

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
NOTICE OF PUBLIC HEARING

December 9, 2019
10:00 a.m. Central Time
Nebraska State Office Building – Lower Level B
301 Centennial Mall South, Lincoln, Nebraska

The purpose of this hearing is to receive comments on proposed changes to Title 180, Chapter 8 of the Nebraska Administrative Code (NAC) – *Radiation Safety Requirements for Analytical X-Ray Equipment*. The chapter outlines the safety requirements for persons using radiation generating equipment on materials in industrial and educational settings. The proposed changes rename the chapter to accurately reflect the types of equipment and uses covered in the regulation; transfer language governing the use of cabinet x-ray systems from 180 NAC 5 to this chapter; reduce interlock testing frequency for cabinet x-ray systems; remove all requirements for devices using radioactive material as the source of radiation; add safety requirements relating to open-beam hand-held radiation generating devices and use of fluoroscopes; and update formatting.

Authority for these regulations is found in Neb. Rev. Stat. § 81-3117(7).

Interested persons may attend the hearing and provide verbal or written comments or mail, fax or email written comments, no later than the day of the hearing to: DHHS Legal Services, PO Box 95026, Lincoln, NE 68509-5026, (402) 742-2382 or dhhs.regulations@nebraska.gov, respectively.

A copy of the proposed changes is available online at <http://www.sos.ne.gov>, or by contacting DHHS at the mailing address or email above, or by phone at (402) 471-8417. The fiscal impact statement for these proposed changes may be obtained at the office of the Secretary of State, Regulations Division, 1201 N Street, Suite 120, Lincoln, NE 68508, or by calling (402) 471-2385.

Auxiliary aids or reasonable accommodations needed to participate in a hearing can be requested by calling (402) 471-8417. Individuals with hearing impairments may call DHHS at (402) 471-9570 (voice and TDD) or the Nebraska Relay System at 711 or (800) 833-7352 TDD at least 2 weeks prior to the hearing.

FISCAL IMPACT STATEMENT

Agency: Department of Health and Human Services	
Title: 180	Prepared by: Julia Schmitt
Chapter: 8	Date prepared: 6/28/2018
Subject: Radiation Safety Requirements For Non-Healing Arts Radiation Generating Devices	Telephone: 402/471-0528

Type of Fiscal Impact:

	State Agency	Political Sub.	Regulated Public
No Fiscal Impact	(<input checked="" type="checkbox"/>)	(<input checked="" type="checkbox"/>)	(<input checked="" type="checkbox"/>)
Increased Costs	(<input type="checkbox"/>)	(<input type="checkbox"/>)	(<input type="checkbox"/>)
Decreased Costs	(<input type="checkbox"/>)	(<input type="checkbox"/>)	(<input type="checkbox"/>)
Increased Revenue	(<input type="checkbox"/>)	(<input type="checkbox"/>)	(<input type="checkbox"/>)
Decreased Revenue	(<input type="checkbox"/>)	(<input type="checkbox"/>)	(<input type="checkbox"/>)
Indeterminable	(<input type="checkbox"/>)	(<input type="checkbox"/>)	(<input type="checkbox"/>)

Provide an Estimated Cost & Description of Impact:

State Agency:

Political Subdivision:

Regulated Public:

If indeterminable, explain why:

PROPOSED REGULATION QUESTIONNAIRE

Title 180 NAC 8

1) Is the regulation essential to the health, safety, or welfare of Nebraskans?

Yes. The purpose of the regulations are to institute and maintain a program to permit development and utilization of sources of radiation for peaceful purposes consistent with the protection of occupational and public health and safety and the environment. The regulations in this chapter apply to entities using radiation generating equipment on materials in industrial and educational settings. The regulations in this chapter do not apply to radiation generating devices used on humans. Ionizing radiation has a number of beneficial uses, including bomb detection, analysis of the elemental composition and microstructure of materials. However, ionizing radiation is potentially harmful if not used correctly. As such, it is important that the regulated entities use radiation in a manner that protects the user and the public.

2) Do the costs of the regulation outweigh the benefits? Provide specific data and reasoning.

Yes. The use of radiation generating equipment provides benefits to the public in a number of industrial and educational settings. Misuse of ionizing radiation can have catastrophic health consequences. The regulations provide safeguards that allow the benefits while minimizing risks.

3) Does a process exist to measure the effectiveness of the regulation? If so, explain.

Yes. Registrants are inspected for compliance with the radiation safety regulations.

4) Has a less restrictive alternative been considered?

The least restrictive alternative has been chosen where possible. For example, the frequency of interlock testing on cabinet x-ray systems has been reduced to annually, open-beam hand-held radiation generating device users no longer need to get Department approval before using the device.

5) Was the regulation solely promulgated due a state statutory requirement? If so, provide citations.

Yes, Neb. Rev. Stat. § 71-3505 (1) requires regulations. However, even if the statute were to be changed to "may", regulations would be needed to ensure public safety and safe radiation use by the regulated entities.

6) Was the regulation promulgated as a result of a federal mandate? If so, include copies of the applicable federal statutes and regulations.

No.

PROPOSED REGULATION POLICY PRE-REVIEW CHECKLIST

Agency: DHHS – Division of Public Health

Title, Chapter of Regulation: Title 180 NAC 8

Subject: Control of Radiation – Radiation Safety Requirements For Non-Healing Arts Radiation Generating Devices

Prepared by: Julia Schmitt

Telephone: 401-471-0528

A. Policy Changes and Impacts

1. What does the regulation do and whom does it impact? Provide a brief description of the proposed rule or regulation and its impacts on state agencies, political subdivisions, and regulated persons or entities.

The regulations in this chapter apply to persons using radiation generating equipment on materials in industrial and educational settings. The regulations in this chapter do not apply to radiation generating devices used on humans. This revision to the regulations include the following changes:

- The name of the chapter was changed from “Radiation Safety Requirements for Analytical X-Ray equipment” to “Radiation Safety Requirements for Non-Healing Arts Radiation Generating Devices” to more accurately reflect what types of equipment and uses are covered by this chapter.
- Regulations governing the use of cabinet x-ray systems were moved from 180 NAC 5 (Industrial Radiography) to this chapter as the majority of the requirements in chapter 5 were not applicable to these devices.
- Interlock testing frequency for cabinet x-ray systems was reduced from 6 months to 12 months.
- All requirements for devices that use radioactive material as the source of radiation were removed from this chapter.
- Open-beam hand-held radiation generating device safety requirements were added to this chapter. Previously, these types of devices were only allowed after getting Department approval.
- General safety requirements governing the use of fluoroscopes used in shielded rooms, bomb detection devices, x-ray gauges,

irradiators and electron beam welders were added to this chapter. Previously there were not specific regulations regarding the safe use of these types of devices and registrants were confused about what regulations applied.

2. Describe changes being proposed to current policy and briefly provide rationale.

There is no change to current policy.

B. Why is the rule necessary? Explain and provide an identification of authorizing statute(s) or legislative bill(s).

1. Update of regulation (repeal of obsolete statutes, reflect current policy, editing or technical language changes, etc.)

This revision re-promulgates Title 180 NAC 8 to comply with the formatting requirements of the Secretary of State. In addition, unnecessary requirements were removed and technical requirements were eased.

2. Annual changes – cost of living, hunting season schedules, etc.

No

3. Law was changed – federal ____ or state ____ [Cite authorizing statute(s) or legislative bill(s)] No

4. Extension of established policy or program, new initiatives or changes in policy (within statutory authority) No

5. Constituent initiated No

6. Financial needs – increases/decreases in fees No

7. Litigation requires changes in rules No

8. Addresses legal or constitutional concerns of Attorney General's office No

9. Implements federal or court mandate No

10. Other (explain)

C. What happens if these rules are not adopted?

Unnecessary language would remain in place, registrants would continue to have to test interlocks every six months on cabinet x-ray systems, open-

beam hand-held radiation generating device users would continue to get Department approval before using the device, registrants with fluoroscopes used in shielded rooms, bomb detection devices, x-ray gauges, irradiators and electron beam welders would remain confused about what safety rules apply to them.

D. Policy Checklist

1. Is this an update or editorial change reflecting essentially no change in policy? **Yes**
2. Does the policy in the proposed regulation reflect legislative intent?
Yes
3. Is the policy proposed in the regulation a state mandate on local government? **No** Is it funded? **N/A**
4. Is the policy proposed in the regulation a federal mandate on local government? **No** Is it funded? **N/A**

E. Fiscal Impact. In addition to completing the required Fiscal Impact Statement (a copy must be attached to this document), the agency must address the following:

1. Will the proposed regulation reduce, increase, or have no change in resources – funds, personnel or FTE? **No change.**
2. Have initial contacts been made with citizens or organizations that may be impacted by the proposed regulation?
We will solicit public comment before a public hearing.
3. Does the proposed regulation impact another agency? **No** Explain the impact. **No impact.**
4. Will the proposed regulation reduce, increase, or have no change on reporting requirements of businesses? **No change.**
5. What is the agency's best estimate of the additional or reduced spending? If there is none, please note. If receipt of federal funds is contingent upon approval of the proposed regulation, then indicate the amount and nature of the federal funds affected, and enclose laws or correspondence from federal officials substantiating the information.

N/A

6. Include a description of the impact that the proposed regulation will have on the number of state employees and how the agency intends to address proposed increases or decreases in FTE.

No Impact.

F. Unique problems or issues and recommendations.

No known problems or issues.

G. Who is expected to be affected, or to oppose or support the proposed regulation? Explain what initial informal contacts have been made with organizations or citizens who may be affected by the regulation prior to the public hearing.

No known supporters or opponents.

DHHS will solicit public comment on the proposed regulations before the public hearing.

H. Are these proposed rules a likely candidate for negotiated rulemaking? Explain. Has the process been completed? If so, explain how the issues were addressed.

No.

TITLE 180 CONTROL OF RADIATION

CHAPTER 8 RADIATION SAFETY REQUIREMENTS FOR NON-HEALING ARTS
RADIATION GENERATING DEVICES

001. SCOPE AND AUTHORITY. This chapter provides special requirements for radiation generating devices. The regulations are authorized by and implement the Radiation Control Act, Nebraska Revised Statute (Neb. Rev. Stat.) §§ 71-3501 to 71-3520. For purposes of this section, non-healing arts x-ray equipment include, but are not limited to, open and closed analytical x-ray equipment, x-ray gauges, cabinet x-ray radiography, security screening units, quality control application devices, ion implantation devices, electron beam welders, non-human use x-ray fluoroscopy, x-ray bomb detection, and x-ray irradiators. The requirements of this chapter are in addition to, and not in substitution for applicable requirements in 180 Nebraska Administrative Code (NAC) 1, 2, 4, 10, 15, and 18.

002. DEFINITIONS. The following definitions apply:

002.01 ACCESSIBLE SURFACE. An accessible surface is a surface that is external or outside of the enclosure or housing provided by the manufacturer. This includes the high-voltage generator, doors, access panels, latches, control knobs, and other permanently mounted hardware and including the plane across the exterior edge of any opening.

002.02 BAGGAGE UNIT. A baggage unit has the same meaning as stated in "Security Screening Unit".

002.03 BEAM PORT. The beam port is the opening on the x-ray apparatus designed to emit a primary beam. This does not include openings on baggage units

002.04 BOMB DETECTION RADIOGRAPHIC EQUIPMENT. Bomb detection radiographic equipment is equipment used solely for the purpose of remotely detecting explosive devices. This definition does not include hand held x-ray bomb detection equipment for the purposes of this chapter.

002.05 CABINET RADIOGRAPHY. Cabinet radiography is industrial radiography using radiation machines not subject to Food and Drug Administration (FDA) performance standards for cabinet x-ray systems, in an enclosed, interlocked cabinet in which the portion of a material being irradiated is contained, and where:

- (A) The radiation machine will not operate unless all openings are closed with interlocks activated;

- (B) The cabinet is shielded so that every location on the exterior meets the conditions for an unrestricted area as defined in 180 NAC 4 of these regulations; and
- (C) The cabinet is constructed or arranged to exclude the entrance of any part of the body of an individual during irradiation.

002.06 CABINET X-RAY SYSTEM. Cabinet x-ray system has the same meaning as set out in Part 21 Code of Federal Regulations (CFR), 21 CFR §1020.40

002.07 CERTIFIED CABINET X-RAY SYSTEM. A certified cabinet x-ray system is a radiation generating device certified by the manufacturer according to 21 CFR §1010.2 as being manufactured and assembled according to the provisions of applicable federal radiation safety performance standards 21 CFR §1010 and 21 CFR §1020.40.

002.08 CERTIFIABLE CABINET X-RAY SYSTEM. A certifiable cabinet x-ray system is an existing uncertified radiation generating device that has been modified to meet the certification requirements specified in 21 CFR §1020.40.

002.09 CLOSED-BEAM X-RAY EQUIPMENT. Closed-beam x-ray equipment is a system where the beam path cannot be entered by any part of the body during normal operation.

002.10 COLLIMATOR. A collimator is a device for restricting the useful radiation in one or more directions.

002.11 CONTROL PANEL. A control panel is a device containing means for regulation and activation of radiation generating equipment or for the preselection and indication of operating factors.

002.12 FAIL-SAFE CHARACTERISTICS DESIGN. A fail-safe characteristics design is a design feature of a unit which causes beam port shutters to close, or otherwise prevents emergence of the primary beam, upon the failure of safety or warning devices.

002.13 HAND HELD X-RAY SYSTEM. A hand held x-ray system is a portable instrument that is designed to operate when held in the hand.

002.14 INDUSTRIAL RADIOGRAPHY. Industrial radiography is an examination of the structure of materials by nondestructive methods utilizing ionizing radiation to make radiographic images.

002.15 INTERLOCK. An interlock is a device or engineered system that prohibits access to an area of radiation hazard either by preventing entry or by automatically removing the hazard.

002.16 LEAKAGE RADIATION. Leakage radiation is all radiation coming from within the source housing, except the useful beam.

002.17 LOCAL COMPONENTS. Local components are part of a radiation generating device x-ray system and includes areas that are struck by x-rays including the radiation source housing, beam port and shutter assemblies, collimators, sample holders, cameras,

goniometers, detectors and shielding, but do not include power supplies, transformers, amplifiers, readout devices, and control panels.

002.18 NORMAL OPERATING PROCEDURES. Normal operating procedures are step-by-step instructions necessary to accomplish the analysis. These procedures must include sample insertion and manipulation, equipment alignment, routine maintenance by the registrant, and data recording procedures which are related to radiation safety.

002.19 OPEN-BEAM CONFIGURATION. An open-beam configuration is a x-ray system where an individual could place some part of their body in the primary beam path during operation.

002.20 PRIMARY BEAM. The primary beam is ionizing radiation coming directly from the radiation source through a beam port into the volume defined by the collimation system.

002.21 RADIATION GENERATING DEVICE (RGD). A radiation generating device is any system, device, subsystem, or component of, which may generate x-rays or particle radiation between 5 kiloelectron volt (keV) and 1 megaelectronvolt (MeV), and is not intended for healing arts use for humans or animals. Radiation generating devices (RGD) are classified in the following ways:

- (A) A mobile radiation generating device is mounted on a permanent base with wheels or casters for moving while completely assembled;
- (B) A portable radiation generating device is designed to be hand-carried;
- (C) A stationary radiation generating device is installed or placed in a fixed location; or
- (D) A transportable radiation generating device is installed in a vehicle or may be readily disassembled for transport or use in a vehicle.

002.22 RADIATION SOURCE OR X-RAY TUBE HOUSING. The radiation source or x-ray tube housing is the portion of an x-ray system that contains the x-ray tube or secondary target. Often the housing contains radiation shielding material or inherently provides shielding.

002.23 SAFETY DEVICE. A safety device is a device, interlock, or system that prevents the entry of any portion of an individual's body into the primary x-ray beam path or that causes the beam to be shut off upon entry into its path.

002.24 SCATTERED RADIATION. Scattered radiation is radiation that has been deviated in direction, energy by passing through matter, or both.

002.25 SECURITY SCREENING UNIT. A security screening unit is a non-human use x-ray system with accessible openings designed for the detection of weapons or bombs, or contraband concealed in baggage, mail, packages, or other commodities or structures.

002.26 SHIELDED ROOM. A shielded room is a room housing a radiation generating device where, when the radiation generating device is set at maximum techniques, the exterior room environs meets the unrestricted area limits of 0.02 milliSievert (2 millirem) in any one hour and 1 milliSievert (100 millirem) in a year at 30 centimeters from the barrier. A shielded room does not include radiation generating equipment meeting the definition of cabinet x-ray systems.

002.27 SHUTTER. A shutter is a moveable device used to block the useful or primary beam emitted from an x-ray tube assembly.

002.28 SOURCE. A source is a point of origin of the radiation.

002.29 WARNING DEVICE. A warning device is a visible or audible signal that warns individuals of a potential radiation hazard.

002.30 X-RAY GENERATOR. A x-ray generator is a portion of an x-ray system that provides accelerating high voltage and current for the x-ray tube.

003. DEVICE SAFETY REQUIREMENTS. Radiation generating devices must meet the requirements of this section.

003.01 WARNING DEVICES. Warning devices must be labeled so their purpose is easily identified. On equipment installed after June 27, 1983, warning devices must have fail-safe characteristics.

003.01(A) WARNING LIGHT LOCATION. An easily visible warning light labeled with the words "X-RAY ON", or words having a similar intent, must be located near any switch that energizes an x-ray tube and must be illuminated only when the tube is energized.

003.02 PORTS. Unused ports on radiation source housings must be secured in the closed position in a way that will prevent unintended opening.

003.03 LABELING. All radiation generating devices must be labeled with a readily visible sign or signs bearing the radiation symbol and the words:

- (A) "CAUTION RADIATION - THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED", or words having a similar intent, near any switch that energizes an x-ray tube.
- (B) For radiation generating devices with designed openings, for object entries, the following must be posted at or near each opening: "CAUTION – X-RAY HAZARD: DO NOT INSERT ANY PART OF THE BODY WHEN SYSTEM IS ENERGIZED", or words having similar intent.
- (C) "CAUTION - HIGH INTENSITY X-RAY BEAM", or words having a similar intent, if applicable, on the x-ray source housing.

003.04 RADIATION SOURCE HOUSING. Each radiation source housing must be subject to the following requirements:

- (A) Each x-ray tube housing must be equipped with an interlock that shuts off the tube if it is removed from the radiation source housing or if the housing is disassembled.
- (B) Each port cover or each x-ray tube housing must be constructed so that, with all shutters closed, the radiation measured at a distance of 5 centimeters (cm) from its surface is not capable of producing a dose in excess of 0.025 milliSievert (2.5 millirem) in one hour. This limit must be met at any specified tube rating.

003.05 GENERATOR CABINET. Each x-ray generator must be supplied with a protective cabinet which limits leakage radiation measured at a distance of 5 cm from its surface so it is not capable of producing a dose in excess of 2.5 microSievert (0.25 millirem) in one hour.

004. AREA REQUIREMENTS. Areas where radiation generating devices are located must meet the requirements of this section.

004.01 RADIATION LEVELS. The local components of radiation generating devices must be located and arranged, and include sufficient shielding or access control, so that radiation levels in any area surrounding the local component group cannot result in a dose to an individual present in that area in excess of the dose limits given in 180 NAC 4-013. For systems utilizing x-ray tubes, these levels must be met at any specified tube rating.

004.02 SURVEYS. Facilities with radiation generating devices must have surveys completed as required by 180 NAC 4-021. The surveys must be sufficient to show compliance with 180 NAC 8-004.01 and must be performed:

- (i) Upon installation of the equipment and at least once every 12 months thereafter;
- (ii) Following any change in the initial arrangement, number, or type of local components in the system;
- (iii) Following any maintenance requiring the disassembly or removal of a local component in the system;
- (iv) During the performance of maintenance and alignment procedures if the procedures require the presence of a primary x-ray beam when any local component in the system is disassembled or removed;
- (v) After bypass of a safety device or interlock;
- (vi) Any time a visual inspection of the local components in the system reveals an abnormal condition; and
- (vii) Whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the limits specified in 180 NAC 4-005.

004.02(A) DEMONSTRATION OF COMPLIANCE. Radiation survey measurements will not be required if a registrant can demonstrate compliance to the satisfaction of the Department with subsection 004.01 in some other manner.

004.03 POSTING. Each area or room containing radiation generating devices must be clearly posted with a sign or signs bearing the radiation symbol and the words "CAUTION X-RAY EQUIPMENT", or words having a similar intent, according to 180 NAC 4-033.

005. OPERATING REQUIREMENTS. This section addresses the operating requirements of radiation generating devices.

005.01 PROCEDURES. Normal operating procedures must be written and available to all operators of radiation generating devices. No individual will be allowed to operate radiation generating devices in any manner other than that specified in the procedures unless the individual has obtained written approval of the radiation safety officer.

005.02 BYPASSING. No individual must bypass a safety device, interlock, or remove shielding unless the individual has obtained the approval of the radiation safety officer. The approval must be for a specified period of time. When a safety device or interlock has been bypassed, a visible sign bearing the words "SAFETY DEVICE NOT WORKING", or words having a similar intent, must be placed on the radiation source housing and at the control switch.

005.03 CONTROL PANEL. The radiation generating device can only be activated from a control panel. All indicators and controls that control the primary beam must be identifiable and visible through the use of labels, symbols, software displays, or the equivalent.

005.04 INTERLOCKS. An interlock must not be used to de-activate the x-ray tube or radiation generating device, except in an emergency or during testing of the interlock system. All interlocks must be of a fail-safe design.

005.05 MULTIPLE SOURCES. If more than one x-ray tube assembly or assemblies or focal spot can be operated sequentially or simultaneously from a control panel, visual indicators must identify which tube assembly or assemblies or focal spot has been selected. The selectors must be able to identify their function.

005.06 REPAIR OR MODIFICATION OF X-RAY TUBE SYSTEMS. Except as specified in subsection 005.02, no operation involving removal of covers, shielding materials, tube housing, modifications to shutters, collimators, or beam stops must be performed without determining that the tube is off and will remain off until safe conditions have been restored. The main switch, rather than interlocks, must be used for routine shutdown in preparation for repairs.

006. TESTING OF SAFETY DEVICES. This section addresses the testing of safety devices for radiation generating devices.

006.01 TESTING INTERVALS. Tests of all safety devices, including but not limited to, interlocks, shutters, warning lights, and required emergency shut-off switches, must be conducted at intervals recommended by the manufacturer but not to exceed 12 months.

006.02 SAFETY DEVICE FAILURE. If any safety device fails during testing, the radiation generating device must be removed from service until the safety device failure is corrected or temporary administrative controls are established and approved in writing by the radiation safety officer.

006.03 RECORDS. Records of safety device tests, check dates, findings, and corrective actions must be available for inspection and maintained for 5 years.

006.04 SAFETY DEVICE TESTING. If testing of a safety device cannot be performed due to manufacturer design, the registrant must document that the safety device will not be tested and specifically why the safety device cannot be tested.

007. PERSONNEL REQUIREMENTS. This section addresses personnel requirements to operate radiation generating devices, except registrants using only cabinet x-ray systems.

007.01 INSTRUCTION. No individual is allowed to operate or maintain radiation generating devices unless the individual has received four hours of instruction in and demonstrated competence in the following:

- (A) Identification of radiation hazards associated with the use of the equipment;
- (B) Significance of the various radiation warning and safety devices and interlocks incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment and extra precautions required in those cases;
- (C) Appropriate operating procedures for the equipment;
- (D) Recognition of symptoms of an acute localized exposure;
- (E) Appropriate procedures for reporting an actual or suspected exposure;
- (F) Radiation protection appropriate for the hazards of the radiation generating device;
and
- (G) Performing surveys where applicable.

007.02 PERSONNEL MONITORING. This subsection addresses personnel monitoring requirements for operators of radiation generating devices.

007.02(A) EXTREMITY DOSIMETRY DEVICES. Extremity dosimetry devices must be provided to and used by:

- (i) Radiation generating device workers using systems having an open-beam configuration and not equipped with a safety device; and
- (ii) Personnel maintaining radiation generating devices if the maintenance procedures require the presence of a primary x-ray beam when any local component in the x-ray system is disassembled or removed.

007.02(B) REPORTED DOSE VALUES. Reported dose values must not be used for the purpose of determining compliance with 180 NAC 4-005 unless evaluated by a qualified expert as specified in 180 NAC 15-004.03.

008. ADDITIONAL REQUIREMENTS FOR CLOSED-BEAM RADIATION GENERATING DEVICES. In addition to the requirements of section 003 through 007, the following requirements apply to all closed-beam radiation generating devices:

008.01 SYSTEM ENCLOSURE. The radiation source, sample or object, detector, and analyzing crystal, if used, must be enclosed in a chamber or coupled chambers that cannot be entered by any part of the body during normal operation.

008.02 RADIATION EMISSION LIMIT. The radiation emission for all closed beam radiation generating devices must not exceed a dose rate of 0.005 milliSievert (0.5 millirem) in one hour at five centimeters outside any accessible surface.

008.03 SECURITY SCREENING UNITS. Security screening units must be provided with means to ensure operator presence at the control area in a position which allows surveillance of the openings and doors during generation of x-radiation.

- (A) During an exposure or preset succession of exposures of one-half second or greater duration, the means provided must enable the operator to terminate the exposure or preset succession of exposures at any time.

- (B) During an exposure or preset succession of exposures of less than one-half second duration, the means provided may allow completion of the exposure in progress but must enable the operator to prevent additional exposures.

009. ADDITIONAL REQUIREMENTS FOR OPEN-BEAM RADIATION GENERATING DEVICES. In addition to the requirements in section 003 through 007, the following requirements apply to all open-beam radiation generating devices not otherwise addressed in this chapter.

009.01 SAFETY DEVICE. Safety devices must meet the following requirements:

- (A) The registrant must document their justification of the use of open-beam instead of closed-beam x-ray systems;
- (B) If the registrant uses an open-beam system, the registrant must consider a safety device which prevents the entry of any portion of the operator's body into the path of the primary beam or which causes the primary beam to be shut off upon entry into its path;
- (C) If the registrant's use of the open-beam radiation generating device does not permit the use of a safety device to prevent direct body exposure, the registrant must maintain a written record of the various safety devices that have been evaluated and reasons for why these devices cannot be used. These records must be available onsite for inspection;
- (D) In place of the safety device described in subsection 009.01(B) above, the registrant must use alternative methods to minimize the possibility of unnecessary exposure. The registrant must maintain documentation describing the alternative methods. This documentation must be available for inspection as long as these methods are employed, plus an additional three years; and
- (E) The safety device requirement may be met for portable open-beam radiation generating devices that are manufactured to be used hand held, or potentially used as hand held, without safety devices, by complying with all the requirements in section 009 prior to use.

009.02 X-RAY ON STATUS. Open-beam radiation generating devices must be provided with a visible and active indication of:

- (i) X-ray tube "on-off" status located near the radiation source housing. The warning lights as required by subsection 003.01(A) can meet this requirement if the warning lights are visible by anyone near the primary beam;
- (ii) Shutter "open-closed" status located at the control panel and near each beam port on the radiation source housing, if the primary beam is controlled with a shutter. The shutter status device must be clearly labeled as to the meaning of the device status. The status light at the control panel can meet the requirement for the status light at the beam port if the status light at the control panel is visible by anyone near the primary beam.

009.02(A) The x-ray tube "on-off" status indicator and the shutter "open-closed" status indicators must be of a fail-safe design.

009.03 SHUTTERS. On open-beam configurations installed after June 27, 1983, each port on the radiation source housing must be equipped with a shutter that cannot be opened unless a collimator or a coupling has been connected to the port.

009.04 PRIMARY BEAM ATTENUATION. In cases where the primary x-ray beam is not intercepted by the detector device under all conditions of operation, protective measures must be provided to avoid exposure to any individual from the transmitted primary x-ray beam.

009.05 OPERATOR ATTENDANCE. The operator must be in immediate attendance at all times when the equipment is in operation except when the area is locked or the equipment is secured to protect against unauthorized or accidental entry.

009.06 CONTROL OF ACCESS. If the radiation generating device is not in a restricted area and is capable of creating a radiation area or a high radiation area, the operator must be able to control access to the radiation generating device at all times during operation and meet the following requirements:

- (A) Radiation areas must be clearly identified. The radiation source must be within a visible perimeter that meets the posting requirements of 180 NAC 4-034.01. The operator must ensure that no one is inside or enters the radiation area during operation of the radiation generating device;
- (B) High radiation areas must be clearly identified. The radiation source must be within a visible perimeter that meets the posting requirements of 180 NAC 4-034. The operator must ensure that no one is inside or enters the high radiation area during operation of the radiation generating device;
- (C) The operator must perform a visual check of the controlled area to ensure it is free of all unauthorized personnel immediately prior to activating the radiation source;
- (D) Surveillance of the exposure area must be maintained during operation, either visually or by other reliable means to ensure that no individual enters the area;
- (E) During the initial exposure, the radiation levels must be measured around the perimeter of the controlled area. The perimeter must be adjusted accordingly to meet the access control requirement for radiation areas or high radiation areas; and
- (F) The survey around the perimeter must be made for each new operating condition and the perimeter adjusted accordingly. The area of operation must be monitored periodically if radiation levels are variable.

010. ADDITIONAL REQUIREMENTS FOR OPEN-BEAM, HAND HELD RADIATION GENERATING DEVICES. In addition to the requirements in section 003 through 007 and 009, the following requirements apply to open-beam, hand held radiation generating devices.

010.01 PROCEDURES. All registrants possessing open-beam, hand held radiation generating devices must have available for review to the Department operating policies and procedures that contain measures to ensure that:

- (A) The operator will not hold the sample during operation of the radiation generating device and that no part of the operator's body will approach or be exposed to the primary beam;
- (B) The operator will not aim the primary beam at themselves or at any individual during operation of the radiation generating device; and
- (C) Operator radiation exposure is as low as reasonably achievable (ALARA).

011. SHIELDED ROOM RADIATION GENERATING DEVICES. Radiation generating devices in a shielded room must meet the requirements of section 003 through 007 and the following:

011.01 POSTING. All entrances to the room containing the radiation generating device must be posted "CAUTION – HIGH RADIATION AREA", or "GRAVE DANGER – VERY HIGH RADIATION AREA", as required by 180 NAC 4.

011.02 ENTRANCE INTERLOCKS. All entrances into the shielded room must be provided with interlocks. After an interlock has been interrupted, broken, or tripped, x-rays must only be produced again from the control panel. Interlocks must not be used to shut off the x-ray equipment except in an emergency or during testing.

011.03 ENTRANCE WARNING DEVICES. All entrances into the shielded room must be provided with a clearly visible warning device that operates only when radiation is being produced. The warning device must be labeled in accordance with subsection 003.01.

011.04 ROOM WARNING LIGHTS. The interior of the shielded room must be provided with flashing or rotating warning lights that only operate when radiation is being produced. These lights must be positioned so they can be observed from any position or orientation in the room. The lights must be posted indicating the meaning of the warning signal and instructions on what to do when the lights are operating; the posting must be legible, clearly visible, and accessible to view.

011.05 AUDIBLE ROOM WARNING DEVICE. An audible warning signal in the room must be activated and give individuals enough time to leave the room prior to the first initiation of radiation after the closing of any opening that can admit personnel. The registrant must post the meaning of the warning signal and instructions on what to do when the signal is operating; the posting must be legible, clearly visible, and accessible to view.

011.06 EMERGENCY SHUT-OFF. If dose rates exceed the High Radiation Area limits, an emergency shut off switch must be accessible to individuals in the high radiation areas. The switch and it's mode of operation must be identified by a clearly visible sign posted adjacent to the switch. The emergency shut-off switch must include a manual reset that must be reset at the switch before x-rays can be produced again from the control panel. After an emergency shut-off switch has been activated, x-rays must only be produced again from the control panel.

011.07 SEPARATE ELECTRICAL SYSTEMS. The interlock system and the emergency shut-off system must be separate electrical or mechanical systems.

011.08 ENTRY INTO THE SHIELDED ROOM. After each exposure and before entry of any personnel, the control panel must indicate that the radiation generating device is no longer producing radiation. If the control panel does not indicate that the radiation generating device is not producing radiation, a survey must be performed upon entry to the shielded room to ensure that the radiation generating device is no longer producing radiation.

011.09 PERSONNEL MONITORING. All personnel associated with the x-ray equipment must be provided with personnel monitoring devices that must be calibrated for the x-ray energies being utilized. Records of personnel exposure must be maintained.

011.10 TRAINING. The registrant must not allow any individual to operate a radiation generating device in a shielded room until that individual has received a copy of, instruction

in, and demonstrated an understanding of, operating and emergency procedures for the unit and competence in its use. Records must be maintained of all operator training.

011.11 CONTROL PANEL SECURITY. The equipment control panel must be provided with a locking device to prevent unauthorized use. The locking device must, when locked, prevent the production of radiation by the equipment.

011.12 MALFUNCTIONS. If a safety or warning device malfunctions, the control panel must be locked in the "off" position. The control panel must not be used, except as necessary for repair or replacement of the malfunctioning safety or warning device, until the safety or warning device is functioning properly.

012. RADIATION GENERATING DEVICES FOR BOMB DETECTION. In addition to the general requirements in section 003 through 007 the following requirements in this section apply to bomb detection radiation generating devices.

012.01 CONTROL PANEL SECURITY. When not in use, each bomb detection radiation generating device must be locked to prevent unauthorized use.

012.02 AREA CONTROL. The registrant must provide security to prevent entry by individuals from any point when the machine is energized during training.

TITLE 180 — CONTROL OF RADIATION

CHAPTER 8 — RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X-RAY EQUIPMENT

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TITLE 180 — CONTROL OF RADIATION

CHAPTER 8 — RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X-RAY EQUIPMENT

8-001 SCOPE AND AUTHORITY

~~8-001.01~~ 180 NAC 8 provides special requirements for analytical x-ray equipment. The regulations are authorized by and implement the Radiation Control Act, Neb. Stat. Rev. §§ 71-3501 to 71-3520. For purposes of this section, analytical x-ray equipment include, but are not limited to, handheld x-ray fluorescence, x-ray spectrography, and x-ray diffraction.

~~8-001.02~~ The requirements of this 180 NAC 8 are in addition to, and not in substitution for applicable requirements in 180 NAC 1, 2, 4, 10, 15, 17 and 18.

8-002 DEFINITIONS: As used in 180 NAC 8, the following definitions apply:

Analytical x-ray equipment means equipment used for x-ray diffraction or fluorescence analysis. ~~Removed.~~

Analytical x-ray system means a group of components utilizing x or gamma rays to determine the elemental composition or to examine the microstructure of materials. ~~Removed.~~

Fail-safe characteristics means a design feature which causes beam port shutters to close, or otherwise prevents emergence of the primary beam, upon the failure of safety or warning device.

Local components means part of an analytical x-ray system and include areas that are struck by x-rays such as radiation source housing, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors and shielding, but do not include power supplies, transformers, amplifiers, readout devices, and control panels.

Normal operating procedures mean step-by-step instructions necessary to accomplish the analysis. These procedures must include sample insertion and manipulation, equipment alignment, routine maintenance by the registrant or licensee, and data recording procedures which are related to radiation safety.

Open-beam configuration means an analytical x-ray system in which an individual could accidentally place some part of his body in the primary beam path during normal operation.

~~Open-beam configuration means an analytical x-ray system in which an individual could accidentally place some part of his body in the primary beam path during normal operation.~~

~~Primary beam means radiation which passes through an aperture of the source housing by a direct path from the x-ray tube or a radioactive source located in the radiation source housing.~~

~~Safety device means a device that prevents the entry of any portion of an individual's body into the primary x-ray beam path or that causes the beam to be shut off upon entry into its path.~~

8-003 EQUIPMENT REQUIREMENTS:

8-003.01 Safety Device.

~~8-003.01A A safety device which prevents the entry of any portion of an individual's body into the primary x-ray beam path or which causes the beam to be shut off upon entry into its path must be provided on all open-beam configurations.~~

~~8-003.01B A registrant or licensee may apply to the Department for an exemption from the requirement of a safety device. Such exemption must be granted provided that the Department makes a finding that the exemption will not constitute a significant risk to the health and safety of the public. Such application must include:~~

- ~~1. A description of the various safety devices that have been evaluated;~~
- ~~2. The reason each of these devices cannot be used; and~~
- ~~3. A description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices.~~

Removed.

8-003.02 Warning Devices

~~8-003.02A Open-beam configurations must be provided with a readily discernible indication of:~~

- ~~1. X-ray tube status (ON-OFF) located near the radiation source housing, if the primary beam is controlled in this manner; and/or~~
- ~~2. Shutter status (OPEN-CLOSED) located near each port on the radiation source housing, if the primary beam is controlled in this manner.~~

~~8-003.02B Warning devices must be labeled so that their purpose is easily identified. On equipment installed after June 27, 1983, warning devices must have fail-safe characteristics.~~

~~8-003.03 Ports:~~ Unused ports on radiation source housings must be secured in the closed position in a manner which will prevent inadvertent opening.

~~8-003.04 Labeling:~~ All analytical x-ray equipment must be labeled with a readily discernible sign or signs bearing the radiation symbol and the words:

- ~~1. "CAUTION - HIGH INTENSITY X-RAY BEAM,"~~ or words having a similar intent, on the x-ray source housing; and
- ~~2. "CAUTION RADIATION - THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED,"~~ or words having a similar intent, near any switch that energizes an x-ray tube if the radiation source is an x-ray tube; or
- ~~3. "CAUTION - RADIOACTIVE MATERIAL,"~~ or words having a similar intent, on the source housing in accordance with 180 NAC 4-033 if the radiation source is a radionuclide.

~~8-003.05 Shutters:~~ On open-beam configurations installed after June 27, 1983, each port on the radiation source housing must be equipped with a shutter that cannot be opened unless a collimator or a coupling has been connected to the port.

~~8-003.06 Warning Lights~~

~~8-003.06A~~ An easily visible warning light labeled with the words "X-RAY ON," or words having a similar intent, must be located:

- ~~1. Near any switch that energizes an x-ray tube and must be illuminated only when the tube is energized; or~~
- ~~2. In the case of a radioactive source, near any switch that opens a housing shutter, and must be illuminated only when the shutter is open.~~

~~8-003.06B~~ On equipment installed after June 27, 1983, warning lights must have fail-safe characteristics.

~~8-003.07 Radiation Source Housing:~~ Each radiation source housing must be subject to the following requirements:

- ~~1. Each x-ray tube housing must be equipped with an interlock that shuts off the tube if it is removed from the radiation source housing or if the housing is disassembled.~~
- ~~2. Each radioactive source housing or port cover or each x-ray tube housing must be so constructed that, with all shutters closed, the radiation measured at a distance of 5 cm from its surface is not capable of producing a dose in excess of 0.025 mSv (2.5 mrem) in one hour. For systems utilizing x-ray tubes, this limit must be met at any specified tube rating.~~

~~8-003.08 Generator Cabinet. Each x-ray generator must be supplied with a protective cabinet which limits leakage radiation measured at a distance of 5 cm from its surface such that it is not capable of producing a dose in excess of 2.5 uSv (0.25 mrem) in one hour.~~

8-004 AREA REQUIREMENTS

~~8-004.01 Radiation Levels: The local components of an analytical x-ray system must be located and arranged and must include sufficient shielding or access control such that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the dose limits given in 180 NAC 4-013. For systems utilizing x-ray tubes, these levels must be met at any specified tube rating.~~

8-004.02 Surveys

~~8-004.02A Radiation surveys, as required by 180 NAC 4-021, of all analytical x-ray systems sufficient to show compliance with 180 NAC 8-004.01 must be performed:~~

- ~~1. Upon installation of the equipment and at least once every 12 months thereafter;~~
- ~~2. Following any change in the initial arrangement, number, or type of local components in the system;~~
- ~~3. Following any maintenance requiring the disassembly or removal of a local component in the system;~~
- ~~4. During the performance of maintenance and alignment procedures if the procedures require the presence of a primary x-ray beam when any local component in the system is disassembled or removed;~~
- ~~5. Any time a visual inspection of the local components in the system reveals an abnormal condition; and~~
- ~~6. Whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the limits specified in 180 NAC 4-005.~~

~~8-004.02B Radiation survey measurements will not be required if a registrant or licensee can demonstrate compliance to the satisfaction of the Department with 180 NAC 8-004.01 in some other manner.~~

~~8-004.03 Posting: Each area or room containing analytical x-ray equipment must be conspicuously posted with a sign or signs bearing the radiation symbol and the words "CAUTION X-RAY EQUIPMENT" or words having a similar intent in accordance with 180 NAC 4-033.~~

8-005 OPERATING REQUIREMENTS

~~8-005.01 Procedures: Normal operating procedures must be written and available to all analytical x-ray equipment workers. No individual will be permitted to operate analytical~~

~~x-ray equipment in any manner other than that specified in the procedures unless the individual has obtained written approval of the radiation safety officer.~~

~~8-005.02 Bypassing: No individual must bypass a safety device or interlock unless the individual has obtained the approval of the radiation safety officer. Such approval must be for a specified period of time. When a safety device or interlock has been bypassed, a readily discernible sign bearing the words "SAFETY DEVICE NOT WORKING", or words having a similar intent, must be placed on the radiation source housing.~~

~~8-005.03 Repair or Modification of X-Ray Tube Systems: Except as specified in 180 NAC 8-005.02, no operation involving removal of covers, shielding materials or tube housing or modifications to shutters, collimators, or beam stops must be performed without ascertaining that the tube is off and will remain off until safe conditions have been restored. The main switch, rather than interlocks, must be used for routine shutdown in preparation for repairs.~~

~~8-005.04 Radioactive Source Replacement, Testing, or Repair: Radioactive source housing must be opened for source replacement, leak testing, or other maintenance or repair procedures only by individuals authorized to specifically conduct the procedures under a license issued by the U.S. Nuclear Regulatory Commission or an Agreement State. Removed.~~

8-006 PERSONNEL REQUIREMENTS

~~8-006.01 Instruction: No individual is permitted to operate or maintain analytical x-ray equipment unless the individual has received four hours of instruction in and demonstrated competence as to:~~

- ~~1. Identification of radiation hazards associated with the use of the equipment;~~
- ~~2. Significance of the various radiation warning and safety devices, and interlocks incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases;~~
- ~~3. Proper operating procedures for the equipment;~~
- ~~4. Recognition of symptoms of an acute localized exposure;~~
- ~~5. Proper procedures for reporting an actual or suspected exposure; and~~
- ~~6. Radiation protection commensurate with the hazards of the device.~~

8-006.02 Personnel Monitoring

- ~~1. Finger or wrist dosimetric devices must be provided to and must be used by:
 - ~~a. Analytical x-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device; and~~
 - ~~b. Personnel maintaining analytical x-ray equipment if the maintenance procedures require the presence of a primary x-ray beam when any local component in the analytical x-ray system is disassembled or removed.~~~~

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- ~~2. Reported dose values must not be used for the purpose of determining compliance with 180 NAC 4-005 unless evaluated by a qualified expert as specified in 180 NAC 15-013.03.~~