

HEARING SUMMARY

REGULATION: 180 NAC 8, Radiation Safety Requirements For Non-Healing Arts Radiation Generating Devices

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1.	No oral or written comments provided by the public.	
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EFFECTIVE

NEBRASKA DEPARTMENT OF
HEALTH AND HUMAN SERVICES

180 NAC 8

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 its 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.