

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES

GUIDANCE DOCUMENT

“This guidance document is advisory in nature but is binding on an agency until amended by such agency. A guidance document does not include internal procedural documents that only affect the internal operations of the agency and does not impose additional requirements or penalties on regulated parties or include confidential information or rules and regulations made in accordance with the Nebraska Administrative Procedure Act. If you believe that this guidance document imposes additional requirements or penalties on regulated parties, you may request a review of the document.”

Pursuant to
Neb. Rev. Stat. § 84-901.03

REGULATORY GUIDE 2.1

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

I. INTRODUCTION

The purpose of this guide is to assist persons providing services to prepare the form **NRH-9 - Application for Registration of Services for Radiation Sources**. Applicants/registrants are encouraged to familiarize themselves with Title 180 NAC – Nebraska Regulations for “Control of Radiation.”

APPLICABLE REGULATIONS

180 NAC 2
180 NAC 6
180 NAC 8
180 NAC 15

All regulations, regulatory guides, and forms are available at: www.dhhs.ne.gov/rad.

CONTACT INFORMATION

DHHS - Division of Public Health
Office of Radiological Health
301 Centennial Mall South
P.O. Box 95026
Lincoln, Nebraska 68509-5026

Phone: 402-471-2079
Fax: 402-471-0169
Email: dhhs.radiationprograms@nebraska.gov
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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:

DHHS - Division of Public Health
Office of Radiological Health
301 Centennial Mall South
P.O. Box 95026
Lincoln, NE 68509-5026.
OR
DHHS.RadiationPrograms@nebraska.gov

Copies of issued guides can be obtained at: www.dhhs.ne.gov/rad.

II. INITIAL REGISTRATION

Items required for Initial Registration (180 NAC 2-005):

1. **Form NRH-9** – Application for Registration of Services for Radiation Sources.
2. **Education/Training** – Education, training, and on-the-job training (OTJ) documentation (if applicable) is required for each qualified individual listed under item 4 of the NRH-9.
3. **Registration Fees** – Annual fees for services outlined in 180 NAC 18-008.02.

III. NRH-9

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.
- Address: 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. **Responsible Contact**

- If this registration is for a corporation, partnership, firm, agency or group, indicate the person who will be the responsible contact for this registration.

3. **Service Types**

- Indicate the services types the registrant (as an entity) will be providing. The regulatory references in the right column indicate the training requirements of the qualified individual performing the type of service indicated.

4. **Training**

- List the names of qualified individual(s) performing the service(s).
- Select the service type(s) you are registering each qualified individual to perform. Qualified individuals can only provide services for which they are registered.
- Indicate the qualified individual has read and understands the requirements of 180 NAC 2.
- Include the training documentation and on-the-job training (OTJ) documentation as required for the corresponding service type(s) selected.
 - o Each service type selected **must** be supported with evidence that the qualified individuals training and experience has met the requirements found in 180 NAC 15.
 - o See also IV. TRAINING REQUIREMENTS of this regulatory guide.

5. **Citizenship or Lawful Presence Attestation**

- Check appropriate box and provide documentation if required.

6. **Certification**

- Individuals or Representatives of a corporation or legal entity must date and sign.
- The Department will return all unsigned applications for proper signature.

IV. TRAINING REQUIREMENTS

1. **Service Types:**

- **A(all):** Installation/Service
- **B1:** Calibration of Diagnostic Radiation Generating Equipment
- **B4:** Calibration of Non-Medical Radiation Generating Equipment
- **D:** Demonstration which includes energizing the Radiation Generating Equipment

- A person performing installation or servicing of radiation generating equipment must have (180 NAC 15-014.01):
 - (A) Formal training in radiation machine assembly, installation, or repair, or an associate's degree in biomedical equipment repair.
 - (B) Six months of supervised on-the-job training on the assembly or repair, or both, of the types of equipment to be serviced.
 - Submit certificate/diploma and/or transcripts from the class/training/degree for each qualified individual. Include the duration of the formal coursework and documentation showing reference to the coursework required.
2. Service Types:
- **C1:** Area Surveys and Shielding Reviews of Diagnostic Radiation Generating Facilities
 - Service Personnel should be a **Qualified Expert** (180 NAC 15-004.03), **Radiological Health Physicist** (180 NAC 15-004.02) or a **Radiological Medical Physicist** (180 NAC 15-004.01).
 - Submit certificate/diploma and/or transcripts from the class/training/degree for each qualified individual. Include the duration of the formal coursework and documentation showing reference to the coursework required.
3. Service Types:
- **B2:** Calibration of CTs
 - **C2:** CT Shielding Reviews
 - Qualified individual should be a **Radiological Health Physicist** (180 NAC 15-004.02) or a **Radiological Medical Physicist** (180 NAC 15-004.01).
 - Submit transcripts or certificate/diploma from the class/training/degree/certifying board for each qualified individual.
4. Service Types:
- **B3:** Calibration of Therapeutic Radiation Generating Equipment
 - **C3:** Therapeutic Reviews
 - Qualified individual should be a **Radiological Medical Physicist** (180 NAC 15-004.01).
 - Submit transcripts or certificate/diploma from the class/training/degree/certifying board for each qualified individual.
5. Service Types:
- **C4:** Non-Medical Area Surveys and Shielding Reviews of Radiation Generating Facilities
 - Qualified individual should be a **Radiological Health Physicist** (180 NAC 15-004.02).
 - Submit transcripts or certificate/diploma from the class/training/degree/certifying board for each qualified individual.

V. REGISTRATION FEES

Each **NRH-9** must be accompanied by a non-refundable registration fee - see Fee List in 180 NAC 18-008.02. Fee amount is **per Service Type**. Make check or money order payable to: Nebraska Department of Health and Human Services. Payment may also be made online at www.ne.gov/radhealth.

VI. CERTIFICATE OF REGISTRATION

Upon receipt of the completed **NRH-9**, training documentation, and registration fee, a determination will be made if the registrant meets the requirements of the regulations.

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

VII. REGISTRATION RENEWAL

- A registration remains in effect for one year. Approximately 30 days before the renewal date, an **NRH-9 – Qualified Individual Personnel** and an **Invoice – Annual Renewal** 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 registration fee by the fee due date.
- Upon receipt of payment, an updated **Certificate of Registration** will be issued.
- If the registrant indicates changes to qualified individual(s) (addition), training documentation and on-the-job (OTJ) training documentation must be submitted for each qualified individual. Qualified individual(s) will not be added to the Registration without documentation on file.

VIII. REGISTRATION CHANGES

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

Such changes may include:

- Address
- Ownership
- Responsible contact
- Qualified Individual – addition or deletion
- Service Types – addition or deletion
- Registration termination

IX. REGISTRATION TERMINATION

Notify the Department, in writing, when a decision is made to terminate a registration of services.

X. OTHER REQUIREMENTS

Assemblers, service providers, and qualified individuals 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.