uses radiation producing devices. Part of this inspection is reviewing any and all records pertaining to your x-ray equipment and its use.

What we expect from you: Allow the KDHE inspector to come into your facility and complete the inspection. Have all records pertaining to your x-ray machines on file so KDHE can review them (what records are expected can be found throughout this document).

Why: This helps KDHE to ensure your compliance with regulations and ensure that x-ray equipment is being used and maintained safely.

K.A.R. 28-35-139. ***Testing and Surveys***

(a) Each licensee or registrant shall make, or cause to be made, those surveys that are necessary for the licensee or registrant to comply with these regulations.

(b) Each licensee or registrant shall perform, upon instructions from the department, or shall permit the department to perform, such reasonable tests as the department deems appropriate or necessary.

What this means: Part of the inspection process involves the KDHE inspector testing your equipment. KDHE also has the right to request you to have your equipment serviced or perform tests on your equipment.

What we expect from you: Allow the KDHE inspector to come into your facility and conduct the inspection and equipment testing. Respond to any requests from KDHE for additional testing by an outside service provider in a timely manner.

Why: This allows KDHE to ensure that your equipment is functioning as it should. The KDHE inspector has equipment that reads the x-ray output of your machines, verifying that your patients only receive as much radiation as you intend.

K.A.R. 28-35-140. *Exemptions*

(a) General provision. The secretary, upon application for an exemption or upon the secretary's own initiative, may grant exemptions or exceptions from the requirements of these regulations, if it is determined that the exemption will not result in an undue hazard to public health and safety, or to property.

What this means: Anything not explicitly allowed by these regulations needs to be approved by KDHE, before being put into practice. Exceptions to regulations can be made, but KDHE maintains the right to evaluate requested exemptions and determine if they pose any risk to operators or patients.

What we expect from you: In dentistry, this primarily applies to hand held x-ray units and radiation monitoring for personnel. Both will be covered later in this document. Essentially, if you have any questions regarding something's compliance with KDHE regulations, notify KDHE by phone or by email with these questions before putting it into practice at your facility.

Why: Again, this is related to the safety of x-ray workers and patients receiving radiation.

K.A.R. 28-35-141. *Additional Requirements*

At the time of registration, at the time of action upon application for license or amendment to the license, or upon inspection, the department shall specify any requirements or conditions of use, or both, that are necessary to ensure compliance with these regulations under the particular usage to which the licensee or registrant proposes to put the source of radiation.

What this means: The KDHE inspector will tell you if you are found to be non-compliant and which regulations you are in violation of.

What we expect from you: Following inspection, if the KDHE inspector has found your facility to be non-compliant, you will be sent a letter outlining any issues. You will be given 30 days to respond to the letter and take any corrective action necessary. If any questions arise while you are in the process of becoming compliant, contact your KDHE inspector for clarification. This regulation also applies to issues of equipment registration and fee payment; you will be informed if you are non-compliant and you are expected to comply in a timely manner.

Why: The letter you receive following an inspection should detail exactly what needs to be fixed and why. This way, there will be no surprises, and you know if you address all of the issues within the letter, you are back in compliance.

K.A.R. 28-35-145 through 28-35-147a. *Registration Fees*

28-35-145. **Initial license and registration fees.** (b) Each person required under part 2 of these regulations to register a radiation machine shall submit to the department a registration form and the applicable nonrefundable registration fees specified in K.A.R. 28-35-147a.

28-35-146. **Annual license and registration fees.** (c) Annual registration fees. Each registrant shall submit to the department a registration form and the applicable nonrefundable annual registration fees specified in K.A.R. 28-35-147a on or before March 1.

28-35-147a. **Schedule of fees.** Each fee for an initial license application or registration shall be equal to the sum of the annual fees for all applicable categories. Each annual fee for a license or registration shall be equal to the sum of the annual fees for all applicable categories.

(k) X-ray machines.

(1) Base registration fee per facility.

Annual fee \$135.00

(2) Registration fee for each x-ray tube at a facility. This fee shall be in addition to the base registration fee.

Annual fee per x-ray tube \$35.00

What this means: Any x-ray machine you possess needs to be registered with KDHE. There are initial and yearly registration fees associated with registration.

What we expect from you: When you buy/sell/dispose of an x-ray producing device, you are expected to inform KDHE and adjust your fees accordingly. Annual fees are due on or before March 1st.

Why: This is another method for tracking use of x-ray machines in Kansas and covers the cost of inspections.

K.A.R. 28-35-148. ***Deliberate Misconduct***

(b) Each individual...who knowingly provides to any licensee, applicant, registrant, contractor, or subcontractor any components, equipment, materials, or other goods or services that relate to a licensee's, registrant's, or applicant's activities in this article shall be prohibited from engaging in deliberate misconduct.

What this means: X-rays are not to be used for anything other than their intended purpose.

What we expect from you: Do not use x-rays for anything other than their intended purpose. In dentistry, this means they are only to be used for the diagnosis and treatment of dental problems. They require an order by a provider and are to be taken by a trained professional.

Why: This is to ensure that x-rays are used safely and responsibly.

Part 2—Radiation Producing Machines

K.A.R 28-35-152. ***Persons registered.***

Any person possessing a registrable item shall register with the department in accordance with the rules and regulations in this part.

What this means: Anyone who owns an x-ray producing device needs to register it with KDHE.

What we expect from you: You are expected to register new equipment and maintain a current registration with KDHE. You are also expected to keep any and all records related to x-ray registration on file at your facility.

Why: Registration of x-ray producing devices allows KDHE to track what specific x-ray equipment is being used, who is using x-ray equipment in Kansas, and provides KDHE with a method for tracking safety concerns and regulatory compliance.

K.A.R. 28-35-153. ***Initial registration.***

Any person who is not registered and who acquires possession of a registrable item shall register with the department, within 30 days of the date of acquiring the item.

What this means: You have 30 days from acquiring an x-ray producing device to register it with KDHE.

What we expect from you: It is your responsibility to print off, fill out, and send in registration forms with appropriate fees to KDHE.

K.A.R. 28-35-155. *Registration form.*

Registration shall be made upon forms devised and furnished by the department. Each registrant shall provide all the information called for by the form and any additional information requested by the department.

What this means: KDHE has provided forms to be used when registering new x-ray equipment. These are available on the KDHE Radiation Control Program Website.

What we expect from you: It is your responsibility to print off, fill out, and send in registration forms with the appropriate fees. Annual registration can be paid by mail with a check, or through email with a credit card.

[Link to our equipment registration page:](http://www.kdheks.gov/radiation/xray equip registration.htm)

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K.A.R. 28-35-158. *Report of change.*

If a change is made on any x-ray equipment or other device producing radiation, or to any installation, so that information on file with the department is no longer accurate, the registrant shall notify the department, in writing, of the change, within 30 days of the date the change was made.

What this means: If the number or type of x-ray producing devices in your possession changes, KDHE must be notified within 30 days.

What we expect from you: It is your responsibility to contact KDHE and report any changes. The X-ray Machine Status Form can be found on the KDHE Radiation Control Website.

K.A.R. 28-35-159. *Registration shall not imply approval.*

A person shall not refer, in any form of advertisement, to the fact a registrable item is registered with the department, or state or imply that any installation registered with the department is approved by the department.

What this means: "State registration" is not synonymous with approval, and should not be advertised.

What we expect from you: Do not advertise that your equipment is state registered or approved.

K.A.R. 28-35-161. *Discontinuance of use.*

If a registrant ceases to use a registrable item or items, for any reason, the registrant or the duly authorized representative of the registrant's estate shall give written notice to the department of the cessation of use. The notice shall be provided within 30 days of the date that the registrant ceases to use the registrable item or items, and shall state the date on which use of the item or items was discontinued and the manner in which the registrable item or items were disposed.

What this means: If you permanently stop using an x-ray machine in your possession, KDHE shall be notified within 30 days.

What we expect from you: It is your responsibility to inform KDHE when you stop using an x-ray producing device.

K.A.R. 28-35-164. *Temporary use or storage of registrable items.*

Any person desiring to bring a registrable item into this state for temporary use or storage shall give written notice to the department before bringing the item into this state. The notice shall be given to the department at least five days before the item is to be brought into this state and shall include the type and energy of the radiation source, the nature and scope of the use or storage, the proposed duration of use or storage, and the exact location where the radiation source is to be used or stored. If, in a specific case, the five day period would impose an undue hardship on the person,

the person, upon application by letter or telegram to the department, may obtain permission to proceed at an earlier date.

What this means: If an x-ray producing device is going to be brought into Kansas, even on a temporary basis, KDHE needs to be notified at least five days before it is brought into Kansas.

What we expect from you: If an x-ray producing device is being brought to your office for demonstration purposes, or to temporarily replace a piece of your equipment that is out for repairs, it is your responsibility to make sure KDHE is notified at least five days before it arrives in Kansas.

K.A.R. 28-35-165. ***Disposal of registered items.***

Whenever any person disposes of a registrable item, or items, by any method, the person, or in the event of the person's death, the representative of the person's estate, shall give written notice to the department of the disposal within 30 days. The notice shall include the date of disposal, the method of disposal, and, if transferred to another person, the name and address of the recipient.

What this means: If an x-ray machine registered to you is sold or scrapped, KDHE shall be notified within 30 days.

What we expect from you: It is your responsibility to print off, fill out, and send in the forms for disposal/transfer of an x-ray machine to KDHE.

Link to X-ray change of status form:

http://www.kdheks.gov/radiation/forms/Xray_machine_status_frm.pdf

Link to affidavit of disassembly:

http://www.kdheks.gov/radiation/forms/AFFIDAVIT_OF_DISASSEMBLY.pdf

K.A.R. 28-35-167 through K.A.R. 28-35-169. ***Shielding Plans***

28-35-167. Shielding plan for radiation producing devices. (a) Before construction, the floor plan or plans, shielding specifications, and equipment arrangement of all new installations, or modifications of existing installations, utilizing ionizing radiation machines shall be submitted to the department for review and consideration for approval.

What this means: Before new construction or remodeling, shielding plans detailing safe storage and use of radiation producing devices need to be submitted to KDHE for review. KDHE may require the use of a radiation physicist or other qualified specialist in testing and creating these plans, at your expense. Initial approval does not mean permanent approval. KDHE can require additional shielding be added or other modifications made if there are changes in equipment or number of exams. You may be required to submit another shielding plan if it is determined that changes are needed.

What we expect from you: It is your responsibility to have a shielding plan made and approved prior to any new construction or remodeling. You must keep all paperwork and communication related to the shielding plan on file for the life of the practice. This paperwork must be available for review at your KDHE inspections.

Why: Shielding plans are required in order to help ensure the safety of your employees, patients, and anyone who could possibly be in the vicinity of the radiation producing devices. They take into account construction material and added shielding to demonstrate radiation levels beyond the immediate area of the radiation producing device.

Link to Shielding Plan Review Form:

http://www.kdheks.gov/radiation/forms/shielding_plan_review_form.pdf

NOTE: Replacement of an existing panoramic unit or Cone Beam CT unit must submit a shielding plan for review. Your shielding plan review is dependent on number of exams done with the Pano or Cone Beam CT's per week and also the energy of the unit. You must review your workload to make sure that you are still current with your shielding plan. This is something that will be looked at during your next inspection with these types of units. It is possible that your facility may have to increase the shielding materials in the walls if your patient workload on the unit has increased from the previous approval.

Part 4—Standards for Protection Against Radiation

K.A.R. 28-35-211d. ***Radiation protection programs.***

(a) Each licensee or registrant shall develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of these regulations. (d) Each licensee or registrant shall, at intervals not to exceed 12 months, review the radiation protection program content and implementation.

What this means: Every facility that uses radiation producing devices needs to have written radiation safety procedures and policies. A program must be in place to ensure these policies are followed and reviewed at least annually. The ALARA principles of time (short exposures), distance (x-ray workers should be at least 6 feet from the x-ray machine when taking exposures), and shielding (lead shielding for patients as well as employees if necessary) should be addressed in these policies.

What we expect from you: It is your responsibility to make and implement a radiation protection program for your facility. A written version needs to be kept on file for review during KDHE inspections. Documentation of annual review of policies and procedures also needs to be maintained and available for KDHE inspection.

Why: The creation of a radiation protection program ensures that everyone working around x-rays knows what is expected of them. It helps ensure employee safety and the responsible use of radiation.

K.A.R. 28-35-212a. ***Occupational Dose Limits for Adults***

(a) Each licensee or registrant shall control the occupational dose to individual adults, (c)(3) All individuals who are associated with the operation of an X-ray system shall be subject to the occupational exposure limits and the requirements for the determination of the doses that are specified in this regulation. (f) Each licensee or registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person

NOTE: *This section also includes information about occupational dose limits for minors, dose to embryo or fetus, dose limits for individual members of the public, and information about preventing deceptive exposure of a monitoring device.*

What this means: The annual dose limit for an occupationally exposed x-ray worker is 5000 mrem. This is most often kept track of through the use of personal dosimetry badges. Monitoring is required by state regulations UNLESS it can be demonstrated that exposure to x-ray workers is minimal.

What we expect from you: It is your responsibility to ensure that your employees are receiving minimal exposure to radiation. It is your responsibility to purchase and correctly use personal monitoring badges for your employees. A waiver may be obtained to release your facility from needing ongoing monitoring IF you can show that your employees receive minimal doses of radiation. This is done by completing a full year of monitoring and sending documentation of

dosimetry readings along with the waiver request to KDHE for review. At that time it will be determined if monitoring can be discontinued. Any monitoring records and waivers must be kept for the life of the practice and made available for review during KDHE inspections, and must be available to employees so they can track their occupational exposure. If you have done monitoring in the past, but have no record of it, KDHE will require you to do it for at least another year. If you have done monitoring in the past, but the types of equipment, safety procedures, or use of radiation has changed at your practice, KDHE may require you to do it for at least another year.

Why: Occupational exposure to radiation, even in small amounts, can have a cumulative effect on x-ray workers. The personal monitoring badges allow an individual's exposure to be tracked and interventions to be made before exposure rates become dangerous.

NOTE: If the worker is likely to receive, in a year the occupational dose requiring monitoring, you must attempt to obtain the records of lifetime cumulative occupational radiation dose from previous facilities. Most dental facilities will not reach this limit, but if it is possible, you must track prior occupational dose.

Link to Exposure Monitoring companies:

http://www.kdheks.gov/radiation/download/radiation_monitor_company.pdf

K.A.R. 28-35-219a. ***Caution Signs and Labels***

(1) Except as otherwise authorized by the department the symbol prescribed by this regulation shall use the conventional radiation caution colors, which are magenta, purple, or black on a yellow background

What this means: In areas where x-rays are regularly used, signs must be posted that alert people to the use of radiation.

What we expect from you: In dentistry, requirements are specific to the equipment. Standard intraoral and panoramic machines should have radiation caution signs on the machines themselves.

Why: Employees and patients need to be aware when they have entered a radiation area or are having an exam involving radiation.

K.A.R. 28-35-222a ***Security and control of sources of radiation***

(a) Each licensee or registrant shall secure from unauthorized removal or access all licensed or registered sources of radiation that are stored in controlled or unrestricted areas. (c) Each registrant shall maintain control of radiation machines that are in a controlled or unrestricted area and that are not in storage.

What this means: X-ray producing devices need to be stored in such a way that they cannot be removed from the premises, and people without proper training cannot access them.

What we expect from you: Most wall mounted intraoral units already meet these requirements. However, care should be taken to prevent the public unsupervised access to them. Hand Held X-ray Units require extra security and control. If you are granted a waiver for a hand held dental X-ray unit, one of the things you must agree to is the security of the unit at the end of each day's use.

Why: X-rays are potentially dangerous; especially in the hands of people without proper training.

K.A.R. 28-35-227d. ***Records of surveys.***

(a) Each licensee or registrant shall maintain records showing the results of surveys and calibrations required by K.A.R. 28-35-217b and K.A.R. 28-35-221a(b). Each licensee or registrant shall retain each of these records for three years after the record is made.

What this means: Any results from inspections, repairs, service calls, and routine calibrations need to be maintained by your office for at least three years.

What we expect from you: If needed, you are expected to be able to produce records requested by your KDHE inspector.

Why: This allows us to ensure that your equipment is being correctly maintained and you are in compliance with various other regulations.

K.A.R. 28-35-227h. ***Records of individual monitoring results.***

(a) Each licensee or registrant shall maintain records of the doses received by all individuals for whom monitoring was required. (e) Each licensee or registrant shall retain each required form or record until the department terminates each pertinent license or registration requiring the record.

What this means: Any records related to employee dose monitoring shall be kept for the life of the practice. Employees need to be able to review their monitoring records.

What we expect from you: It is your responsibility to ensure that monitoring records are maintained on site until registration of your facility is terminated, and to allow employees access to their radiation exposure records. Even if you had your employees monitored years ago, and received a waiver from the department allowing for cessation of monitoring, you must be able to produce monitoring records and the waiver for review during KDHE inspections.

Why: Compliance with this regulation provides documentation that your employees are receiving minimal radiation doses.

K.A.R. 28-35-228a. ***Reports of theft or loss of sources of radiation.*** (a) Each licensee or registrant shall report... to the department the theft or loss of the following sources of radiation immediately after the occurrence becomes known to the licensee or registrant. (b) The licensee or registrant shall also submit a report, in writing, within 30 days after learning of stolen, lost, or missing sources of radiation.

What this means: X-ray producing devices need to be stored in such a way that they cannot be removed from the premises, and people without proper training cannot access them. If, despite proper precautions, one of your registered devices is stolen, KDHE must be notified immediately. A written report must be submitted to KDHE within 30 days.

What we expect from you: Most wall mounted intraoral units already meet these requirements. However, care should be taken to prevent the public unsupervised access to them. Hand Held X-ray Units require extra security and control. If you are granted a waiver for a hand held dental X-ray unit, one of the things you must agree to is the security of the unit at the end of each day's use. It is your responsibility to alert KDHE immediately, and file a report within 30 days, if one of your devices goes missing.

Why: X-rays are potentially dangerous; especially in the hands of people without proper training.

K.A.R. 28-35-229a. ***Notification of incidents.***

(a) Immediate notification. Each licensee or registrant shall immediately notify the department by telephone, telegraph, mailgram or facsimile of any incident involving any source of radiation possessed by the licensee or registrant which may have caused or threatens to cause: (1) (A) a total effective dose equivalent to any individual of 25 rems (250 mSv) or more of radiation.

What this means: If a monitored individual or a patient receives more than the monthly allowable dose, KDHE must be notified immediately.

What we expect from you: This is EXTREMELY unlikely to happen in a dentist's office. However, if overexposure does occur, it is your responsibility to notify KDHE immediately.

Why: This allows KDHE to track overexposures and help prevent them from happening again.

Part 5—Use of X-rays in the Healing Arts

K.A.R. 28-35-242. *General Requirements*

(c) Limitations on human use. An individual shall not be exposed to the useful beam, unless the exposure is for healing arts purposes and each exposure has been authorized by a licensed practitioner of the healing arts, or by an individual licensed to practice dentistry or podiatry within the authority granted to the individual by Kansas licensing laws applying to dentists and podiatrists. Deliberate exposure for the following purposes shall be specifically prohibited under this subsection; (1) Exposure of an individual for patient positioning, training, demonstration, or other purposes, unless a healing arts purpose exists and a proper prescription has been provided; and (2) exposure of an individual for the purpose of healing arts screening without the prior written approval of the department.

What this means: X-rays are not to be taken of anyone unless it is medically warranted and explicitly ordered by a dentist or other provider licensed to practice in the state of Kansas.

What we expect from you: It is your responsibility to ensure that any x-rays, panoramic images, or cone beam CT scans performed in your office are medically warranted. Deliberate exposure for positioning, training, demonstration or other purposes unless a healing arts purpose exists and a proper prescription has been provided is prohibited. Also prohibited is exposure for healing arts screening without the proper approval of KDHE.

Why: The damaging effects of radiation are cumulative. Therefore, it is important to ensure that any exposure is not unnecessarily adding to a patient's lifetime dose.

K.A.R. 28-35-242a. *Administrative Requirements*

(a)(1) An X-ray system not meeting the provisions of these regulations shall not be operated for diagnostic purposes. (2) Each individual who operates any X-ray system shall be instructed in the safe operating procedures and shall be competent in the safe use of the equipment... Any combination of interview, observation, and testing may be used by the secretary to determine compliance.

What this means: All employees that take x-rays, panoramic images, or cone beam CT scans, need to be trained how to safely use the equipment.

What we expect from you: It is your responsibility to ensure that your employees are trained to use the x-ray equipment. It is also your responsibility to maintain records documenting their training, and provide these records for review during KDHE inspections. In a dental setting, x-ray workers are not required to be a licensed x-ray operator by the state of Kansas. However, on the job, school based, or vendor provided training is required.

Why: Having a properly trained staff ensures not only their safety, but the safety of your patients.

K.A.R. 28-35-242a(a)(3). *Technique Chart*

A chart shall be made available to the operator of each diagnostic X-ray system that specifies, for each examination performed with the system, the following information:

(A) The technique factors to be utilized, taking into account the patient's body part and anatomical size, body part thickness, and age

What this means: A technique chart must be made available to the operator of each diagnostic X-ray system that specifies the technique factors that take into account the patient size, body part, etc.

What we expect from you: In your office, what is the technique used for a bitewing? What about other frequently taken images? How do you adjust the technique for a pediatric patient? Or a very large patient? The answers to these questions, as well as other similar information specific to panoramic and cone beam CT machines, shall be available to the x-ray worker. Each x-ray machine shall have a technique chart posted next to the control panel to ensure proper techniques are being utilized. These charts shall be available for review during KDHE inspections.

Why: This ensures that patients are not overexposed during their exams.

K.A.R. 28-35-242a(a)(4). *Safety Procedures*

The registrant of a facility shall create and make available to all X-ray operators written safety procedures, including patient holding procedures and any restrictions on the operating techniques required for the safe operation of the particular X-ray system. The registrant shall ensure that the operator demonstrates familiarity with these procedures.

What this means: Written procedures to ensure safe use of x-rays need to be created and made available to your staff.

What we expect from you: It is your responsibility to create x-ray safety procedures to be followed in your office. These procedures should address issues of patient and x-ray worker safety, as well as any restrictions on the x-ray equipment. It is also your responsibility to ensure that your employees are familiar with all safety procedures, have access to written versions, and review the procedures at least annually. Specific safety issues to be included in your procedures are addressed in following regulations. Employees shall be able to demonstrate proper use of all x-ray equipment, including the x-ray unit and image receptor system (film, phosphor plates or digital radiography).

Why: This ensures that all of your employees consistently follow the same procedures when it comes to the safe use of radiation producing equipment.

K.A.R. 28-35-242a(a)(5). *Patient holding/shielding*

Except for patients who cannot be moved out of the room, only the staff, ancillary personnel, and any other individuals required for the medical procedure or training shall be in the room during the radiographic exposure. All of the following requirements shall be met for each individual other than the patient being examined: (A) Each individual shall be positioned so that no part of the body will be struck by the useful beam unless the body part is protected by not less than 0.5 millimeter of lead-equivalent material. (6) Gonad shielding of not less than 0.5 millimeter of lead-equivalent material shall be used during radiographic procedures...except for cases in which this shielding would interfere with the diagnostic procedure. (7)(C) The human holder shall be instructed in personal radiation safety and shall be protected in accordance with these regulations. (D) No individual shall be used routinely to hold film or patients. (F) Each facility shall have a sufficient number of leaded aprons and gloves available to provide protection to all personnel who are involved with X-ray operations and who are otherwise not shielded.

What this means: Only staff and any other individuals required for the procedure are to be in the room during radiographic exposure. If there must be staff in the room, they shall be positioned so that no part of their body will be struck by the x-ray beam unless they are protected by not less than a 0.5 mm lead apron. The X-ray operator shall be protected by not less than a 0.25 mm lead apron. Gonadal shielding shall be available and utilized unless it gets in the way of producing a diagnostically useful image. No individual shall be the designated "holder."

What we expect from you: In a dental facility, all of your x-ray machines must have the ability to be operated from outside of the exam room. During a normal exam, the operator should press the exposure switch from outside of the exam room. If a patient requires holding to get a diagnostically useful image, the x-ray worker must protect themselves with a lead apron and make sure no part of their body is in the path of the x-ray beam. Lead shielding for patients shall be available and used whenever possible. It is your responsibility to make sure your employees are aware of and abide by these safety regulations.

Why: This helps ensure that your employees and patients are not receiving unnecessary radiation.

K.A.R. 28-35-242a(a)(8)(A). *Film Screen*

The speed of the screen and film combinations used shall be the fastest speed that is consistent with the diagnostic objective of the examinations.

(B) The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.

What this means: Film speed determines film sensitivity. The faster the film, the less exposure required to produce a good image. The fastest film that works with your system and provides you with good diagnostic images should be used. Regardless of what film speed is used, patients should be subjected to the smallest amount of radiation necessary to produce a useful image.

What we expect from you: It is your responsibility to ensure that the film being used is appropriate for your equipment and for the desired images. It is also your responsibility to ensure that the lowest radiation dose necessary to produce good images is used. For a bitewing image taken on film, patient dose should not exceed 249 mR. This is one of the things the KDHE inspector will test during inspections. If 249 mR is exceeded, it is your responsibility to get your machine calibrated and/or adjust your technique. For phosphor plates, patient dose should not exceed 200 mR. For direct digital sensors, patient dose should not exceed 100 mR. This data is from N.E.X.T. studies that have been conducted in the past across the nation.

Why: Adhering to this regulation makes sure that your patients do not receive excessive radiation during routine x-rays.

K.A.R. 28-35-242a(b). *Records.*

Each registrant shall maintain the following minimum information for each X-ray system, for inspection by the department: (1) The maximum rating of technique factors; (2) the model and serial numbers of all certifiable components; (3) the aluminum-equivalent filtration of the useful beam, including any routine variation; (4) tube rating charts and cooling curves; (5) records of surveys, calibrations, maintenance, and modifications performed on the X-ray system after the effective date of this regulation, with the name of each person who performed these services; (6) a scale drawing of the room in which a stationary X-ray system is located, indicating the use of areas adjacent to the room and an estimation of the extent of occupancy by any individuals in these areas; (7) a copy of all correspondence with the department regarding that X-ray system.

What this means: KDHE can and will inspect paperwork related to any x-ray producing devices in your possession. This includes the operator's manual and installation manual, which should include all of the technical specifications referenced in this regulation. Documentation of any maintenance, modification, or repair done to the x-ray equipment, including the name of the person performing the work, shall be maintained for the life of the machine. Other paperwork that must be maintained and readily available include a scale drawing of the x-ray room and all correspondence with KDHE.

What we expect from you: It is your responsibility to keep all records related to your x-ray equipment. This includes, but is not limited to; an operators manual, model and serial numbers, maintenance records, radiation monitoring records, a scale drawing of the x-ray room and occupancy estimations of surrounding areas (these are part of your shielding plan), and any communications with KDHE.

Why: This regulation serves as a protection for you. By maintaining copies of all paperwork related to your x-ray producing devices, you ensure that there can be no questions about maintenance or anything else related to regulation compliance.

K.A.R. 28-35-242a(c). *X-ray utilization log.*

Except for veterinary facilities, each registrant shall maintain an X-ray log containing each patient's identifier, the type of each examination, and the date on which each examination was performed.

When the patient or film is provided with human auxiliary support, the name of the human holder shall be recorded.

What this means: Records must be kept demonstrating that x-rays were taken. These should include patient information and date taken, as well as if a human holder was used during the exposures.

What we expect from you: The KDHE inspector will ask about your patient charts containing x-ray orders for patients. If your facility can produce information about how many patients were x-rayed per month, KDHE will generally accept that you have some way to keep track of who was x-rayed. If there is another person that is in the room during exposure, holding the film or patient, this information must be included in the patient's chart as the "holder's log."

Why: This allows KDHE to track how often x-rays are being utilized at your facility. Maintaining these types of records will also assist you in your billing and charting.

K.A.R. 28-35-242a(d)(1)(A). *Manual film processing*

Each manual film-developing system shall meet all of the following requirements: (i) The processing tanks shall be constructed of mechanically rigid, corrosion-resistant material. (ii) The temperature of the solutions in the tanks shall be maintained within the range of 60 F to 80 F. All film shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer (iii) Devices shall be utilized that indicate the actual temperature of the developer and signal the passage of a preset time appropriate to the developing time required.

What this means: The facility must have suitable equipment for handling and processing film according to KDHE regulations. If this is a manual system, the processing tank must be constructed of appropriate material and the temperature of the solutions must be maintained at the proper range. All film shall be developed in accordance to time-temperature relationships recommended by the film manufacturer or the time-temperature chart in KDHE regulations.

What we expect from you: It is your responsibility to make sure that any manual film processing occurring at your facility is being done per manufacturer's specifications. Equipment and chemicals used for processing as well as processing technique should be in line with the requirements for the film. You must have a thermometer and timer to use to manually develop films. Temperature and immersion times need to be posted in the dark room.

Why: X-ray film processing/image processing is important. Correct film processing directly impacts the readability of your films as well as the x-ray doses received by your patients.

K.A.R. 28-35-242a(d)(1)(B) *Automatic film processing*

Each automatic processor and any other closed processing system shall meet all of the following requirements: (i) All film shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer. (ii) The specified developer temperature and immersion time shall be posted in the darkroom or on the automatic processor.

What this means: Automatic film processors need to be used as the manufacturer intended. All film needs to be developed in the appropriate time and temperature settings as specified by the manufacturer.

What we expect from you: It is your responsibility to ensure that your automatic processor meets KDHE regulations. This includes changing out/replenishing chemicals and any maintenance or repairs. Temperature and time specifications must be posted on the processor.

Why: X-ray film processing/image processing is important. Correct film processing directly impacts the readability of your films as well as the x-ray doses received by your patients.

K.A.R. 28-35-242a(d)(2)(B) ***Darkroom/Film storage***

The darkroom shall be lighttight and shall use safe lighting so that any film type exposed in a cassette to X-radiation sufficient to produce an optical density measuring from one to two when processed does not exhibit an increase in density greater than 0.1 when exposed in the darkroom for two minutes with all safe lights on. If daylight film-handling boxes are used, these boxes shall prevent any fogging of the film. (D) All film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a lighttight container. (F) Outdated X-ray film shall not be used for diagnostic radiographs.

What this means: Film needs to be stored and handled in such a manner that it is not exposed to light. Precautions include using a lighttight darkroom and film handling boxes. Film should be stored in a cool, dry, lighttight place. Expired film should not be used.

What we expect from you: It is your responsibility to ensure that your film in being stored and handled in a way that does not compromise the integrity of the film. This is partially achieved by utilizing a lighttight darkroom and film handling boxes. It is your responsibility to ensure that film is being stored correctly and expired film is not being used.

Why: X-ray film handling is important. Correct film handling directly impacts the readability of your films as well as the x-ray doses received by your patients.

K.A.R. 28-35-242b. ***General Requirements for all diagnostic x-ray systems***

(a) Warning label. The control panel containing the main power switch shall bear this or an equivalent warning statement, which shall be legible and accessible to view: "WARNING: This X-ray unit could be dangerous to patient and operator unless safe exposure factors and operating instructions are observed." (b) Battery charge indicator. On each battery powered X-ray generator, a visual means shall be provided on the control panel to indicate whether the battery is in a state of charge for proper operation. (c) Leakage radiation from the diagnostic source assembly. The leakage radiation from the diagnostic source assembly measured at a distance of one meter in any direction from the source shall not exceed 25.8 C/kg (100 milliroentgens) in one hour when the X-ray tube is operated at the leakage technique factors specified by the manufacturer.

What this means: All x-ray producing devices are required to have warning labels on the control panel. All battery powered x-ray machines are required to have a mechanism for displaying how charged the battery is. Radiation leakage from diagnostic x-ray machines must be less than 100 milliroentgens per hour at a distance of one meter from the source.

What we expect from you: It is your responsibility to ensure that all of your equipment is labeled correctly and functioning properly. Warning labels should be easy to read and should not be removed from the equipment. Battery operated equipment should be capable of holding a charge that can produce diagnostic level x-rays. A mechanism for determining this must be visible on the control panel. Significant radiation leakage from the x-ray source is prohibited. If leakage is suspected, it is your responsibility to have it evaluated by a qualified expert and repaired.

Why: Like so many other regulations, these three have to do with safety. Operators should be aware that the equipment they are using is potentially dangerous. Operators should also be aware if their battery operated equipment is charged enough to produce a good image before they expose the patient. This will help cut down on repeat exposures. Radiation leakage isn't good for anyone, especially x-ray workers who are around the equipment daily.

K.A.R. 28-35-242b(e)(1). ***Half-value layer.***

(A) The half-value layer of a given X-ray tube potential shall not be less than the values shown in table I in this paragraph. Linear interpolation and extrapolation may be used if necessary to determine the half-value layer at an X-ray tube potential that is not listed in table I. (Table I can be found on page 297 of the Kansas Administrative Regulations.)

(C) The required minimal half-value layer of the useful beam shall include the filtration contributed by all materials that are permanently located between the source and the patient.

(2) Filtration controls. For each X-ray system that has variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter or filters and shall prevent an exposure, unless the minimum amount of filtration necessary to produce the required HVL is in the useful beam for the given kVp that has been selected.

What this means: Half-value layer refers to the amount of a material (usually aluminum or aluminum equivalent) required to reduce the x-ray beam's intensity by half for a given kVp. This measurement is used to determine if an x-ray producing device has enough filtration to prevent excessive amounts of radiation from going anywhere other than the intended target. Calculations for half-value layer include any material that is a part of the x-ray machine permanently attached, such as the tube housing. Half-value layer of a given x-ray tube must meet the HVL table in KDHE regulations (Table I located on page 297 of the Kansas State Administrative Regulations). For each x-ray system that has variable kVp and variable filtration for the useful beam, a device must link the kVp selector with the filter or filters and will prevent exposure, unless the minimum amount of filtration necessary to produce the required HVL is in the useful beam for the given kVp that has been selected.

What we expect from you: For most intraoral units, the attached collimator provides sufficient filtration to satisfy these regulations. It is your responsibility to ensure that the collimators are properly attached and the unit is only used when the collimator is on. For machines with variable kVp, such as cone beam CT units, there should either be enough permanent filtration to sufficiently attenuate the beam at the highest possible kVp setting, or there should be additional filtration that is added when higher kVps are selected. It is your responsibility to ensure that these machines are installed to manufacturer's specifications and all necessary filtration is in place.

Why: Adhering to these KDHE regulations will significantly reduce exposure to anywhere other than the intended target. This will help protect your employees and patients from unnecessary radiation.

K.A.R. 28-35-242b(f). *Multiple tubes*

If two or more radiographic tubes are controlled by one exposure switch, each tube that has been selected shall be clearly indicated before initiation of the exposure. This indication shall be both on the X-ray control panel and at or near the tube housing assembly that has been selected.

What this means: Any machine that possesses multiple x-ray tubes must have a means of clearly showing which tube is selected before an exposure. This must be visible in two places: on the control panel and near the tube housing.

What we expect from you: If you have a multiple tube machine, it is your responsibility to make sure that the tube indicators are working correctly. It is also your responsibility to have them repaired if the tube indicators malfunction.

Why: Complying with this KDHE regulation will prevent any mix-ups regarding tube selection, and therefore prevent unnecessary exposures.

K.A.R. 28-35-242b(g). *Mechanical support of the tube head*

The tube housing assembly supports shall be adjusted so that the tube housing assembly remains stable during each exposure, unless tube housing movement is a designed function of the X-ray system.

What this means: Unless designed as a hand held unit, the x-ray machine should be able to hold the position it is put in for an exposure without support from an x-ray worker.

What we expect from you: It is your responsibility to make sure that your employees are not holding the x-ray tube housing during exposures. If the tube cannot hold its position, it is your responsibility to have it repaired. The only exception to this is the hand held Nomad units.

Why: This regulation prevents unnecessary exposure to your employees. It allows them to stand outside of the exam room during exposures. In the case of the Nomad units, they have a built-in shield that, when used correctly, significantly reduces exposure to the user.

K.A.R. 28-35-242b(h). ***Technique indicators***

(1) The technique factors to be used during each exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors that are set before the exposure shall be indicated.

What this means: Selected kVp, mA, seconds, pulses, etc. must be clearly visible on the control panel of every x-ray unit before an exposure is made.

What is expected from you: It is your responsibility to ensure that the technique displays on all of your units are working, and to have them repaired if they are not.

Why: Having working exposure displays allows patient specific technique selection and therefore reduces unnecessary exposure.

K.A.R. 28-35-242b(h)(2)(i). ***Maintaining compliance***

All diagnostic X-ray systems and their associated components used on humans and certified pursuant to the federal X-ray equipment performance standard in 21 CFR part 1020 shall be maintained in compliance with the applicable requirements of that standard.

What this means: All diagnostic X-ray systems and their components used on humans must be in compliance with federal x-ray equipment performance standard 21 CFR part 1020.

What we expect from you: It is your responsibility to be familiar with the federal regulations relating to ionizing radiation, and to make sure your equipment is in compliance. If your machine is not in compliance, it is your responsibility to get it repaired. Performance standard 21 CFR part 1020 can be found at <https://www.gpo.gov/fdsys/pkg/CFR-2012-title21-vol8/pdf/CFR-2012-title21-vol8-part1020.pdf>

K.A.R. 28-35-244a. ***Radiographic other than Fluoroscopic, dental intraoral or CT***

*****Cephalometric or panoramic x-ray units must meet this part of the regulations*****

(a) Beam limitation, except for mammographic systems. Each registrant shall ensure that the useful beam is collimated to the area of clinical interest. This requirement shall be deemed to have been met if a positive beam-limiting device meeting the manufacturer's specifications and the requirements of this regulation has been used or if evidence of collimation is shown on at least three sides or three corners of the film, including projections from the shutters of the collimator, cone cutting at the corners, and borders at the film's edge.

What this means: Panoramic and cephalometric exposures must be limited to the area of interest. Manual or automatic collimation satisfy this regulation, as does permanently affixed devices limiting the area that can be exposed.

What we expect from you: It is your responsibility to ensure that your x-ray workers are trained to collimate down to the area of clinical interest.

Why: This prevents unnecessary exposure to the useful beam.

K.A.R. 28-35-244a(b). ***Radiation exposure control***

(1) Exposure initiation. A means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, including the depression of a switch. Radiation exposure shall not

be initiated without such an action. In addition, it shall not be possible to initiate an exposure when the timer is set to a “zero” or “off” position if either position is provided.

(2) Exposure indication. A means shall be provided for visual indication observable at or from the operator’s protected position whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(3) Exposure termination. A means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a present number of pulses, or a preset radiation exposure to the image receptor. Except for dental panoramic systems, termination of each exposure shall cause the automatic resetting of the timer to its initial setting or to “zero.”

What this means: Radiation exposure control has several parts that must be met for KDHE regulations. There must be some deliberate action on the part of the operator to initiate exposure; this includes pushing a button. There must be a visual indication that can be seen by the operator whenever x-rays are produced and there must be an audible signal to indicate the exposure has ended. There also must be a mechanism for the exposure to terminate after the preselected time, exposure (mA) or number of pulses has been reached. Essentially, the exposure should automatically terminate once the parameters of the exposure have been met.

What we expect from you: It is your responsibility to ensure that any equipment you possess or purchase is equipped with these capabilities. If any of these safety mechanisms stop working, it is your responsibility to have them repaired prior to taking any more x-rays with the broken equipment.

Why: These regulations provide x-ray workers with a way to monitor the progress of an exposure, which allows them to more safely do their job.

K.A.R. 28-35-244a(b)(5). ***Exposure control location***

The X-ray exposure control shall be placed so that the operator can view the patient while making any exposure. (6) Operator protection, except for veterinary systems. (A) Stationary systems. Each stationary X-ray system shall be required to have the X-ray control permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure.

What this means: The exposure control needs to be placed so that the x-ray worker can watch their patient during the exposure, but remain protected.

What we expect from you: It is your responsibility to ensure that the design of the imaging room and location of x-ray equipment allows for these KDHE regulations to be met. Employees must be educated on the importance of stepping outside the exam room or behind a protective barrier when x-rays are being taken. It is your responsibility to ensure that your employees are in compliance with these KDHE regulations.

Why: Operator and patient safety. By viewing the patient during an exposure, the x-ray worker can watch for motion and consequently cut down on repeat exposures due to motion artifacts. Employees who routinely work around radiation producing devices need to be provided with the means to limit their exposure.

K.A.R. 28-35-244a(b)(6)(B). ***Mobile and portable systems***

*****Hand Held X-ray units are still prohibited in Kansas Regulations*****

A portable/mobile x-ray dental unit must have a tube stand so the x-ray tube housing assembly does not need to be hand held during exposures.

If a dental facility wishes to purchase a Hand Held Dental X-ray unit, they must complete a hand held x-ray waiver form and submit it to KDHE for approval before use. There are several conditions that the facility must agree to follow in order to maintain this approval. It is also possible that the facility may be asked to acquire exposure monitoring for a period of time with this purchase. It is possible that the facility may have done monitoring in the past, but with the change in equipment and for the determination of occupational dose with this equipment, the facility may be asked to repeat monitoring.

*****Currently, the only hand held dental units granted waivers in the state of Kansas are the Aribex NOMAD Pro and NOMAD Pro 2*****

Link to RH-92 Request for Hand Held X-ray Waiver form:

http://www.kdheks.gov/radiation/download/RH-92_Handheld_Dental_Unit_Waiver.pdf

K.A.R. 28-35-247a. ***Intraoral Dental Radiographic Systems***

(a) Source-to-skin distance (SSD). X-ray systems designed for use with an intraoral image receptor shall be provided with a means to limit the SSD to not less than either of the following:

(1) 18 centimeters if operable above 50 kVp; or (2) 10 centimeters if operable at 50 kVp only.

(b) kVp limitations. Dental X-ray machines with a nominal fixed kVp of less than 50 kVp shall not be used to make diagnostic dental radiographs of humans.

(c) Beam limitation. Each radiographic system designed for use with an intraoral image receptor shall be provided with a means to limit the X-ray beam so that the beam at the minimum SSD is containable in a circle with a diameter of no more than seven centimeters.

What this means: The source to skin distance (SSD) between the x-ray producing device and the patient, cannot be less than 18 cm if operable above 50 kVp or 10 cm if operable at 50 kVp only. Dental radiographic machines that have a fixed kVp of less than 50 are not permitted for human use. X-ray systems, specifically used for intraoral exams, must possess a means to limit the beam to a circle with a diameter no greater than 7 cm.

What we expect from you: Most intraoral units are manufactured to meet these specifications. It is your responsibility, however, to make sure that you only possess or purchase equipment that is compliant with these KDHE regulations.

Why: Because of the relatively mobile nature of intraoral units, these regulations ensure that there are built in safety features to prevent misuse of the machines.

K.A.R. 28-35-247a(d)(1). ***Exposure initiation***

(A) A means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, including the depression of a switch. Radiation exposure shall not be initiated without such an action. (B) When the timer is set to a “zero” or “off” position, if either position is provided, an exposure shall not be possible. (2) Exposure indication. A means shall be provided for a visual indication observable at or from the operator’s protected position whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated. (3)(A)

A means shall be provided to terminate each exposure at a preset time interval, a preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. (B) An X-ray exposure control shall be incorporated into each X-ray system so that each exposure can be terminated by the operator at any time, except for exposures of one-half second or less. (C)

Each termination of an exposure shall cause the automatic resetting of the timer to its initial setting or to “zero.”

What this means: Radiation exposure control has several parts that must be met for KDHE regulations. There must be some deliberate action on the part of the operator to initiate exposure; this includes pushing a button. There must be a visual indication that can be seen by the operator whenever x-rays are produced and there must be an audible signal to indicate the exposure has

ended. If the machine is set to “zero” or “off,” it must not be possible to take an exposure. There also must be a mechanism for the exposure to terminate after the preselected time, exposure (mA) or number of pulses has been reached. Essentially, the exposure should automatically terminate once the parameters of the exposure have been met.

What we expect from you: It is your responsibility to ensure that any equipment you possess or purchase is equipped with these capabilities. If any of these safety mechanisms stop working, it is your responsibility to have them repaired prior to taking any more x-rays with the broken equipment.

Why: These regulations provide x-ray workers with a way to monitor the progress of an exposure, which allows them to more safely do their job.

K.A.R. 28-35-247a(d)(4). ***Exposure duration or timer linearity.***

For each system that provides for the independent selection of exposure time settings, the average ratios (X_1) of exposure to the indicated timer setting, in units of $C\ kg^{-1}\ s^{-1}$ (mR/s), obtained at any two clinically used time settings shall not differ by more than 0.10 times their sum. The linearity is calculated using the following equation:

$$(X_1 - X_2) \leq 0.10 (X_1 + X_2)$$

where X_1 and X_2 are the average ratios of exposure to the indicated timer setting. The exposure duration or timer linearity must also meet regulations in this part.

What this means: An increase in time should produce proportional increases in radiation exposure.

What we expect from you: When your machine is installed, the vendor should ensure that it is operating within manufacturer specifications. This includes checking the linearity. Linearity is also one of the things the KDHE inspector will check during inspections. If your KDHE inspector informs you that the linearity is off, it is your responsibility to have the unit serviced and brought back to within manufacturer specifications. If you notice any changes in your images that could be caused by issues with timer linearity, it is your responsibility to have the machine serviced.

Why: Linearity is one way to check that your machine is functioning properly. A properly functioning machine reduces radiation doses and saves everyone time and money.

K.A.R. 28-35-247a(d)(5). ***Exposure control location and operator protection.***

(A) Each stationary X-ray system shall be required to have the X-ray exposure control permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure.

What this means: Stationary x-ray units, including intraoral, must have the exposure controls mounted somewhere so that the operator is protected from radiation during the exposure.

What we expect from you: All of the intraoral units in your office need to have the exposure switch outside of the exam room. If it is an older unit where this is not possible, the exposure switch must be on the end of a long cord that allows the x-ray worker to be at least 6 feet away from the unit and the patient during exposure. The only exception to this rule is if you use a Nomad Pro handheld unit that is registered with KDHE and have received the required waiver. Anyone using a Nomad Pro unit must complete training to ensure that it is being used safely.

Why: X-ray workers are more susceptible to the negative effects of radiation due to their continued exposure. Complying with these KDHE regulations helps to reduce the cumulative dose your employees receive.

K.A.R. 28-35-247a(e). **Reproducibility**

When the equipment is operated with an adequate power supply as specified by the manufacturer, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05 for any specific combination of selected technique factors.

What this means: Reproducibility refers to the ability of an x-ray unit to consistently create the same exposure when the same technique factors are selected.

What we expect from you: When your machine is installed, the vendor should ensure that it is operating within manufacturer specifications. This includes checking the reproducibility. Reproducibility is also one of the things the KDHE inspector will check during inspections. If the KDHE inspector informs you that the reproducibility is off, it is your responsibility to have the unit serviced and brought back to within manufacturer specifications. If you notice any changes in your images that could be caused by issues with reproducibility, it is your responsibility to have the machine serviced.

Why: Reproducibility is one way to check that your machine is functioning properly. A properly functioning machine reduces radiation doses and saves everyone time and money.

K.A.R. 28-35-247a(f). **mA and mAs linearity**

The requirements specified in this subsection shall apply when the equipment is operated with a power supply as specified by the manufacturer for any fixed X-ray tube potential within the range of 40 percent to 100 percent of the maximum rated mA or mAs.

(1) Equipment that provides for the independent selection of X-ray tube current (mA). The average ratios (X_1) of exposure to the indicated milliampere-seconds product, in units of $C\text{ kg}^{-1}\text{ mAs}^{-1}$ (or mR/mAs), obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum. The linearity is calculated using the following equation:

$$X_1 - X_2 \leq 0.10 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at each of two consecutive tube current settings, or at two settings differing by no more than a factor of two if the tube current selection is continuous.

(2) Equipment that has a combined X-ray tube current-exposure time product (mAs) selector but not a separate tube current (mA) selector. The average ratios (X_1) of exposure to the indicated milliampere-seconds product, in units of $C\text{ kg}^{-1}\text{ mAs}^{-1}$ (or mR/mAs), obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum. The linearity is calculated using the following equation:

$$X_1 - X_2 \leq 0.10 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at any two mAs selector settings, or at two settings differing by no more than a factor of two if the mAs selector provides continuous selection.

What this means: An increase in mAs should produce proportional increases in radiation exposure.

What we expect from you: When your machine is installed, the vendor should ensure that it is operating within manufacturer specifications. This includes checking the linearity. Linearity is also one of the things the KDHE inspector will check during inspections. If the KDHE inspector informs you that the linearity is off, it is your responsibility to have the unit serviced and brought back to within manufacturer specifications. If you notice any changes in your images that could be caused by issues with linearity, it is your responsibility to have the machine serviced.

Why: Linearity is one way to check that your machine is functioning properly. A properly functioning machine reduces radiation doses and saves everyone time and money.

K.A.R. 28-35-247a(f)(3). **Measuring compliance**

Determination of compliance shall be based on 10 exposures taken within one hour, at each of two settings. These two settings may include any two focal spot sizes, unless one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this regulation, “focal spot size” shall mean the nominal focal spot size specified by the X-ray tube manufacturer.

What this means: Machine compliance is based on 10 exposures taken within an hour at two different exposure settings. These 10 exposures provide the information needed to determine linearity, reproducibility and radiation dose received by your patients.

What we expect from you: This regulation basically describes what the KDHE inspector will do during an inspection while testing your machines. Any time your machine is repaired or a new one is installed, the vendor should do something similar to ensure you are in compliance. It is ultimately your responsibility to ensure that your machine is in compliance. If the KDHE inspector tells you that it is not in compliance, it is your responsibility to get it fixed.

Why: This regulation provides a consistent means of testing for machine compliance.

K.A.R. 28-35-247a(g). **Accuracy**

The deviation of technique factors from the indicated values for kVp and exposure time, if time is independently selectable, shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer’s specifications, the deviation shall not exceed 10 percent of the indicated value for kVp and 20 percent for time.

What this means: The kVp, and seconds indicated on your control panel should be the actual kVp and seconds that make up the exposure. These values are allowed minimal deviation; 10% for kVp and 20% for time.

What we expect from you: Accuracy is another thing the KDHE inspector will test during inspections. If the KDHE inspector tells you it needs to be fixed, it is your responsibility to get it fixed. If you notice any changes in your images that could be caused by issues with accuracy, it is your responsibility to have the machine serviced.

Why: Accuracy is one way to check that your machine is functioning properly. A properly functioning machine reduces radiation doses and saves everyone time and money.

K.A.R. 28-35-247a(h). **Administrative controls**

(1) Patient-holding and film-holding devices shall be used when the techniques permit.

(2) The tube housing and the position indication device (PID) shall not be handheld during an exposure.

(3) Each X-ray system shall be operated so that the useful beam at the patient’s skin does not exceed the requirements of this regulation.

What this means: Mechanical devices will be used to help hold a patient or film if available and the technique permits it. No part of a stationary intraoral unit besides the exposure switch should be held during an exposure. The only exception to this is if your facility owns a Nomad Pro and has acquired the necessary waiver. When the useful beam connects with the patient’s skin, it must be in compliance with all applicable regulations.

What we expect from you: It is your responsibility to ensure that your employees are using radiation producing devices appropriately. If a patient requires holding to get a diagnostically useful image, mechanical holding devices must be used when possible. Unless you possess a Nomad Pro and the required waiver, no one in your office should ever hold the x-ray tube during an exposure. The cone collimators should always be on a unit when x-rays are being taken as this limits the useful beam when it contacts the patient’s skin. It is your responsibility to make sure everyone in your facility is trained to be safe around x-rays.

Why: This helps ensure that your employees and patients are not receiving unnecessary radiation.

K.A.R. 28-35-248a. *Computed tomography (CT) x-ray systems*

*****With the addition of Cone Beam CT technology in Dental facilities, KDHE regulations will need to be updated. As soon as there is an update, information will be distributed to all that have this type of equipment.*****

Right now there is no specific guidance for Cone Beam CT units in Kansas. KDHE is regulating against the CT regulations in place currently, but many of the current CT regulations do not apply. KDHE has been using manufacturer specifications for what is required for these units. Most, if not all, of these types of units require some kind of Quality Assurance or Quality Control practices. If you are in doubt, refer to your User's Manual and QA/QC manual to see what is required for your particular unit. Some units require a physicist survey annually as well as calibration or preventative maintenance.

If your facility replaces a panoramic unit with a cone beam CT unit, a shielding review plan must be completed for the new unit and submitted to the department for review. These shielding review plans use the patient workload on the unit to determine if more shielding is necessary to protect employees, patients and the general public. If you provide a low number of exams to the qualified expert for the shielding plan and your facility is inspected and found to be completing a much higher number of exams, you will be asked to submit another shielding plan and you may be required to shield the area.

K.A.R. 28-35-255. *Healing Arts screening*

Each person who wants to conduct a healing arts screening program shall be required to obtain the secretary's written approval before initiating the program.

What this means: Healing Arts Screening is defined as the testing of human beings using X-ray machines for the detection or evaluation of health indications when the test is performed without any prior examination and without any specific and individual order by a licensed practitioner of the healing arts. These regulations outline what is required in order to do a healing arts screening. All screening programs must be approved by KDHE before beginning.

What is expected from you: It is your responsibility to submit all required documentation for review by KDHE and waiting for approval before starting a healing arts screening program.

Why: Tracking healing arts screenings allows KDHE to ensure that if exams are being done without a doctor's order, they are being done responsibly and with a clear purpose. KDHE has observed a facility get a new Cone Beam CT and offer a CBCT scan free with an exam. This is walking the fine line with the order of events and examination after the CT scan. There MUST be an indication that this exam is warranted.

K.A.R. 28-35-256. *Training for X-ray system operators.*

The following subjects shall be included in the training of X-ray equipment operators, as applicable: (a) Familiarization with the following: (1) Identification of controls; (2) the function of each control; and (3) how to use technique charts; (b) radiation protection using the following: (1) Collimation; (2) filtration; (3) gonad shielding and, if used, other patient protection devices; (4) restriction of X-ray tube radiation to the image receptor; (5) personnel protection (c) film processing, including the following: (1) Film speed as related to the patient's exposure to radiation; (2) film processing parameters; and (3) a quality assurance program; (d) emergency procedures, which shall include the termination of exposure if an automatic timing device fails; (e) the proper use of personnel dosimetry, if required; and (f) understanding the units of radiation.

What this means: This regulation applies to all in the dental field. Anyone working with x-ray equipment should be familiar with the listed concepts.

What is expected from you: Most of this training may be provided in schooling for Dental Assistants and Dental Hygienists, but vendors and service providers should be training the operators if there is a change in the equipment or the way that images are processed. It is your responsibility to ensure your employees are trained in x-ray basics as well as the specific equipment they use. It is also your responsibility to maintain records of their training or certifications. It should be noted that training must NOT be performed using volunteers or employees as training subjects. All exposures must be done on patients with a valid order.

Why: Proper training of x-ray workers improves patient and employee safety.

Part 10—Notices, Instructions and Reports

K.A.R. 28-35-332. *Posting of notices to workers*

(a) Each licensee or registrant shall post current copies of the following documents: (2) the license, or certificate of registration (3) the operating procedures applicable to work under the license or registration; and (4) any notice of violation involving radiological working conditions (c) Department form RH-3 shall be posted by each licensee or registrant where individuals work in or frequent any portion of a controlled area. (d) Documents, notices or forms shall be posted to allow individuals engaged in work under the license or registration to observe them on the way to or from any particular work location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.

What this means: This regulation is pretty self-explanatory; it lists documents and notices required to be posted and accessible to workers.

What we expect from you: It is your responsibility to ensure that your Kansas X-ray registration certificate and RH-3 form are posted. The KDHE RH-3 form must be posted where individuals work or any portion of a controlled area. This form explains the different parts of KDHE regulations as well as other useful information for x-ray workers.

Why: By adhering to these regulations, you are showing your employees that you are registered with KDHE and your x-ray equipment is regularly inspected.

[Link to Notice to Employees RH-3 Form:](http://www.kdheks.gov/radiation/forms/Form_RH-3.pdf)

http://www.kdheks.gov/radiation/forms/Form_RH-3.pdf

K.A.R 28-35-333(a). *Instructions to workers*

Each licensee or registrant shall ensure that each individual

(2) is instructed in all of the following subjects: (A) Health protection problems associated with exposure to radioactive material or radiation to the individual and potential offspring; (B) precautions or procedures to minimize exposure; and (C) the purposes and functions of protective devices employed; (4) is informed of the individual's responsibility to report promptly to the licensee or registrant any condition that has caused or could cause any of the following: (A) A violation of these regulations; (B) a violation of a license or registration; or (C) unnecessary exposure to radiation or radioactive material; (6) is informed of the radiation exposure reports that workers may request.

What this means: X-ray workers are to be kept informed of the uses of radiation in the workplace. They are to be educated on the potential safety hazards of working with radiation. They are to be instructed in how to properly use lead shielding and other means to minimize their occupational exposure as well as the exposure of their patients. All radiation workers are required to report improper or dangerous uses of radiation or violations of these regulations to KDHE.

What we expect from you: It is your responsibility to ensure your employees are aware of the dangers of working around radiation and how to protect themselves and their patients. Many facilities satisfy this regulation by holding regular radiation safety meetings to make sure everyone is on the same page. If you decide to do this, documentation of the meetings and who was in attendance must be kept for KDHE to review during inspections.

Why: Having employees educated in radiation safety will help cut down on unnecessary exposure to not only themselves, but also patients.

K.A.R. 28-35-335. *Presence of representatives of licensees or registrants and workers during inspection.*

(a) Each licensee or registrant shall afford to the department, at all reasonable times, opportunity to inspect materials, machines, activities, facilities, premises, and records maintained by the licensee or registrant. (b) During an inspection, department inspectors may consult privately with workers. (g) Department inspectors may refuse to permit accompaniment by an individual who deliberately interferes with a fair and orderly inspection.

What this means: Registrants must allow KDHE the opportunity to inspect their facility. KDHE inspectors may talk privately with workers and may refuse accompaniment by anyone interfering with the inspection process.

What we expect from you: Please let the KDHE inspector do the inspections without interference. Allow the KDHE inspector to speak with your employees privately, if requested.

Why: The goal of the KDHE inspector is to conduct the inspection as quickly and efficiently as possible with the least amount of inconvenience for all involved.

K.A.R. 28-35-337. *Requests by workers for inspections*

(a) Any worker or representative of workers who believes that a violation of... these regulations or a license conditions exists or has occurred... may request an inspection by giving notice of the alleged violation to the department. Any such notice shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of the workers. A copy shall be provided to the licensee or registrant by the department no later than at the time of inspection except that, upon the request of the worker giving the notice, the worker's name and the name of individuals referred to shall not appear in the copy or on any record published, released, or made available by the department, except for good cause shown.

(b) If, upon receipt of the notice, the department determines that the complaint meets the requirements of subsection (a), and that there are reasonable grounds to believe that the alleged violation exists or has occurred, an inspection shall be made as soon as practicable, to determine if the alleged violation exists or has occurred. Inspections pursuant to this section need not be limited to matters referred to in the complaint. (c) No licensee or registrant shall discharge or in any manner discriminate against any worker because the worker has filed any complaint, or instituted or caused to be instituted any proceeding under these regulations, or has testified or is about to testify in any proceeding, or because of the exercise by the worker on behalf of the worker or others of any option afforded by this part.

What this means: Employees can contact KDHE and request an inspection. If their request is deemed reasonable, the KDHE inspection will be scheduled at KDHE's convenience. The requesting employee shall not be removed from their position or otherwise discriminated against.

What we expect from you: If an employee of yours brings something to the attention of KDHE that warrants an inspection, you are expected to assist KDHE as necessary and allow KDHE to inspect your facility. You are not allowed to retaliate against the complainant.

Why: It is important that employees be allowed to voice their concerns with KDHE without fear of retaliation.