TITLE 180 CONTROL OF RADIATION

CHAPTER 2 REGISTRATION OF RADIATION GENERATING EQUIPMENT FACILITIES AND SERVICES

2-001 Scope and Authority....1
2-002 Definitions....1
2-003 Exemptions....2
2-004 Application for Registration of Radiation Generating Equipment Facilities....2
2-005 Application for Registration of Servicing and Services....3
2-006 Issuance of Certificate of Registration (NRH-4 and/or NRH-9)....5
2-007 Specific Terms and Condition of Certificates of Registration....5
2-008 Responsibilities of the Registrant....5
2-009 Expiration/Termination of Certificate of Registration....7
2-010 Renewal of Certificate of Registration....7
2-011 Assembler and/or Transfer Obligation....7
2-012 Out-of-State Radiation Generating Equipment....8

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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TITLE 180 CONTROL OF RADIATION

CHAPTER 2 REGISTRATION OF RADIATION GENERATION EQUIPMENT FACILITIES AND SERVICES

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.

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.

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.

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 μSv) 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.

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.

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: Each person having a radiation generating equipment facility must:

2-004.01 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.
t
2-004.02 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.

2-004.03 Each registrant 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.

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.

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

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.

2-004.07 To register or reregister sources of radiation in accordance with rules and regulations adopted and promulgated by the Department will be subject to a fine.

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.

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.

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.

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).

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); ~~and~~ 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), ~~and~~ 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);~~,~~ ~~and~~ 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.)

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.

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.

2-006 ISSUANCE OF CERTIFICATE OF REGISTRATION (NRH-4 AND/OR NRH-9)

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

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.

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.

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.

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.

2-007.04 The registrant is responsible for complying with 180 NAC and any conditions of the certificate of registration.

2-008 RESPONSIBILITES 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.

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.

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.

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.

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.

2-009 EXPIRATION/TERMINATION OF CERTIFICATE OF REGISTRATION

2-009.01 Expiration of Certificate

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.

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.

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.

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.

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.

2-011 ASSEMBLER AND/OR TRANSFER OBLIGATION[1]

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]In 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) attached hereto as pages 611-612, except the stricken text of Attachment Number 2-1 and incorporated herein by this reference, shall suffice in lieu of any other report by the assembler.

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.

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 2 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.

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.

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.
4. Submit the appropriate fee as specified in 180 NAC 18-008.

NEBRASKA DEPARTMENT OF
HEATLH AND HUMAN SERVICES
RADIOLOGICIAL HEALTH
X-RAY PROGRAM

For Department Use Only
Regist. No. _____
State _____ **Co.** _____
~~**Priority** _____ **Fee Det. No.** _____~~
Region

APPLICATION FOR REGISTRATION OF RADIATION GENERATING EQUIPMENT

Instructions: Type or Print except where indicated. Retain one copy for your files and submit original application to: Nebraska Dept. of Health and Human Services , Radiological Health, 301 Centennial Mall South, P O Box 95026, Lincoln, NE 68509-5026.

1.a Legal Name and Street address of Applicant (Institution, Firm, Person, etc.)

Applicant Name: _____

Address: _____

_____

City, State Zip: _____

Telephone #: _____

FAX #: _____

eMail Address:

1.b Street address(es) at which Radiation Generating Equipment will be used. (If different than 1.a)

(1) Permanent Address: _____

_____

City, State Zip: _____

(2) Temporary Job Sites Throughout Nebraska? ❒ Yes ❒ No

2. Billing Information

Address(if different than 1.a):

_____

_____

Person to Contact: _____

Telephone #: _____

3. Radiation Safety Officer (RS0) (See 180 NAC 2-004.02,or 21-007.01B)

_____

Title: _____

Telephone #: _____

4. Type of Practice (see Instruction Sheet) _____

5. RADIATION GENERATING EQUIPMENT (USE ADDITIONAL SHEETS IF NECESSARY)

List each machine on a separate line.

Type	# Tubes	Control Manufacturer	Control. Model No.	Control. Serial No.	Date Installed	Date Manufactured	Control Room #

6. I do hereby accept the responsibility of radiation safety officer.

Type or print name of Radiation Safety Officer from item 3. | Signature of Radiation Safety Officer | Date

7. 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~~8. 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.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 our knowledge.

_____
Applicant Name from Item 1.a.

By: _____ *Date:* _____
Signature of certifying official authorized to act on behalf of applicant

_____
Print Name and Title of certifying official

Your Application will not be processed without items 6., 7., and 8. being completed.

!

FORM NRH-4a (Additional Machines) **Registration No. _____**

Effective Date ~~7-11-09~~

5a. LIST ADDITIONAL MACHINES ON THIS SHEET

List each machine on a separate line.

Type	# Tubes	Control Manufacturer	Control. Model No.	Control Serial No.	Date Installed	Date Manufactured	Control Room #

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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:**
☐ A. Installation/Service (If "A" is checked, please check at least one of the 3 items below.)	
☐ A1. Installation/Assembly (including initial Electronic Calibration) of Radiation Generating Equipment	180 NAC 15-033
☐ A2. Service/repair of Radiation Generating Equipment	180 NAC 15-033
☐ A3. Measurement of Radiation Generating Equipment output	180 NAC 15-033
☐ B. Calibration (If "B" is checked, please check at least one the 3 items below)	
☐ B1. Calibration of Diagnostic Radiation Generating Equipment	180 NAC 15-033
☐ B2. Calibration of CTs	180 NAC 15-013.01 or 15-013.02
☐ B3. Calibration of Therapeutic Radiation Generating Equipment	180 NAC 15-013.01
☐ B4. Calibration of Non-Medical Radiation Generating Equipment	180 NAC 15-033
☐ C. Consultations (If "C" is checked, please check at least one the 3 items below)	
☐ C1. Health Physics Consultations of Diagnostic Radiation Generating Facilities	180 NAC 15-013.01 or 15-013.02 or 15-013.03
☐ C2. Health Physics Consultations for CT Facilities	180 NAC 15-013.01 or 15-013.02
☐ C3. Health Physics Consultations for Therapeutic Facilities	180 NAC 15-013.01
☐ C4. Health Physics Consultations for Non-Medical Radiation Generating Facilities	180 NAC 15-013.02 or 15-013.03
☐ D. Reviews (If "D" is checked, please check at least one of the 3 items below.)	
☐ D1. Area Surveys and shielding reviews of Diagnostic Radiation Generating Facilities	180 NAC 15-013.01 or 15-013.02 or 15-013.03
☐ D2. CT Shielding Facility Reviews	180 NAC 15-013.01 or 15-013.02
☐ D3. Therapeutic Facility Reviews	180 NAC 15-013.01
☐ D4. Non-Medical area Surveys and shielding reviews of Radiation Generating Facilities	180 NAC 15-013.02
☐ E. Demonstration which includes energizing the radiation generating equipment	180 NAC 15-033
☐ F. Sales	No training is required
☐ 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

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

~~6~~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.

ATTACHMENT 2-1

21 CFR 1020.30(d)

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(d) *Assemblers' responsibility.* An assembler who installs one or more components certified as required by paragraph (c) of this section shall install certified components that are of the type required by §1020.31, 1020.32, or 1020.33 and shall assemble, install, adjust, and test the certified components according to the instructions of their respective manufacturers. Assemblers shall not be liable for noncompliance of a certified component if the assembly of that component was according to the component manufacturer's instruction.

(1) *Reports of assembly.* All assemblers who install certified components shall file a report of assembly, except as specified in paragraph (d)(2) of this section. The report will be construed as the assembler's certification and identification under §§1010.2 and 1010.3 of this chapter. The assembler shall affirm in the report that the manufacturer's instructions were followed in the assembly or that the certified components as assembled into the system meet all applicable requirements of §§1020.30 through 1020.33. All assembler reports must be on a form prescribed by the Director, CDRH. Completed reports must be submitted to the Director, the purchaser, and, where applicable, to the State agency responsible for radiation protection within 15 days following completion of the assembly.

(2) *Exceptions to reporting requirements.* Reports of assembly need not be submitted for any of the following:

(i) Reloaded or replacement tube housing assemblies that are reinstalled in or newly assembled into an existing x-ray system;

(ii) Certified accessory components that have been identified as such to CDRH in the report required under §1002.10 of this chapter;

(iii) Repaired components, whether or not removed from the system and reinstalled during the course of repair, provided the original installation into the system was reported; or

(iv)(A) Components installed temporarily in an x-ray system in place of components removed temporarily for repair, provided the temporarily installed component is identified by a tag or label bearing the following information:

Temporarily Installed Component
This certified component has been assembled, installed, adjusted, and tested by me according to the instructions provided by the manufacturer.
Signature
Company Name
Street Address, P.O. Box
City, State, Zip Code
Date of Installation

(B) The replacement of the temporarily installed component by a component other than the component originally removed for repair shall be reported as specified in paragraph (d)(1) of this section.

(e) *Identification of x-ray components.* In addition to the identification requirements specified in §1010.3 of this chapter, manufacturers of components subject to this section and §§1020.31, 1020.32, and 1020.33, except high-voltage generators contained within tube housings and beam-limiting devices that are integral parts of tube housings, shall permanently inscribe or affix thereon the model number and serial number of the product so that they are legible and accessible to view. The word "model" or "type" shall appear as part of the manufacturer's required identification of certified x-ray components. Where the certification of a system or subsystem, consisting of two or more components, has been authorized under paragraph (c) of this section, a single inscription, tag, or label bearing the model number and serial number may be used to identify the product.

(1) *Tube housing assemblies.* In a similar manner, manufacturers of tube housing assemblies shall also inscribe or affix thereon the name of the manufacturer, model number, and serial number of the x-ray tube which the tube housing assembly incorporates.

(2) *Replacement of tubes.* Except as specified in paragraph (e)(3) of this section, the replacement of an x-ray tube in a previously manufactured tube housing assembly certified under paragraph (c) of this section constitutes manufacture of a new tube housing assembly, and the manufacturer is subject to the provisions of paragraph (e)(1) of this section. The manufacturer shall remove, cover, or deface any previously affixed inscriptions, tags, or labels that are no longer applicable.