



## **REGULATORY GUIDE 2.1**

### GUIDE FOR THE PREPARATION OF APPLICATION FOR REGISTRATION OF SERVICES FOR RADIATION GENERATING EQUIPMENT

### A. INTRODUCTION

The purpose of this guide is to provide assistance to persons providing services in preparing the application for Certificate of Registration of Services for Radiation Sources (Form NRH-9). 180 NAC 2- (Control of Radiation-Ionizing) contains the requirements that must be met to receive a certificate. Other applicable regulations are 180 NAC 2, 6, 15, 18 and 21.

### **B. APPLICATION**

Complete an NRH-9 (Application for Registration of Services for Radiation Sources) and submit any additional information required such as training.

### **REGISTRATION FEES**

Each Application for Registration of Services for Radiation Sources will be accompanied by a non-refundable fee. The fee list listed in 180 NAC 18-008.02. The check or money order should be made payable to the Nebraska Department of Health and Human Services.

Mail the invoice and payment to the Nebraska Department of Health and Human Services, Division of Public Health, Office of Radiological Health, 301 Centennial Mall South, P.O. Box 95026, Lincoln, NE. 68509-5026.

Upon receipt of the application and proper fee, a determination will be made if the registrant meets the requirements of the regulations (including submittal of training and experience, indicated services provided, procedures and etc.)

Upon approval, the Department will issue a Certificate of Registration.

### NEBRASKA DEPARTMENT OF HEALTH & HUMAN SERVICES (DHHS), REGULATORY GUIDES

Regulatory Guides are issued to describe and make available to the public acceptable methods of implementing specific parts of Title 180 NAC Nebraska regulations, "Control of Radiation," to delineate techniques used by the staff in evaluating specific problems or postulated accidents, or to provide guidance to applicants, licensees, or registrants. Regulatory Guides are not substitutes for regulations, and compliance with them is not required. Methods and solutions different from those set out in the guides will be acceptable if they provide a basis for the DHHS, Division of Public Health, Office of Radiological Health, to make necessary determination to issue or continue a license or certificate of registration.

Comments and suggestions for improvements in these Regulatory Guides are encouraged at all times and they will be revised, as appropriate, to accommodate comments and to reflect new information or experience. Comments should be sent to the DHHS, Division of Public Health, Office of Radiological Health, 301 Centennial Mall South, P.O. Box 95026, Lincoln, NE 69509-5026. OR radiation.programs@nebraska.gov

Requests for single copies of issued guides (which may be reproduced) should be made in writing to the address above.

### C. CONTENTS OF NRH-9

See the NRH-9 Application at the end of this guide. Complete the application which includes:

### 1. Name and Street Address of Applicant (Individual or Company)

List either the individual, corporation, partnership, firm, agency, etc., who will be responsible for all matters concerning this regulation.

Location: The place of business should be specifically designated. Use of a Post Office Box as a place of business is not acceptable, but can be referenced for mailing purposes.

### 2. Person to Contact for Further Information

If this registration is for a corporation, partnership, firm, agency or group, submit the name of the person who will be in charge of radiation services.

### 3. Types of Services to be Performed

Check the services that the registrant will be providing. The right column's reference states the training requirement for the person providing the service.

### 4. <u>Training</u>

- A. List the name of the individual(s) to provide the service(s).
- B. Circle the service(s) the individual will be providing. (An individual can only provide services that the registrant is registered to provide.)
- C. Each individual providing service must read and understand the requirements of 180 NAC 2.
- D. Provide the documentation of the training required for the services the individual will be providing. Item 3 lists where to find the training requirements. Each service provided must be supported with evidence that the individual's training and experience has met the requirements found in 180 NAC 15 to qualify to perform the service:
  - (1) Requirements for:

Installation/Service (A1, A2, A3),

Calibration of Diagnostic Radiation Generating Equipment (B1)

Calibration of Non-Medical Radiation Generating Equipment (B4) and

Demonstration which includes energizing the radiation generating equipment (E),

are found in 180 NAC 15-033. Please provide course outlines or syllabus of the formal course work for the service personnel. Include the duration of the formal coursework and documentation showing reference to the coursework required.

<u>180 NAC 15-033.01</u> A minimum of eight hours of formal course work or as approved by the Department should be completed and include the following:

- 1. Radiation physics and instrumentation
- 2. Radiation protection
- 3. Mathematics pertaining to the use and measurement of radioactivity
- 4. Biological effects of radiation

<u>180 NAC 15-033.02</u> On-the-job training should include hands-on experience installing and/or servicing radiation generating equipment and associated radiation generating equipment components. On-the-job training must be for six months under the supervision of an individual who has completed the training in 180 NAC 15-033.

(2) Requirements for:

Calibration of Therapeutic Radiation Generating Equipment (B3), Health Physics Consultations for Therapeutic (C3), and

Therapeutic Reviews (D3)

are found in 180 NAC 14-013.01 (Radiological Medical Physicist). Please provide documentation and training.

<u>180 NAC 15-013.01</u> Radiological Medical Physicist means a person having the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs. This person must have training and experience in the clinical applications of radiation physics. This person must have at least the following:

- 1. Is certified by the American Board of Radiology in Therapeutic Radiological Physics, Roentgen Ray and Gamma Ray Physics, X-Ray and Radium Physics; or Radiological Physics; or the American Board of Medical Physics in Radiation Oncology Physics or the Canadian College of Medical Physics, certification must be in the specialty the individual will be clinically practicing, or
- 2. Holds a Master's or Doctor's Degree in physics, medical physics, other physical science, engineering, applied mathematics, nuclear physics, biophysics, radiological physics, or health physics and has completed one year of full time training in medical physics and an additional year of full time work experience under the supervision of a Radiological Medical Physicist that meets the requirements of 15-013.01, item 1 at a medical institution. Full time training and full time work experience must be in the specialty the individual will be clinically practicing.
- (3) Requirements for:

Calibration of CTs(B2), Health Physics Consultations for CT facilities (C2) and CT Shielding Reviews (D2) are to be performed by a Radiological Health Physicist (180 NAC 15-013.02) or a Radiological Medical Physicist (180 NAC 15-013.01) Please provide documentation and training.

180 NAC <u>15-013.02</u> Radiological Health Physicist with reference to radiation protection, means a person having the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs (for example, persons having relevant certification from the American Board of Radiology or American Board of Health Physics, or those having equivalent qualifications). With reference to shielding design, a person having particular knowledge and training in the field of medical x-ray and gamma-ray shielding. This person must have at least the following:

- Is certified by the American Board of Health Physics or the American Board of Radiology in Therapeutic Radiological Physics, Roentgen Ray and Gamma Ray Physics, X-Ray and Radium Physics, or Radiological Physics; or the American Board of Medical Physics in Radiation Oncology Physics or the Canadian College of Medical Physics; or
- 2. A Master's or a Doctor's degree in a physical or natural science or equivalent, biophysics, radiological physics or health physics, plus one year full year of experience in radiation protection and measurements, or
- 3. A Bachelor's Degree in a physical or natural science or equivalent, plus three (3) years of training and experience in radiation protection and measurements and a written statement from a radiological health physicist as defined in 180 NAC 15-013.02, items 1 or 2 that two years of training and experience in radiation protection and measurements were obtained under his or her supervision.
- (4) Requirements for:

Health Physics Consultations for Non-Medical area Surveys and shielding reviews of Radiation Generating Facilities (D4)

are to be performed by a Radiological Health Physicist (180 NAC 15-013.02). Please provide documentation and of training.

(5) Requirements for:

Health Physics Consultations of Diagnostic Radiation Generating Facilities (C1) and Area Surveys and Shielding Reviews of Diagnostic Radiation Generating Facilities (D1) are to be preformed by a Qualified Expert (180 NAC 15-013.03), Radiological Health Physicist (180 NAC 15-013.02) or a Radiological Medical Physicist (180 NAC 15-013.01). Please provide documentation and of training.

<u>180 NAC 15-013.03</u> Qualified Expert means an individual who has demonstrated to the satisfaction of the Department that (s)he possesses the knowledge and training to measure ionizing radiation, to

evaluate safety techniques, and to advise regarding radiation protection needs. This person must have at least the following:

- 1. A Bachelor's Degree in a physical or natural science, and one year of experience in radiation protection and measurements, or
- 2. A Certificate or an Associate Degree from an accredited radiological technology school and one year of experience in radiation protection and measurements.
- (6) Requirements for:

Health Physics Consultations for Non-Medical Radiation Generating Facilities (C4) are to be preformed by a Qualified Expert (180 NAC 15-013.03), Radiological Health Physicist (180 NAC 15-013.02) or a Radiological Medical Physicist (180 NAC 15-013.01). Please provide documentation and of training.

- (7) Attach procedures for x-ray facility shielding reviews per 180 NAC 2-005.06, item 2.
- 5. If Applicable Attach procedures for x-ray shielding reviews per 180 NAC 2-005.04, item 4
- 6. <u>Citizenship Attestation</u> Check appropriate box and provide and provide documentation if required.

### 7. <u>Certification</u>.

Individuals or representatives of a corporation or legal entity filing the application must date and sign NRH Form 9. The Department will return all unsigned applications for proper signature.

### D. REGISTRATION RENEWAL

A registration remains in effect for one year. Approximately 30 days before the renewal date a "Registration of Services Form" along with the annual fee will be sent to the registrant. The registrant will need to certify the accuracy of the information, sign the registration and submit the appropriate annual fee by the fee due date. Upon receipt of payment an updated registration will be issued.

### 180 NAC 2-008 requires that a registrant notify this Department in writing within thirty (30) days of any change which would render the information contained in the registration no longer accurate per 180 NAC 2-008. E. REGISTRATION TERMINATION

Notify this Department, in writing, when a decision is made to termination a registration of services.

### Contact this Department at:

Office of Radiological Health Nebraska Department of Health and Human Services Division of Public Health 301 Centennial Mall South P.O. Box 95026 Lincoln, NE. 68509-5026 FAX (402)471-0169 Phone: (402)471-2168 radiation.programs@nebraska.gov http://dhhs.ne.gov/rad

### F. OTHER REQUIREMENTS

Assemblers, services and servicing personnel must provide the registrant with instruction manuals, manufacturer specification and other information, as required by the Federal Performance Standard, and 180 NAC 2, which are applicable to newly installed x-ray systems and components.



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

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

<ul> <li>4. Training: (At least one individual must be qualified for each of the requested service(s) listed in 3.A through E and G)</li> <li>4.A. Submit name of individual qualified and which service the individual is to provide.</li> <li>4.B. Attach training requirements for each individual. (See item 3. On Page 1 of this form for training requirements references.)</li> <li>4.C. Each individual applying for registration must read and understand the requirements of 180 NAC 2.</li> </ul>					
Name of Individual	Name of Individual				
Circle Service(s) Individual is Providing	Circle Service(s) Individual is Providing				
AI, A2, A3, B1, B2, B3, B4, C1, C2, C3, C4 D1, D2, D3, D4 E, G.	Al, A2, A3, B1, B2, B3, B4, C1, C2, C3, C4, D1, D2, D3, D4, E, G				
Training Documentation for individual is attached.	Training Documentation for individual is attached.				
This individual has read and understands the requirements of 180 NAC 2	This individual has read and understands the requirements of 180 NAC 2				
<u></u>					
Name of Individual	Name of Individual				
Circle Service(s) Individual is Providing	Circle Service(s) Individual is Providing				
AI, A2, A3, B1, B2, B3, B4, C1, C2, C3, C4, D1, D2, D3, D4, E, G	AI, A2, A3, B1, B2, B3, B4, C1, C2, C3, C4, D1, D2, D3, D4, E, G.				
Training Documentation for individual is attached.	Training Documentation for individual is attached.				
This individual has read and understands the requirements of 180 NAC 2	This individual has read and understands the requirements of 180 NAC 2				
Name of Individual	Name of Individual				
Circle Service(s) Individual is Providing	Circle Service(s) Individual is Providing				
AI, A2, A3, B1, B2, B3, B4 C1, C2, C3, C4 D1, D2, D3, D4 E, G.	Al, A2, A3, B1, B2, B3, B4 C1, C2, C3, C4 D1, D2, D3, D4 E, G.				
□ Training Documentation for individual is attached.	Training Documentation for individual is attached.				
This individual has read and understands the requirements of 180 NAC 2	This individual has read and understands the requirements of 180 NAC 2				
Name of Individual	Name of Individual				
Circle Service(s) Individual is Providing	Circle Service(s) Individual is Providing				
AI, A2, A3, B1, B2, B3, B4 C1, C2, C3, C4, D1, D2, D3, D4, E, G.	AI, A2, A3, B1, B2, B3, B4 C1, C2, C3, C4, D1, D2, D3, D4, E, G.				
Training Documentation for individual is attached.	Training Documentation for individual is attached.				
This individual has read and understands the requirements of 180 NAC 2	This individual has read and understands the requirements of 180 NAC 2				
Name of	Name of				
Individual Circle Service(s) Individual is Providing	Individual Circle Service(s) Individual is Providing				
Al, A2, A3, B1, B2, B3, B4 C1, C2, C3, C4, D1, D2, D3, D4, E, G.	AI, A2, A3, B1, B2, B3, B4 C1, C2, C3, C4 D1, D2, D3, D4 E, G				
Training Documentation for individual is attached.	Training Documentation for individual is attached.				
This individual has read and understands the requirements of 180 NAC 2	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: OR

□ I am a citizen of the United States

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

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.

Signature

Ву<u>:</u>

Date:

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.