

HEARING SUMMARY

REGULATION: 180 NAC 2, Registration Of Radiation Generating Equipment Facilities and Services

DATE OF HEARING: November 1, 2019

Name/Affiliation of Person Commenting	Comments	Department Response
1. Ahaileas Harisis/Atomos Physics LLC	Supports all changes made to 180 NAC 2. Changes adequately reflect that a consultation may include shielding reviews and area surveys.	No changes will be made at this time based on comments received.
2.		
3.		

EFFECTIVE

NEBRASKA DEPARTMENT OF
HEALTH AND HUMAN SERVICES

180 NAC 2

TITLE 180 CONTROL OF RADIATION

CHAPTER 2 REGISTRATION OF RADIATION GENERATING EQUIPMENT FACILITIES
AND SERVICES

001. SCOPE AND AUTHORITY. 180 Nebraska Administrative Code (NAC) 2 provides for the registration of radiation generating equipment facilities and for the registration of persons installing, repairing, calibrating, demonstrating, selling radiation generating equipment. Person providing service consultations on radiation protection, health physics, radiation measurements, area surveys and facility shielding reviews are also registered. These regulations are authorized by and implement the Nebraska Radiation Control Act, Nebraska Revised Statute (Neb. Rev. Stat.) §§ 71-3501 to 71-3520. In addition to the requirements of 180 NAC 2, all registrants are subject to the applicable provisions of 180 NAC 1, 4, 5, 6, 8, 9, 10, 15, 18, and 20.

002. DEFINITIONS. The following definitions apply to this chapter.

002.01 ASSEMBLER. An assembler is any person engaged in the business of assembling, replacing, or installing one or more components into an x-ray system or subsystem. The term includes the owner of an x-ray system or their employees or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.

002.02 CONSULTATION. Consultation is the act of providing professional or expert advice on radiological matters.

002.03 FACILITY. A facility is the location at which one or more radiation generating devices or sources of radiation are installed or located within one building, vehicle, or under one roof and are under the same administrative control.

002.04 INSTALLATION OR INSTALL. Installation is the assembly, placement, or other actions including, but not limited to, initial calibration or operability checks that allow a radiation machine to be used in a new location or after being moved from one location to another.

002.05 RADIATION SAFETY OFFICER (RSO). A radiation safety officer (RSO) is an individual who has the knowledge of and the authority and responsibility to apply appropriate radiation protection regulations and practices, who is specifically named on a certificate of registration, and who is the primary contact with the Department.

002.06 SERVICE. Service is the repair, calibration, routine maintenance or other checks or examinations performed on a radiation machine, other than those actions taken during the installation of a radiation machine.

002.07 STORAGE. Storage is a condition where a device or source has been made inoperable.

003. EXEMPTIONS. The following exemptions apply to this chapter.

003.01 ELECTRONIC EQUIPMENT. Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of this chapter as long as the dose equivalent rate averaged over an area of 10 square centimeters does not exceed 0.5 millirem (5 micro Sieverts) per hour at 5 centimeters from any accessible surface of equipment.

003.02 IN TRANSIT OR STORAGE. Radiation generating equipment while in transit or storage is exempt from the requirements of this chapter.

003.03 INOPERABLE EQUIPMENT. Inoperable x-ray radiation generating equipment is exempt from the requirements of this chapter. For the purpose of this chapter, an inoperable radiation machine is one that cannot be energized, without repair or modification, when connected to a power supply.

003.04 FORECLOSURE, BANKRUPTCY, OR OTHER DEFAULT OF PAYMENT. A person that takes possession of a radiation machine as the result of foreclosure, bankruptcy, or other default of payment may possess the machine without registering it. If the machine is energized, it must be under the supervision of a person registered according to this section and must be energized only to demonstrate that the machine is operable for sale, lease, or transfer purposes.

003.05 TELEVISION RECEIVERS. Domestic television receivers are exempt from the requirements of this chapter.

004. APPLICATION FOR REGISTRATION OF RADIATION GENERATING EQUIPMENT FACILITIES. A person with radiation generating equipment at a facility must apply for registration with the Department.

004.01 APPLICATION. The applicant must:

- (A) Submit a complete application provided by the Department within 30 days of installation of radiation generating equipment; and
- (B) Include a non-refundable fee as specified in 180 NAC 18-008.

004.02 RADIATION SAFETY OFFICER. The applicant must designate a radiation safety officer on the application form. The radiation safety officer must carry out the following responsibilities:

- (A) Prepare operating and safety procedures and keeping them updated;

- (B) Inform the Department of lost or stolen radiation generating equipment or overexposures;
- (C) Know radiation protection policies and procedures;
- (D) Stop unsafe practices;
- (E) Keep records;
- (F) Train employees; and
- (G) Ensure that these regulations are followed.

004.03 RADIATION GENERATING EQUIPMENT SERVICES. The registrant must prohibit any person from furnishing radiation generating equipment services, as described in 180 NAC 2-005.04, until that person provides evidence that they are registered with the Department as required by 180 NAC 2-005. A list of these registrants is available from the Department.

005. APPLICATION FOR REGISTRATION OF SERVICES OF RADIATION GENERATING EQUIPMENT. A person who is engaged in the business of installing radiation generating equipment or is engaged in the business of providing radiation generating equipment servicing, radiation measurements, or other services must apply for registration of services with the Department.

005.01 APPLICATION. The applicant must:

- (A) Submit a complete application provided by the Department at least 30 days prior to furnishing any service; and
- (B) Include a non-refundable fee as specified in 180 NAC 18-008.
- (C) Provide additional information requested by the Department to determine whether the registration should be issued or denied.

005.02 DOCUMENTATION. The applicant must specify for each individual providing services on the registration application:

- (A) That each individual has read and understands the requirements of this chapter; and
- (B) The services each individual is applying for; and
- (C) The training and experience that qualifies the individual to perform the services that have been specified on the application for that individual. The applicant must submit to the Department documentation of the specific training and experience, as required by 180 NAC 15-004, or 15-014, or both, that qualifies each individual to provide the type of service they will be providing.

005.03 SERVICE TYPES. Applicants must be registered and be trained to provide each of the types of services they perform. The types of services are:

- (A) INSTALLATION OR SERVICE. Installation or service includes installation and assembly, including initial calibration, and the service or repair of radiation generating equipment and associated radiation generating equipment components. It also includes the measurement of radiation generating equipment output. A person performing installation or service must meet the requirements of 180 NAC 15-014;
- (B) CALIBRATION. Calibration includes a check, adjustment, or systematically bringing radiation generating equipment into manufacturer's specifications. A person performing calibration of:

- (i) Diagnostic radiation generating equipment other than computed tomography (CT) or cone beam computed tomography (CBCT) must meet the requirements of 180 NAC 15-014;
 - (ii) Computed tomography (CT) or cone beam computed tomography (CBCT) must meet the requirements of 180 NAC 15.004.01 or 180 NAC 15.004.02;
 - (iii) Therapeutic radiation generating equipment must meet the training requirements 180 NAC 15-004.01; and
 - (iv) Nonmedical radiation generating equipment must meet the training requirements of 180 NAC 15-014;
- (C) REVIEW OR CONSULTATION. Review or consultation includes area surveys, shielding reviews, and health physics consultations. A person performing review or consultation services of:
- (i) Diagnostic radiation generating equipment other than computed tomography (CT) and cone beam computed tomography (CBCT) must meet the training requirements of 180 NAC 15-004.01, 180 NAC 15.004.02, or 180 NAC 15-004.03;
 - (ii) Computed tomography (CT) or cone beam computed tomography (CBCT) must meet the training requirements of 180 NAC 15-004.01 or 180 NAC 15.004.02;
 - (iii) Therapeutic radiation generating equipment must meet the training requirements of 180 NAC 15-004.01; and
 - (iv) Non-medical radiation generating equipment must meet the training requirements of 180 NAC 15-004.02;
- (D) DEMONSTRATION. Persons demonstrating radiation generating equipment that includes energizing the radiation generating equipment must meet the requirements 180 NAC 15-014; and
- (E) SALES. Sales the selling of radiation generating equipment. No training is required.

005.04 LIMITATION. A person may not perform services that are not specifically stated for that person on the certificate of registration issued by the Department.

005.05 INSTRUCTION MANUALS, SPECIFICATIONS AND OTHER INFORMATION. A person performing installation or service to radiation generating equipment must provide the registrant with instruction manuals, manufacturer specifications, and other information, as required by Part 21 Code of Federal Regulations (CFR) as published on April 1, 2017, and Title 180, which are applicable to the newly installed x-ray systems or components.

006. ADDITIONAL REQUIREMENTS. Registrants must comply with conditions in the certificate of registration or other requirements incorporated by rule, regulation or order regarding the registrant's receipt, possession, use, and transfer of radiation generating equipment, radiation source servicing, radiation measurements, or services that the Department determines are necessary to:

- (A) Minimize danger to occupational and public health and safety; and
- (B) Prevent loss or theft of radiation generating equipment subject to Title 180.

007. SPECIFIC TERMS AND CONDITIONS OF CERTIFICATES OF REGISTRATION. A certificate of registration issued under this chapter is subject to the provisions of Neb. Rev. Stat. §§ 71-3501 to 17-3520, and to these regulations.

007.01 TRANSFER OF REGISTRATION. A certificate of registration issued under 180 NAC 2 cannot be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, to any person unless the Department authorizes the transfer in writing.

007.02 LOCATION AND PURPOSE LIMITATION. A person registered by the Department for radiation generating equipment use under 180 NAC 2 must confine use and possession of the registered radiation generating equipment to the locations and purposes authorized in the certificate of registration.

007.03 COMPLIANCE. The registrant is responsible for complying with Title 180 and any conditions of the certificate of registration.

008. RESPONSIBILITIES OF THE REGISTRANT. The responsibilities of the registrant are as follows.

008.01 NOTIFICATION. The registrant must notify the Department in writing within 30 days of any change that would make the information contained in the application for registration no longer accurate.

008.02 TEMPORARY USE OF RADIATION GENERATING EQUIPMENT. Radiation generating equipment used for clinical trial evaluations, temporary replacement, or demonstration may be used for up to 60 days without registration. Radiation generating equipment used for more than 60 days for those purposes must be registered.

008.03 BANKRUPTCY. In the event of a voluntary or involuntary petition for bankruptcy the registrant must notify the Department, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy. The notification must include:

- (A) The bankruptcy court that the petition for bankruptcy was filed and the date of the filing of the petition; and
- (B) A copy of the petition for bankruptcy to the Department.

008.04 APPROVAL NOT IMPLIED. No person, in any advertisement, will refer to the fact that their facility is registered with the Department in agreement with 180 NAC 2-004, and no person will state or imply that any activity under that registration has been approved by the Department.

009. EXPIRATION OF CERTIFICATES OF REGISTRATION. Each certificate of registration will expire at the end of the day on the expiration date stated on the registration. Expiration does not relieve the registrant of the requirements of Title 180.

010. RENEWAL OF CERTIFICATE OF REGISTRATION. Application for renewal of Registration must be filed according to 180 NAC 2-004 or 180 NAC 2-005.

010.01 TERMINATION OF REGISTRATION. If a registrant does not renew the certificate of registration as required by this chapter on or before the expiration date on the certificate of registration, the registrant must notify the Department and:

- (A) Request termination of the certificate of registration in writing;
- (B) Submit a record of disposition of the radiation generating equipment, and

(C) Pay any outstanding fees per 180 NAC 18-008.

011. ASSEMBLER OR TRANSFER OBLIGATION. A person who sells, leases, transfers, lends, disposes, assembles, or installs radiation generating equipment or components which affect radiation output in this State must notify the Department within 15 days of:

- (A) The full name and address of persons who have received this equipment;
- (B) The manufacturer, model, and serial number of each radiation generating equipment transferred; and
- (C) The date of transfer of radiation generating equipment.

011.01 ASSEMBLER'S REPORT. In the case of diagnostic x-ray systems which contain certified components, the registrant may submit a copy of the assembler's report (Form FDA 2579) prepared in compliance with requirements of 21 CFR §1020.30(d), in place of any other report by the assembler.

011.02 REQUIREMENTS OF ASSEMBLER'S. No person may make, sell, lease, transfer, lend, assemble, or install radiation generating equipment or the components used in connection with radiation generating equipment unless those components and equipment, when properly placed in operation, meet the requirements of Title 180.

012. OUT-OF-STATE RADIATION GENERATING EQUIPMENT. Whenever any radiation generating equipment registered in another state or by the federal government is to be brought into the State, for any temporary use, the person proposing to bring the equipment into the State must give written notice to the Department at least three working days before the equipment is to be used in the State. The notice must include the:

- (A) Type of radiation generating equipment;
- (B) Nature, duration, and scope of use;
- (C) Exact location or locations where the radiation generating equipment is to be used; and
- (D) State or states where the equipment is registered.

012.01 HARDSHIP. If the three working days period would impose an undue hardship on the person, the Department may grant permission to proceed sooner.

012.02 REQUIREMENTS FOR USE OF OUT-OF-STATE RADIATION GENERATING EQUIPMENT. A person referred to in 180 NAC 2-012 must:

- (A) Comply with all applicable regulations of the Department;
- (B) Supply the Department with other information as the Department may request;
- (C) Not operate within the State on a temporary basis in excess of 180 calendar days per year; and,
- (D) Submit the appropriate fee as specified in 180 NAC 18-008.