

April 16, 2020

INFORMATION NOTICE: KS IN 2020-01

Temporary Guidance for X-ray Registrants and Physicists in Kansas During the COVID-19 Pandemic

ADDRESSEES

All Kansas X-ray Registrants and Physicists

PURPOSE

The Kansas Department of Health and Environment (KDHE) is issuing this Information Notice to inform registrants and physicists about temporary guidance during the COVID-19 pandemic.

DESCRIPTION OF CIRCUMSTANCES

KDHE – Radiation Control Program has received numerous inquiries regarding COVID-19 and its impacts on our Kansas medical facilities. Our X-ray and Mammography Program has prepared the following information to address some of the common questions from our registrants.

DISCUSSION

Contacting KDHE Radiation Control Program during the current COVID-19 situation

Email: The KDHE X-ray inbox is being checked daily Monday – Friday. These emails will be answered as quickly as possible. Email is preferred as your X-ray inspectors are working remotely during this COVID-19 situation. It will ensure that you get the quickest answer to your questions or concerns. The email address is kdhe.xray@ks.gov.

Phone: The main phone number for the Radiation Control Program is 785-296-1560. A voicemail can be left at this number, but it may take extra time to have your call returned. Voicemail cannot be checked as frequently due to the COVID-19 situation and staff working remotely.

Mail: If you have no access to email, you can still contact your X-ray inspection staff by mail. Keep in mind, mail may not be picked up daily and a reply to mail will take longer than an email due to our staff working remotely. The mailing address is KDHE, Radiation Control Program, X-ray Compliance Section, 1000 SW Jackson, Suite 330, Topeka, KS 66612.

Mammography Units and Mammography Questions

The Food and Drug Administration (FDA) Division of Mammography Quality Standards (DMQS) has received numerous inquiries regarding COVID-19 and its increasing impact on mammography facilities. The FDA has temporarily postponed domestic inspections including ones performed under contract with its state regulatory partners. As a result, KDHE is not currently performing Mammography inspections. This may affect all Kansas facilities performing mammography.

FDA has provided guidance for all MQSA mammography facilities addressing several frequently asked questions. These include the timing of physicist surveys and MQSA inspections as well as facility instructions for those who choose to cease mammography operations. This also includes some information about facilities that continue to operate

and have circumstances that may lead to non-compliances during their upcoming inspection. The information can be found at the following link: https://www.fda.gov/radiation-emitting-products/mammography-quality-standards-act-and-program/mqsa-inspection-information-related-covid-19?utm_campaign=2020-03-19%20CDRH%20Safety%20Comm%20%E2%80%93%20MQSA%20Inspections%20and%20COVID-19&utm_medium=email&utm_source=Eloqua

All other X-ray Units

Physicists:

If you are receiving calls or emails with questions from facilities about their annual physicist surveys of X-ray equipment that is due in March, April, or May 2020 (as well as possibly into the future months) and you are not currently traveling to complete these surveys during the COVID-19 situation, KDHE – Radiation Control Program has the following guidance to document these circumstances:

If you are contacted by a facility about their annual physicist survey of equipment, such as fluoroscopy, CT, CBCT, therapy accelerators, as well as all other equipment, please have them contact our department by email at kdhe.xray@ks.gov.

After receiving an email notification from the facility, KDHE will send a notification form to the facility to be completed and returned to our department which will document the situation for our records. After the COVID-19 situation has resolved, KDHE Radiation Control Program is requiring the physicist annual survey be completed within 16 months of the previous survey (Further guidance will be given if the timeframe extends past 16 months due to the COVID-19 situation.). No enforcement action will be taken by KDHE for these delayed physicist surveys.

Facilities:

Facilities that are not able to keep their annual schedule for physicist surveys of fluoroscopy, CT, CBCT, therapy accelerators, as well as all other equipment, should contact our department by email at kdhe.xray@ks.gov. After the KDHE Radiation Control Program receives the email notification, a response form will be sent to the facility which must be completed and returned to our department. After the COVID-19 situation has resolved, the physicist must return to complete the annual survey within 16 months of the previous survey (Further guidance will be given if the timeframe extends past 16 months due to the COVID-19 situation.) No enforcement action will be taken by KDHE for these delayed physicist surveys.

Notification Form for Physicist Survey delays/postponements

Physicists:

KDHE – Radiation Control Program has developed a form to document the change in the annual schedule for physicist surveys at a facility. If the facility was scheduled to have their physicist survey in March, April, May, or possibly June 2020, our department is requesting the facility contact KDHE by email at kdhe.xray@ks.gov to obtain the appropriate form to complete and return for review. This form will be placed in the facility's registration file for documentation purposes, to avoid possible violations of regulations at their next X-ray inspection. If the facility needs any specific questions answered about the notification form or how to complete the form, they should email kdhe.xray@ks.gov.

****NOTE: The form that has been developed is only to be used in the event of an emergency, such as this COVID-19 situation. This form is not approved for use under normal operating conditions.

Facilities:

KDHE – Radiation Control Program has developed a form to document the change in the annual schedule for physicist surveys at a facility. If you were normally scheduled to have your annual physicist surveys in March, April, May, or June 2020, contact KDHE by email at kdhe.xray@ks.gov to obtain the appropriate form to complete and return to

KDHE for review. This form will be placed in your registration file for documentation purposes, to avoid possible violations of regulations at your next X-ray inspection.

If you have any specific questions about the notification form or how to complete it, contact KDHE by email at: kdhe.xray@ks.gov.

****NOTE: The form that has been developed is only to be used in the event of an emergency, such as this COVID-19 situation. This form is not approved for use under normal operating conditions.

Where to send the notification form

Facilities:

After completing the notification form, send it by email to kdhe.xray@ks.gov.

If email is not an option, the form can also be mailed to: KDHE, Radiation Control Program, X-ray Compliance Section, 1000 SW Jackson, Suite 330, Topeka, KS 66612.

****NOTE: During this time, mail may not be picked up daily. A reply to regular mail will take longer than an email due to our staff working remotely.

Questions about Equipment Repairs

Equipment may need repair during this COVID-19 situation. Some repairs may be simple, but other repairs may affect the output of the X-ray unit and require consultation with a physicist. This physicist consultation may be completed by phone or email if the service report contains appropriate testing data. This service report must provide testing data to verify the X-ray unit is meeting manufacturer specifications.

KDHE has received communication from the American Association of Physicists in Medicine (AAPM) requesting the relaxation of regulation requirements for physicist surveys on X-ray equipment from 12 months up to 16 months. KDHE – Radiation Control Program has decided to temporarily extend the length of time between required physicist surveys. At this time, your facility will have up to 16 months to acquire your annual physicist survey if it was due between March and June of 2020. This is a temporary extension and will resume the normal period of 12 months when the COVID-19 situation resolves. If the COVID-19 situation goes past June 2020, there will be additional guidance available from KDHE – Radiation Control Program.

The information below addresses the service documentation and physicist consultation documentation that KDHE is requesting from the facility.

Equipment Repair – Normal Repairs

Facilities:

Any facility with **equipment that has been repaired** during this time is required to request a copy of the service order from the service provider. If the X-ray unit has required QA procedures, these QA procedures must be completed and all testing with a passing score before the unit is put back into use.

The facility must provide the documentation below to KDHE during the COVID-19 situation to ensure repairs are completed and equipment is functioning properly after the repair since KDHE X-ray inspectors will not be in the field completing inspections at this time.

This service order **must**:

1. Describe the work completed on the X-ray unit
2. Document all testing data to show the X-ray unit is meeting all manufacturer specifications
3. Contain the service company name and contact information

4. Include the date service was completed
5. Include the printed name and signature of the person completing the service
6. Be submitted to KDHE Radiation Control Program to be entered into the registrant file

Major Equipment Repair or Component Replacement (that will require physicist surveys)

Physicists:

Any facility that has a major equipment repair or component replacement (anything that will affect the output of the unit) must provide written documentation of physicist consultation (conducted in person, or by phone or email) to give their approval for the facility to continue to use the X-ray unit. The facility will be required to complete any QA procedures for the specific X-ray unit and test with a passing score before the unit is put back into use. The approval from the physicist must include written documentation for the facility to provide to KDHE. If the physicist does not approve the X-ray unit to be put back into use, the unit must be placed out of service.

Facilities:

Any facility that has major equipment repair or component replacement (anything that will affect the output of the unit) must provide written documentation of physicist consultation and approval prior to continuing use of the X-ray unit. If the X-ray unit has required QA procedures, all QA procedures must be completed and all testing with a passing score before the X-ray unit is put back into use. If the physicist does not approve the X-ray unit to be used on patients, the X-ray unit must be placed out of service.

Within 6 months from the time after the COVID-19 situation has resolved to the extent that physicists are able to travel and enter facilities again, the physicist must complete annual surveys on all equipment that is or was due during the COVID-19 situation.

The facility must provide the physicist documentation listed below to KDHE.

This documentation **must:**

1. Contain physicist company name, contact information, and date of consultation
2. Include physicist name and signature
3. Include description of the consultation with the registrant about the specific repair of the unit
4. Include an explanation of the physicist plan for future survey or any other pertinent information to ensure the equipment is operating properly and meeting all QA recommendations from the physicist
5. Be submitted to KDHE Radiation Control Program to be entered into the registrant file

Proposed Changes to Mobile Chest X-ray Procedures in Facilities

KDHE has received inquiries about alterations to standard mobile chest X-ray protocols. As the COVID-19 pandemic continues to evolve, KDHE has become aware of the need for revised guidance on radiation protection in relation to mobile chest X-rays and infection control. To help slow the potential spread of the virus during mobile chest X-rays, several changes in standard policy and procedures have been proposed for implementation at hospitals in Kansas.

Imaging through a physical barrier:

To minimize contamination of the mobile X-ray unit, various barriers could be used such as plastic or glass. If imaging is done through glass, the glass should not have additional lead equivalent added. If there is a structural component to the glass which could interfere with the image, the radiologist or physicist should evaluate the glass or plastic before imaging.

Physicists:

Some of your facilities may be consulting with you about technique changes and calculations of dose to staff with proposed changes in mobile chest X-ray protocols during this time. An example of a request already received by KDHE involves utilizing a technique which allows the X-ray unit to remain outside the isolation room, making the X-ray

exposure through the glass door or window. The digital receptor is passed into the room to other hospital staff who place the image receptor behind the patient. A holder's log is kept to document exposure to staff in the room during the X-ray. This holder's log must document the first and last name of the person in the room during exposure as well as an estimated dose to the hospital staff in the room for each exam. (This will require some calculations from the physicist to determine possible doses. Due to the possibility of the staff being limited or changing over time, it is imperative that a record of each hospital staff member is recorded and maintained.)

KDHE is allowing these types of changes in mobile chest X-ray policy but requests the revised facility policy be submitted to KDHE. This submission may be done after the changes have been implemented to allow for continued care without any delays.

Facilities:

If your facility has implemented or is proposing implementation of policy changes for mobile chest X-ray procedures in order to minimize the spread of COVID-19 and prevent contamination of the X-ray unit, KDHE recommends that you consult with your physicist to help with these changes. Some of the changes may require patient technique increases to allow for exposure through windows or glass doors. The changes may also include calculations of dose to other staff that may have to help position image detectors in the patient room during the X-rays of isolation patients.

The policy changes must provide for radiation safety of the X-ray staff and other possible hospital staff involved with the care of the patient. All staff that may be in the isolation room must wear lead aprons and if directly adjacent to the patient during the exposure, thyroid collar. Staff inside the room should be as far from the patient as possible during the X-ray exposure, unless the patient needs direct assistance during the exam.

A holder's log must document the first and last name of the any nursing or care staff in the room during exposure as well as an estimated dose to that staff member during the X-ray. (This will require some calculations from the physicist to determine possible doses. Due to the possibility of staff being limited or changing over time, it is imperative that a record of each hospital staff member is recorded and maintained.)

To prevent patient care without delays, your facility may make changes to mobile chest X-ray policies and procedures at this time, but a copy of the procedure change must be sent to KDHE for review and possible further guidance prior to or as soon as possible after your changes are implemented.

Guidance on Registration and Use of X-ray Units at Temporary Facilities During the COVID-19 Pandemic

Registration of X-ray units:

Governor Laura Kelly recently signed an executive order (EO 20-19) which allows professional certifications or registrations to remain active, provided they were active and in good standing as of March 12, 2020. This remains in effect through termination of the disaster declaration plus an additional 90 days. You will remain active and in good standing through this time, but it will not extend the expiration date of subsequent renewal of annual registration, nor will fees associated with 2020 registration or subsequent renewals be waived.

KDHE is still processing renewal of registration (if not already paid for 2020) and encourage you to submit registration of new equipment as normal, however, KDHE will not be completing enforcement actions on registration during the disaster declaration.

The following information will address registration of X-ray units in different scenarios that may become necessary during the current COVID-19 pandemic.

1. Mobile X-ray (radiographic) units used in an extension of an existing registered facility (example: tent in parking lot)

It would be considered the same facility when existing mobile X-ray (radiographic) units are used in tents or other buildings in the same vicinity of the registered facility. Current regulations state that new X-ray units need to be registered within 30 days. In accordance with EO 20-19 referenced previously, KDHE will extend the registration deadline for new X-ray units during the COVID-19 crisis. Existing and already registered mobile X-ray (radiographic) units can be used in these areas without additional registration notification.

2. Mobile X-ray (radiographic) units used in a new location by an existing registrant

A mobile X-ray (radiographic) unit already registered to the facility could be moved and used at the new facility, as long as the ownership is the same.

3. Mobile X-ray (radiographic) unit used in a previously closed facility (example: closed hospital)

A mobile X-ray (radiographic) unit already registered at an existing facility, could be moved and used at the previously closed facility, as long as the ownership is the same. For any units that would be installed for use in a single room/location, the facility would need to notify and register such unit with KDHE. In accordance with EO 20-19 referenced previously, KDHE will extend the registration deadline for these X-ray units during the COVID-19 crisis. If the unit is installed in a room that previously had shielding approved, as long as that shielding is still in place, no new shielding review would need to be completed. If the facility is in use longer than 90 days, the shielding should be verified by a physicist. If this is not possible, send an email to kdhe.xray@ks.gov to obtain further guidance. If the facility is opened and run by the federal government (example: FEMA), state registration would not be required.

4. Mobile X-ray (radiographic) unit used in a non-traditional medical setting (example: Convention Center)

If the non-traditional setting is being run by an existing facility, a mobile X-ray (radiographic) unit already registered to the facility could be moved and used. For any units that would be installed for use in a single room/location, the facility would need to notify and register such unit/facility with the KDHE within 90 days of the first use. If this is not possible, send an email to kdhe.xray@ks.gov to obtain further guidance.

If the non-traditional setting is run by a state government entity or private entity not previously registered with the state, all units would need to be registered within 90 days of the first use. If this is not possible, send an email to kdhe.xray@ks.gov to obtain further guidance.

If the non-traditional setting is run by the federal government (example: FEMA), state registration would not be required.

5. Portable, handheld X-ray units

Portable, handheld X-ray units are not approved in Kansas to be used for chest X-rays or any X-ray except dental X-rays.

Shielding requirements

This applies to Mobile X-ray (radiographic units, fixed radiographic units, CT units on a coach, at CT units installed into a “permanent” room in a facility.

1. Mobile X-ray (radiographic) Units

Mobile X-ray (radiographic) units are designed to move from one location to another and do not require a shielding evaluation to be completed. No one should be within 6 feet of the patient and the radiation source when exposures are made.

2. Fixed Radiographic Unit

For an X-ray unit installed for use in a single room/location, the registrant should provide an initial radiation protection survey with at least four points indicated, one on each side of the location (with appropriate scatter readings) including a general layout of the location with primary barrier and boundaries indicated. The boundaries should not exceed the public exposure limit. No one should be within 6 feet of the patient or radiation source when exposures are made unless a mobile shield is used. For any unit in use for more than 90 days, a complete shielding review would need to be completed. If this is not possible, contact kdhe.xray@ks.gov for further guidance.

3. CT unit on a coach brought to the facility

The coach should be parked in an area with low occupancy and boundary controls should be used. The registrant should provide a radiation protection survey with at least four points indicated, one on each side of the location (with appropriate scatter readings) including a general layout of the location with the boundaries indicated. The boundaries should not exceed the public exposure limit.

4. CT unit installed in a “permanent” room at a temporary facility

For a unit installed for use in a single room/location, the registrant should provide an initial radiation protection survey with at least four points indicated, one on each side of the room/locations (with appropriate scatter readings) including a general layout of the location with primary barrier and boundaries indicated. The boundaries should not exceed the public exposure limit. For any unit in use for more than 90 days, a complete shielding review would need to be completed. If this is not possible, send an email to kdhe.xray@ks.gov for further guidance.

X-ray use in a temporary location

Operator:

1. Personal monitoring badge should be used
2. The operator must stand 6 feet from the primary beam and use an apron or mobile shield during exposure. This operator must be able to control access to this controlled area during the X-ray exposure.

X-ray performance on gurney patients: When the beam is directed toward the image receptor placed behind the patient (AP), no additional shielding should be required posterior to the receptor. This only applies if the beam is appropriately collimated to minimize scatter radiation and ALARA techniques is utilized.

Gurney patients: All gurney patients should be placed 6 feet apart or incorporate the use of a mobile shield to decrease the likelihood of receiving scatter radiation from other patients (receiving X-rays).

Standing patients: To reduce the need for additional posterior shielding when the beam is directed toward an image receptor placed in front of the patient (PA), the image receptor must be placed adjacent to a location with low occupancy or with a wall having high natural shielding such as brick or concrete.

Ideally, the image receptor should not be held by a person. If possible, a cassette holder should be used. If this is not an option, the patient should be imaged on a gurney. In the event that neither of these is possible, no one individual should be designed to hold the image receptor every time. If possible, staff should be rotated to keep their dose to the minimum amount possible.

All patients: The image receptor/X-ray beam must be located at least 6 feet away from side walls unless the walls are constructed of natural shielding such as brick or concrete.

Waiting patients: All other patients should be located away from the X-ray area with boundaries in place to ensure compliance with the public dose limit.

Maintaining Control of the Radiation Source: When not in use, the X-ray unit should be secured from unauthorized use.

Personal Shielding: Adequate lead aprons, gloves, and thyroid shields should be available to all staff within 6 feet of these mobile exams.

General COVID-19 Information on the State Website

KDHE – Radiation Control program realizes that the COVID-19 situation may continue to rapidly change. The State of Kansas has a website with general COVID-19 information. This information is available at the link to follow.

<https://govstatus.egov.com/coronavirus>

There is a phone hotline to call at : 866-534-3463 (866-KDHEINF). This is for general COVID information and is not related to X-ray or radiation.

The phone hotline hours are as follows:

Monday - Friday, 8:30 am - 5:30 pm

Saturday, 10 am - 2 pm

Sunday, 1 - 5 pm

You can also email questions to: covid-19@ks.gov