

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
NOTICE OF PUBLIC HEARING

November 1, 2019
1:00 p.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 2 of the Nebraska Administrative Code (NAC) – *Registration of Radiation Generating Equipment Facilities and Services*. The regulations govern the registration of radiation generating equipment facilities and the registration of persons installing, repairing, calibrating, demonstrating, and selling radiation generating equipment. The proposed changes merge two categories of service registration for entities that provide consultation and radiation shielding review services to x-ray equipment registrants; remove duplicative statutory language from the regulation; 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

Please check one.

Draft Final

Has this statement been reviewed & approved by FAPA Unit (MLTC & CFS) or Budget Unit (PH)? Yes No

Agency: Department of Health and Human Services	
Title: 180	Prepared by: Julia Schmitt
Chapter: 2	Date prepared: 06/24/2019
Subject: Registration of Radiation Generating Equipment Facilities and Services	Telephone: 402/471-0528

Type of Fiscal Impact:

Please check all that apply

	State Agency	Political Sub.	Regulated Public
No Fiscal Impact	(<input type="checkbox"/>)	(<input checked="" type="checkbox"/>)	(<input type="checkbox"/>)
Increased Costs	(<input type="checkbox"/>)	(<input type="checkbox"/>)	(<input type="checkbox"/>)
Decreased Costs	(<input type="checkbox"/>)	(<input type="checkbox"/>)	(<input checked="" type="checkbox"/>)
Increased Revenue	(<input type="checkbox"/>)	(<input type="checkbox"/>)	(<input type="checkbox"/>)
Decreased Revenue	(<input checked="" 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: Two categories of service registrations for entities that provide consultation and radiation shielding review services to registrants that have x-ray equipment were merged. This change will impact sixteen registrants, who will each be paying \$200 less in registration fees each year. This means a decrease of \$3200/yr in revenue for the program. This amount can be absorbed in the current budget.

Political Subdivision: No impact.

Regulated Public: Two categories of service registration for entities that provide consultation and radiation shielding review services to registrants that have x-ray equipment were merged. This change will impact sixteen registrants, who will each be paying \$200 less in registration fees each year.

If indeterminable, explain why:

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.

TITLE 180 — CONTROL OF RADIATION

CHAPTER 2 — REGISTRATION OF RADIATION GENERATING EQUIPMENT FACILITIES AND SERVICES

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FORMS

- Form NRH-4 — Application for Registration of Radiation Generating Equipment
- Form NRH-4a (Additional Machines)
- Form NRH-9 — Application for Registration of Services for Radiation Sources

ATTACHMENT

- Attachment 2-1 — 21 CFR 1020.30(d)

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EFFECTIVE DATE _____ NEBRASKA DEPARTMENT OF
NOVEMBER 28, 2016 _____ HEALTH AND HUMAN SERVICES _____ 180 NAC 2

TITLE 180 _____ CONTROL OF RADIATION

CHAPTER 2 _____ REGISTRATION OF RADIATION GENERATION EQUIPMENT FACILITIES
AND SERVICES

2-001 SCOPE AND AUTHORITY

2-001.01 180 NAC 2 provides for the registration of radiation generating equipment facilities and for the registration of persons providing radiation generating equipment installation, radiation measurements services such as installation, repair, calibration, demonstration, sales, radiation protection, health physics consultations, radiation measurements, survey and facility shielding reviews. The regulations are authorized by and implement the Nebraska Radiation Control Act, Neb. Rev. Stat. §§71-3501 to 71-3520. **Moved to 2-001 as modified.**

2-001.02 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, 16, 17, 18, 20 and 21. **Moved to 2-001 as modified.**

2-002 DEFINITIONS: For purposes of 180 NAC 2:

Assembler means 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 his/her employee or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.

Consultation means the act of providing professional or expert advice on radiological matters.

Facility means the location at which one or more devices or sources are installed and/or located within one building, vehicle, or under one roof and are under the same administrative control.

Installation or Install means 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.

Radiation Safety Officer (RSO) means 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.

Service means 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. Added definition.

2-003 EXEMPTIONS

2-003.01 Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of 180 NAC 2, providing dose equivalent rate averaged over an area of 10 square centimeters does not exceed 0.5 mrem (5 μ Sv) per hour at 5 cm from any accessible surface of such equipment. The production, testing, or factory servicing of such equipment will not be exempt. **Remains in 2-003.01 as modified.**

2-003.02 Radiation generating equipment while in transit or storage incident thereto are exempt from the requirements of 180 NAC 2.

2-003.03 Inoperable x-ray radiation generating equipment is exempt from the requirements of 180 NAC 2. For the purpose of 180 NAC 2, an inoperable radiation machine means a radiation machine that cannot be energized when connected to a power supply without repair or modification. **Remains in 2-003.03 as modified.**

2-003.04 Domestic television receivers are exempt from the requirements of 180 NAC 2.

2-004 APPLICATION FOR REGISTRATION OF RADIATION GENERATING EQUIPMENT FACILITIES: **Remains in 2-004 as modified.**

2-004.01 Each person having a radiation generating equipment facility must apply for registration of such facility with the Department within thirty (30) days following the commencement of the operation of a radiation generating equipment facility. Application for registration must be completed on form NRH-4 furnished by the Department and contain all the information required by the form NRH-4 and accompanying instructions. **Remains in 2-004.01 as modified.**

2-004.02 Each person having a radiation generating equipment facility must designate on the application form an individual to be responsible for radiation protection. A radiation safety officer will be designated on the application form. The radiation safety officer will carry out the following responsibilities:

1. Preparing operating and safety procedures and keeping them updated;
2. Informing this Department of lost or stolen radiation generating equipment or overexposures;
3. Knowing policies and procedures;
4. Stopping unsafe practices;
5. Keeping records;
6. Training employees; and
7. Insuring that 180 NAC is followed. **Remains in 2-004.02 as modified.**

8. 2-004.03 Each person having a radiation generating equipment facility must prohibit any person from furnishing radiation generating equipment servicing or services as described in 180 NAC 2-005.04 to his/her radiation generating equipment facility until such person provides evidence that s/he has been registered with the Department as a provider

of services in accordance with 180 NAC 2-005. A list of these registrants will be available for distribution by the Department. **Remains in 2-004.03 as modified.**

~~2-004.04~~ The Department at any time after the filing of the original application may require further statements in order to enable the Department to determine whether the certification or registration should be issued or denied. **Removed.**

~~2-004.05~~ Each application for a certificate of registration must be accompanied by the fee prescribed in 180 NAC 18-008. **Removed.**

~~2-004.06~~ The applicant's proposed radiation generating equipment, facilities, and operating and safety procedures must be adequate to minimize danger to occupational and public health and safety. **Removed.**

~~2-004.07~~ Failure to register or reregister sources of radiation in accordance with rules and regulations adopted and promulgated by the department must be subject to a fine of not less than fifty dollars nor more than two hundred dollars. **Removed.**

~~2-004.08~~ An application for use of a radiation generating equipment must be signed by the applicant and the radiation safety officer if the radiation safety officer is someone other than the applicant. **Removed.**

2-005 APPLICATION FOR REGISTRATION OF SERVICING AND SERVICES

~~2-005.01~~ Each person who is engaged in the business of installing radiation generating equipment or is engaged in the business of furnishing radiation generating equipment servicing, radiation measurements, and/or other services must apply for registration of such services with the Department at least 30 days prior to furnishing any such services. **Moved to 2-005 as modified.**

~~2-005.02~~ The application for registration must be completed on form NRH-9 furnished by the Department. It must contain all the information required by the form NRH-9 and be signed by the applicant or registrant or a person duly authorized to act for and on the applicant's or registrants behalf.

- ~~1.~~ The Department at any time after the filing of the original application may require further statements in order to enable the Department to determine whether the certification or registration should be issued or denied.
- ~~2.~~ Each application for a certificate of registration must be accompanied by the fee prescribed in 180 NAC 18-008. **Moved to 2-005.01 as modified.**

~~2-005.03~~ Each person applying for registration under 180 NAC 2 must specify:

- ~~1.~~ That s/he has read and understands the requirements of 180 NAC 2; and
- ~~2.~~ The services for which s/he is applying for registration; and

3. ~~The training and experience that qualify him/her to discharge the services for which s/he is applying for registration. The applicant must submit to the Department written documentation of the specific training and experience that qualifies each individual to provide the service. (See 180 NAC 15-013 and 15-033).~~ **Moved to 2-005.02 as modified.**

~~2-005.04 For the purpose of 180 NAC 2-005, services may include but are not limited to:~~

1. ~~Installation/Service: This includes installation/assembly (including initial electronic calibration) and the service/repair of radiation generating equipment and associated radiation generating equipment components. It also includes the measurement of radiation generating equipment output. (See 180 NAC 15-033 for training requirements);~~

2. ~~Calibration: This includes the calibration of diagnostic radiation generating equipment other than Computed Tomography (CT) facilities (See 180 NAC 15-033 for training requirements), CT (See 180 NAC 15-013.01 and 15-013.02 for training requirements); therapeutic radiation generating equipment (See 180 NAC 15-013.01 for training requirements); and non-medical radiation generating equipment (See 180 NAC 15-033 for training requirements);~~

3. ~~Consultations: This includes health physics consultation for diagnostic radiation generating facilities other than CT facilities (See 180 NAC 15-013.01, 15-013.02 or 15-013.03 for training requirements), CT facilities (See 180 NAC 15-013.01 or 15-013.02 for training requirements), therapeutic (See 180 NAC 15-013.01 for training requirements); and non-medical radiation generating facilities (See 180 NAC 15-013.02 or 15-013.03 for training requirements);~~

4. ~~Reviews: This includes area surveys and shielding reviews of diagnostic radiation generating facilities other than CT and therapeutic facilities (See 180 NAC 15-013.01, 15-013.02 or 15-013.03 for training requirements), area surveys and shielding reviews of CT facilities (See 180 NAC 15-013.01, 15-013.02 for training requirements); area surveys and shielding reviews of therapeutic facilities (See 180 NAC 15-013.01 for training requirements) and non-medical radiation generating facilities (See 180 NAC 15-013.02 for training requirements);~~

5. ~~Demonstration: Demonstration which includes energizing the radiation generating equipment (See 180 NAC 15-033); and~~

6. ~~Sales: This includes the sales of radiation generating equipment. (No training is required.)~~

Moved to 2-005.03 as modified.

~~2-005.05 No individual may perform services which are not specifically stated for that individual on the certificate of registration issued by the Department.~~ **Moved to 2-005.04 as modified.**

~~2-005.06~~ In addition to the requirements of 180 NAC 2-005.01 through 2-005.05

~~1.~~ Assemblers, services and servicing personnel must provide the registrant with instruction manuals, manufacturer specifications and other information, as required by the Federal Performance Standard, and these Regulations, which are applicable to the newly installed x-ray systems or components.

~~2.~~ Applicants for x-ray facility shielding review must submit procedures.

Moved to 2-005.05 as modified.

~~2-006~~ ISSUANCE OF CERTIFICATE OF REGISTRATION (NRH-4 AND/OR NRH-9) As modified from 2-006.02

~~2-006.01~~ Upon a determination that an applicant meets the requirements of the regulations, the Department will issue a Certificate of Registration. Removed.

~~2-006.02~~ The Department may incorporate in the Certificate of Registration at the time of registration or thereafter by rule, regulation or order, such additional requirements and conditions with respect to the registrant's receipt, possession, use and transfer of radiation generating equipment, radiation source servicing, radiation measurements and/or services it deems appropriate or necessary in order to:

~~1.~~ Minimize danger to occupational and public health and safety;

~~2.~~ Require additional records and keeping of additional records as maybe appropriate or necessary; and

~~3.~~ Prevent loss or theft of radiation generating equipment subject to Title 180.

Moved to 2-006 as modified.

~~2-007~~ SPECIFIC TERMS AND CONDITIONS OF CERTIFICATES OF REGISTRATION

~~2-007.01~~ Each certificate of registration issued in accordance to 180 NAC 2 will be subject to the applicable provisions of the Nebraska Radiation Control Act, Neb. Rev. Stat. §§ 71-3501 to 17-3520 now or hereafter in effect, and to the applicable rules and order of the Department. Moved to 2-007 as modified.

~~2-007.02~~ A certificate of registration issued or granted under 180 NAC 2 can not be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, to any person unless the Department authorizes the transfer in writing. Moved to 2-007.01 as modified.

~~2-007.03~~ Each person registered by the Department for radiation generating equipment use in accordance with 180 NAC 2 will confine use and possession of the radiation generating equipment registered to the locations and purposes authorized in the certificate of registration. Moved to 2-007.02 as modified.

~~2-007.04~~ The registrant is responsible for complying with 180 NAC and any conditions of the certificate of registration. Moved to 2-007.03 as modified.

2-008 RESPONSIBILITIES OF THE REGISTRANT

~~2-008.01~~ The registrant will notify the Department in writing within 30 days of any change which would render the information contained in the application for registration no longer accurate.

~~2-008.02~~ The following criteria applies to temporary replacement radiation generating equipment and radiation generating equipment used for clinical trial evaluations. Radiation generating equipment used for clinical trial evaluations, temporary replacement, or demonstration may be used for up to 60 days without adding the radiation generating equipment to an existing certificate of registration. If the use period will exceed 60 days, the facility will be required to add the radiation generating equipment to their certificate of registration and a fee will be assessed. Radiation generating equipment must be registered in accordance with 180 NAC 2.

No fees will be assessed for the operation of radiation generating equipment for clinical trial evaluations or loaner or demonstration radiation generating equipment used for a period of 60 days or less at a facility with a current certificate of registration.

Remains in 2-008.02 as modified.

~~2-008.03~~ The following applies to voluntary or involuntary petitions for bankruptcy:

- ~~1.~~ Each registrant will notify the Department, in writing, immediately following the filing of voluntary or involuntary petition for bankruptcy.
- ~~2.~~ The notification will include the bankruptcy court in which the petition for bankruptcy was filed; and the date of the filing of the petition;
- ~~3.~~ A copy of the "petition for bankruptcy" must be submitted to the Department along with the written notification.

Remains in 2-008 as modified.

~~2-008.04~~ Receipt, transfer, and disposal of radiation generating equipment. The registrant will ensure that records of receipt, transfer, and disposal of radiation generating equipment are made and/or maintained for each unit of radiation generating equipment. Records of receipt, transfer, and disposal of radiation generating equipment will include the following:

- ~~1.~~ Manufacturer's name and model and serial number from the control panel; and
- ~~2.~~ Date of the receipt, transfer, and disposal.

Removed.

~~2-008.05~~ Approval not implied: No person, in any advertisement, will refer to the fact that s/he or his/her facility is registered with the Department pursuant to the provision of 180 NAC 2-004, and no person will state or imply that any activity under such registration has been approved by the Department. Moved to 2-008.04

2-008.06 Inventory

~~2-008.06A~~ Each registrant will annually inventory all radiation generating equipment possessed. The inventory will include the manufacturer's name, model, and serial number of the control panel and will be made and maintained for inspection by the Department in accordance with 180 NAC 4-046.

~~2-008.06B~~ Notification is required within 30 days of any change of radiation generating equipment inventory. This includes installation or removal and the disposition of any equipment disposed of or transferred. The assembler's notification of installation may be accepted in lieu of notification by the registrant. This does not relieve the registrant of the responsibility to assure that proper notification had been made.

Removed 2-008.06.

~~2-009~~ EXPIRATION/TERMINATION OF CERTIFICATE OF registration Remains in 2-009 as modified.

~~2-009.01~~ Expiration of Certificate Removed.

~~2-009.01A~~ Except as provided by 180 NAC 2-010.02, each certificate of registration will expire annually on the anniversary of the date issued. Expiration does not relieve the registrant of the requirements of 180 NAC 2. Moved to 2-009 as modified.

~~2-009.01B~~ If a registrant does not renew the certificate of registration per 180 NAC 2, the registrant will on or before the expiration date on the certificate of registration:

1. Terminate use of all radiation generating equipment;
2. Submit a record of disposition of the radiation generating equipment; and
3. Pay any outstanding fees per 180 NAC 18-008.

Moved to 010.01 as modified.

~~2-009.02~~ Termination of Registration: When a registrant decides to terminate all activities involving radiation generating equipment authorized under the certificate of registration the registrant must notify the Department immediately and:

1. Request termination of the certificate of registration in writing;
2. Submit a record of disposition of the radiation generating equipment, and
3. Pay any outstanding fees per 180 NAC 18-008.

Removed.

~~2-010~~ RENEWAL OF CERTIFICATE OF REGISTRATION

~~2-010.01~~ Application for renewal of Registration must be filed in accordance with 180 NAC 2-004 or 180 NAC 2-005. Moved to 2-010.

~~2-010.02~~ In any case in which a registrant has filed an application in proper form for renewal, such existing certificate of registration will not expire until the application status has been finally determined by the Department. Removed.

~~2-011 ASSEMBLER AND/OR TRANSFER OBLIGATION¹~~

~~2-011.01 Any 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:~~

- ~~1. The full name and address of persons who have received this equipment;~~
- ~~2. The manufacturer, model, and serial number of each radiation generating equipment transferred; and~~
- ~~3. The date of transfer of each radiation generating equipment.~~

Moved to 2-011. Added new 2-011.01 verbage.

~~2-011.02 No person may make, sell, lease, transfer, lend, assemble, or install radiation generating equipment or the components used in connection with such equipment unless such components and equipment, when properly placed in operation and used, meet the requirements of 180 NAC.~~

~~2-012 OUT-OF-STATE RADIATION GENERATING EQUIPMENT~~

~~2-012.01 Except, as provided by 180 NAC 2-008.02, whenever any radiation generating equipment which is 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 such equipment into the State shall give written notice to the Department (at least three working days) before such equipment is to be used in the State. The notice must include:~~

- ~~1. The type of radiation generating equipment;~~
- ~~2. The nature, duration, and scope of use; and~~
- ~~3. The exact location(s) where the radiation generating equipment is to be used; and~~
- ~~4. States in which this equipment is registered.~~

Moved to 2-012 as modified.

~~2-012.02 If, for a specific case, the (two working day) period would impose an undue hardship on the person, upon application to the Department, permission to proceed sooner may be granted. Moved to 2-012.01 as modified.~~

~~2-012.03 The person referred to in 180 NAC 2-012 .01 shall:~~

- ~~1. Comply with all applicable regulations of the Department;~~
- ~~2. Supply the Department with such other information as the Department may reasonably request; and~~
- ~~3. Not operate within the State on a temporary basis in excess of 180 calendar days per year.~~

¹In the case of diagnostic x-ray systems which contain certified components, a copy of the assembler's report (Form FDA 2579) prepared in compliance with requirements of 21 CFR Chapter 1, Section 1020.30(d), must suffice in lieu of any other report by the assembler.

EFFECTIVE DATE _____ NEBRASKA DEPARTMENT OF
NOVEMBER 28, 2016 _____ HEALTH AND HUMAN SERVICES _____ 180 NAC 2

4. ~~Submit the appropriate fee as specified in 180 NAC 18-008.~~
Moved to 2-012.02 as modified.

Removed all forms below.



APPLICATION FOR REGISTRATION OF RADIATION GENERATING EQUIPMENT

Type or print except where indicated.
Retain one copy for your records.
Refer to NRH-4 Instructions as needed.

Submit original application to:

Nebraska Dept. of Health and Human Services
Office of Radiological Health
301 Centennial Mall South
P.O. Box 95026
Lincoln, NE 68509-5026

Department Use-Only	
County	Reg. Number
State	Region
Priority	Label
Renewal Date	Fee

1.a LEGAL NAME AND STREET ADDRESS (INSTITUTION, FIRM, PERSON, ETC.)			
Applicant/ Facility Name:			
Address:			
City, State, Zip:			
Telephone:		FAX:	
E-Mail:			
1.b RADIATION GENERATING EQUIPMENT LOCATION (IF DIFFERENT THAN 1.a)			
Applicant/ Facility Name:			
Address:			
City, State, Zip:			
Telephone:		FAX:	
Temporary job sites throughout Nebraska? <input type="checkbox"/> Yes <input type="checkbox"/> No			
2. BILLING INFORMATION			
Address (if different than 1.a):			
City, State, Zip:			
Telephone:		FAX:	
Contact Person:			
3. PRACTICE TYPE (SEE NRH-4 INST)			

4. RADIATION GENERATING EQUIPMENT (use additional sheets if necessary—NRH-4a)

List each machine on a separate line:

Machine Type (See NRH-4 Inst)	Number Tubes	Control Manufacturer	Control Model No.	Control Serial No.	Manufacture Date	Install Date	Master Control Location

5. RADIATION SAFETY OFFICER (RSO) (see 180 NAC 2-004.02 or 21-007.01B)

Radiation Safety Officer (Print or Type)	Signature	Date

6. ATTESTATION AND CERTIFICATION

For the purpose of complying with Neb. Rev Stat. §§. 4-108 through 4-114, I attest as follows:

Check only ONE box below:

I am a citizen of the United States

I am a qualified alien under the Federal Immigration and Nationality Act.

Immigration status and alien number: _____

USCIS documentation enclosed.

Application is for a separate legal entity (Ex: corporation, partnership, etc.) Explain: _____

I hereby attest that my response and the information provided on this form and any related application for public benefits are true, complete and accurate and I understand that this information may be used to verify my lawful presence in the United States.

The applicant and any official executing this document on behalf of the applicant named in Item 1.a. certify that this application is prepared in conformity with the Nebraska Department of Health and Human Services Title 180 Regulations for Control of Radiation and that all information contained herein, including any supplements attached hereto, is true and correct to the best of their knowledge.

Certifying Official (Print or Type)	Applicant/Facility Name (see item 1.a)
Signature	Date

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**NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
 DIVISION OF PUBLIC HEALTH
 RADIOLOGICAL HEALTH**

APPLICATION FOR REGISTRATION OF SERVICES FOR RADIATION GENERATING EQUIPMENT

INSTRUCTIONS: (Use additional sheets where necessary.)

- **Type or print except where indicated.**
- Retain one copy for your files
- Submit original application to: Department of Health and Human Services, Division of Public Health, Radiological Health, 301 Centennial Mall South, P.O. Box 95026, Lincoln, NE 68509-5026.
- Submit annual fee per 180 NAC 18-008.
- Upon approval of the application a "Certificate of Registration for Radiation Generating Equipment." will be issued.

1. Name and Street Address of Applicant's Business (Individual or Company)	
Applicant Name:	_____
Address:	_____
City, State Zip+4	_____
Telephone #:	FAX#
E-mail Address:	_____

2. Name of Person Responsible to Contact Regarding this Application	
Name _____	Telephone # _____

3. Types of Services to be performed (Please check all appropriate boxes.)	Training Requirements References:
<input type="checkbox"/> A. Installation/Service (If "A" is checked, please check at least one of the 3 items below.)	
<input type="checkbox"/> A1. Installation/Assembly (including initial Electronic Calibration) of Radiation Generating Equipment	180 NAC 15-033
<input type="checkbox"/> A2. Service/repair of Radiation Generating Equipment	180 NAC 15-033
<input type="checkbox"/> A3. Measurement of Radiation Generating Equipment output	180 NAC 15-033
<input type="checkbox"/> B. Calibration (If "B" is checked, please check at least one the 3 items below)	
<input type="checkbox"/> B1. Calibration of Diagnostic Radiation Generating Equipment	180 NAC 15-033
<input type="checkbox"/> B2. Calibration of CTs	180 NAC 15-013.01 or 15-013.02
<input type="checkbox"/> B3. Calibration of Therapeutic Radiation Generating Equipment	180 NAC 15-013.01
<input type="checkbox"/> B4. Calibration of Non-Medical Radiation Generating Equipment	180 NAC 15-033
<input type="checkbox"/> C. Consultations (If "C" is checked, please check at least one the 3 items below)	
<input type="checkbox"/> C1. Health Physics Consultations of Diagnostic Radiation Generating Facilities	180 NAC 15-013.01 or 15-013.02 or 15-013.03
<input type="checkbox"/> C2. Health Physics Consultations for CT Facilities	180 NAC 15-013.01 or 15-013.02
<input type="checkbox"/> C3. Health Physics Consultations for Therapeutic Facilities	180 NAC 15-013.01
<input type="checkbox"/> C4. Health Physics Consultations for Non-Medical Radiation Generating Facilities	180 NAC 15-013.02 or 15-013.03
<input type="checkbox"/> D. Reviews (If "D" is checked, please check at least one of the 3 items below.)	
<input type="checkbox"/> D1. Area Surveys and shielding reviews of Diagnostic Radiation Generating Facilities	180 NAC 15-013.01 or 15-013.02 or 15-013.03
<input type="checkbox"/> D2. CT Shielding Facility Reviews	180 NAC 15-013.01 or 15-013.02
<input type="checkbox"/> D3. Therapeutic Facility Reviews	180 NAC 15-013.01
<input type="checkbox"/> D4. Non-Medical area Surveys and shielding reviews of Radiation Generating Facilities	180 NAC 15-013.02
<input type="checkbox"/> E. Demonstration which includes energizing the radiation generating equipment	180 NAC 15-033
<input type="checkbox"/> F. Sales	No training is required
<input type="checkbox"/> G. Other	Dependent on service requested.

4. Training: (At least one individual must be qualified for each of the requested service(s) listed in 3.A through E and G)

4.A. Submit name of individual qualified and which service the individual is to provide.

4.B. Attach training requirements for each individual. (See item 3. On Page 1 of this form for training requirements references.)

4.C. Each individual applying for registration must read and understand the requirements of 180 NAC 2.

Name of Individual _____

Circle Service(s) Individual is Providing

Al, A2, A3, B1, B2, B3, B4, C1, C2, C3, C4, D1, D2, D3, D4, E, G.

Training Documentation for individual is attached.

This individual has read and understands the requirements of 180 NAC 2

Name of Individual _____

Circle Service(s) Individual is Providing

Al, A2, A3, B1, B2, B3, B4, C1, C2, C3, C4, D1, D2, D3, D4, E, G

Training Documentation for individual is attached.

This individual has read and understands the requirements of 180 NAC 2

Name of Individual _____

Circle Service(s) Individual is Providing

Al, A2, A3, B1, B2, B3, B4, C1, C2, C3, C4, D1, D2, D3, D4, E, G

Training Documentation for individual is attached.

This individual has read and understands the requirements of 180 NAC 2

Name of Individual _____

Circle Service(s) Individual is Providing

Al, A2, A3, B1, B2, B3, B4, C1, C2, C3, C4, D1, D2, D3, D4, E, G.

Training Documentation for individual is attached.

This individual has read and understands the requirements of 180 NAC 2

Name of Individual _____

Circle Service(s) Individual is Providing

Al, A2, A3, B1, B2, B3, B4, C1, C2, C3, C4, D1, D2, D3, D4, E, G.

Training Documentation for individual is attached.

This individual has read and understands the requirements of 180 NAC 2

Name of Individual _____

Circle Service(s) Individual is Providing

Al, A2, A3, B1, B2, B3, B4, C1, C2, C3, C4, D1, D2, D3, D4, E, G.

Training Documentation for individual is attached.

This individual has read and understands the requirements of 180 NAC 2

Name of Individual _____

Circle Service(s) Individual is Providing

Al, A2, A3, B1, B2, B3, B4, C1, C2, C3, C4, D1, D2, D3, D4, E, G.

Training Documentation for individual is attached.

This individual has read and understands the requirements of 180 NAC 2

Name of Individual _____

Circle Service(s) Individual is Providing

Al, A2, A3, B1, B2, B3, B4, C1, C2, C3, C4, D1, D2, D3, D4, E, G.

Training Documentation for individual is attached.

This individual has read and understands the requirements of 180 NAC 2

Name of Individual _____

Circle Service(s) Individual is Providing

Al, A2, A3, B1, B2, B3, B4, C1, C2, C3, C4, D1, D2, D3, D4, E, G.

Training Documentation for individual is attached.

This individual has read and understands the requirements of 180 NAC 2

Name of Individual _____

Circle Service(s) Individual is Providing

Al, A2, A3, B1, B2, B3, B4, C1, C2, C3, C4, D1, D2, D3, D4, E, G

Training Documentation for individual is attached.

This individual has read and understands the requirements of 180 NAC 2

Use additional sheet(s) for additional names and information

IF APPLICABLE

5. Attach procedures for x-ray facility shielding reviews. (See 180 NAC 2-005.04, item 4)

6. CITIZENSHIP ATTESTATION

It is not necessary to complete the Attestation part of this application below if the application is for a corporation or other separate legal entity. Explain why: (For example: This application is for a corporation, partnership, etc.) _____

OR

If the entity is owned by an individual, complete the United States Citizenship Attestation Form below.

UNITED STATES CITIZENSHIP ATTESTATION FORM

For the purpose of complying with Neb. Rev Stat. §§. 4-108 through 4-114, I attest as follows:

I am a citizen of the United States OR

I am a qualified alien under the Federal Immigration and Nationality Act, my Immigration status and alien number are as follows: _____ and I am providing a copy of my USCIS documentation.

I hereby attest that my response and the information provided on this form and any related application for public benefits are true, complete and accurate and I understand that this information may be used to verify my lawful presence in the United States.

Name (type or print first, middle, last) _____

Signature _____

Date _____

7. CERTIFICATION

(This Item must be completed by applicant.)

The applicant and any official executing this document on behalf of the applicant named in Item 1., certify that this application is prepared in conformity with the Nebraska Department of Health and Human Services, Title 180, Regulations for Control of Radiation and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

Applicant Name From Item 1.

By: _____ Date: _____
Signature

Print Name and Title of certifying official authorized to act on behalf of the applicant

Registration Does Not Imply Approval or Disapproval of Service

Your Application will not be processed without items 6. and 7. being completed.

