

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 3.2

GUIDE FOR PREPARING APPLICATIONS FOR ACADEMIC, RESEARCH AND DEVELOPMENT, AND OTHER LICENSES OF LIMITED SCOPE

1) INTRODUCTION

This document serves as a supplement to the Nuclear Regulatory Commission (NRC) guidance document NUREG-1556, Volume 7, Revision 1, “*Consolidated Guidance About Materials Licenses*” and addresses items specific to Title 180 NAC (Nebraska Administrative Code) that differ from NUREG-1556, Volume 7, Revision 1.

All correspondence should be addressed to the Nebraska Department of Health and Human Services, referred to as “the Department”.

PURPOSE AND SCOPE

The purpose of this guide is to provide assistance to applicants and licensees as they prepare applications for new licenses, license amendments, and license renewals for academic, research and development, and other licenses of limited scope.

This guide is intended to provide you, the applicant and licensee, with information that will enable you to understand specific regulatory requirements and licensing policies as they apply specific licenses of limited scope. The information in this guide is not a substitute for training in radiation safety or for developing and implementing an effective radiation safety program.

After you are issued a license, you must conduct your program in accordance with:

- The statements, representations, and procedures contained in your application;
- The terms and conditions of the license; and
- Title 180 NAC.

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 69509-5026.

OR
DHHS.RadiationPrograms@nebraska.gov

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

APPLICABLE REGULATIONS

180 NAC 3-011	180 NAC 10
180 NAC 3-016 through 3-022	180 NAC 13
180 NAC 3-025 through 3-027	180 NAC 15
180 NAC 4	180 NAC 18

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

2) FILING AN APPLICATION

An application for radioactive material license should be completed on Form NRH-5, provided by the Department, or equivalent.

- If using the NRH-5 form:
 - Complete Items 1 through 5, and 16 on the form; and
 - For Items 6 through 15, submit additional information on supplementary pages if needed.
- If using an equivalent application form:
 - Make sure the application contains all information required by the NRH-5 form. Missing information will delay the application.
 - The application must be accompanied by a Citizenship or Lawful Presence Attestation Form which can be found at <http://dhhs.ne.gov/Pages/Radiation-Control-Forms.aspx>. All licensees and registrants are required to complete this form and have it on file per Neb. Rev. §§ 4-108 through 4-114. The application will not be processed without Attestation on file.

Mail the original application to:
DHHS - Division of Public Health
Office of Radiological Health
301 Centennial Mall South
P.O. Box 95026
Lincoln, Nebraska 68509-5026

An electronic copy of the application would be appreciated in addition to the original mailed copy. The electronic copy may be sent to DHHS.RadiationPrograms@nebraska.gov.

Retain one copy of the completed application for yourself, as the license will require you to possess and use radioactive material in accordance with the statements and representations in your application and any supplements to it.

3) LICENSE FEES

A non-refundable application fee is required for all specific licenses and must be submitted with any **NEW** application. The applicant should refer to 180 NAC 18-005 to determine the amount that should accompany the application. Application review will not begin until the proper fee is received by the Department.

The check or money order should be made payable to: *Nebraska Department of Health and Human Services*. Online payment options are available at www.ne.gov/go/radhealth.

A fee should NOT be submitted with an application renewal or amendment. All current licensees will be billed annually as stipulated in 180 NAC 18-005, according to the expiration month of their current license.

4) CONTENTS OF AN APPLICATION

The following comments apply to the indicated items of Form NRH-5.

Item 1.a. Applicant's Name and Mailing Address

If the applicant is a corporation or other legal entity, list the name and address of the corporation. Individuals should only be designated as the applicant if they are acting in a private capacity and the use of the radioactive material is not connected with their employment with a corporation or other legal entity.

The address specified here should be the mailing address to which correspondence should be sent. This may or may not be the same as the address at which the material will be used, as specified in Item 1.b.

Item 1.b. Locations of Use

List each location of storage or use by the street address, city, and State or other descriptive address (such as 3 miles west on Highway 81, Any Town, State). A Post Office Box address is not acceptable.

Specify whether each location is where operations will be conducted or only the storage location of sources and devices. If operations will be conducted at temporary job sites, check the appropriate box. If a device will be used in a permanent facility or facilities, give the specific address of each if different from 1.a.

Item 2. Application Contact Person

Submit the name of the individual who knows your program and can answer questions about the application. Notify the Department if the contact changes. Notification of a contact change is for information only and would not be considered an application for a license amendment.

Item 3. Self-explanatory

Item 4. Individual User(s)

Submit the names of the persons who will directly supervise the use of radioactive material or who will use radioactive material without supervision.

Item 5. Individuals Responsible for Radiation Safety Program

All licensees must have a Radiation Safety Officer (RSO) designated by the corporation's management. A statement should be included with the application outlining the named individual's duties and responsibilities. A sample statement of duties can be found on page E-3 in NUREG 1556, Volume 7, Revision 1. The RSO is expected to coordinate the safe use of radioactive materials and to ensure compliance with Title 180 and conditions of the license.

Typical duties of the radiation safety officer can be found in Appendix E in NUREG-1556, Volume 7, Revision 1.

If you would like your RSO to have the authority to submit license applications, renewals, amendments, or termination paperwork, you will need to submit a delegation of authority to make legally binding statements. The document must be signed by a management representative.

Further information on the responsibilities of the RSO and the required training for an RSO can be found in Section 8.7 and Appendix E in NUREG-1556, Volume 7, Revision 1.

Item 6. Radioactive Material Data

Describe the radioactive material by isotope, chemical and/or physical form, and activity. Specify a separate possession limit for each nuclide. Possession limits requested should cover the total anticipated inventory, including stored materials and waste, and should be commensurate with the applicant's needs and facilities for safe handling.

If using sealed or plated sources, list the isotope, manufacturer, and model number of each sealed source or plated source. If a source will be used in a gas chromatograph, gauge, or other device, provide the manufacturer and model number of the device.

Clearly describe the ways in which radioactive materials will be used. Provide enough detail to allow the Department to determine the potential for exposure to both radiation workers and the general public.

Further information on radioactive material and proposed use can be found in Sections 8.5 and 8.6 in NUREG 1556, Volume 7, Revision 1.

Items 7-8. Training and Experience

Submit a resume of the training and experience of each person who will directly supervise the use of material, who will use material without supervision, or who will have responsibilities for radiological safety. At a minimum, these items must be completed for each individual named in Items 4 and 5.

Training should cover:

- a) Principles and practices of radiation protection;
- b) Radioactive measurements, standardization, and monitoring techniques and instruments;
- c) Mathematics and calculations basic to the use and measurement of radioactivity; and
- d) Biological effects of radiation.

The description of the use of radioactive materials should include the specific isotopes handled, the maximum quantities of materials handled, where the experience was gained, and the type of use. The qualifications, training, and experience of each person should be commensurate with the material and its use as proposed in the application.

Training and Experience Requirements for Laboratory and Industrial Use of Radioactive Material Personnel are as follows:

- For Millicurie Quantities
Radiation Safety Officer and/or Authorized User:
 - A college degree at the bachelor level, or equivalent training and experience in the physical or biological sciences or in engineering; and
 - Forty (40) hours of formal instruction in:
 - Radiation physics and instrumentation;
 - Radiation protection;
 - Mathematics pertaining to the use and measurement of radioactivity; and
 - Biological effects of radiation; and
 - Demonstrate an understanding of operating and emergency procedures and Title 180 NAC or their equivalent.

- For Microcurie Quantities
Radiation Safety Officer and/or Authorized User:
 - Forty (40) hours of formal instruction in:
 - Radiation physics and instrumentation;
 - Radiation protection;
 - Mathematics pertaining to the use and measurement of radioactivity; and
 - Biological effects of radiation; and
 - Demonstrate an understanding of operating and emergency procedures and Title 180 NAC or their equivalent.

Further information on training and experience requirements for the Radiation Safety Officer and Authorized Users can be found in Section 8.7 in NUREG 1556, Volume 7, Revision 1.

Items 9-10. Radiation Detection Instruments and Calibration of Instruments

For each radiation detection instrument, provide the manufacturer's name and model number, the number of each type of instrument available, the type of radiation detected (alpha, beta, gamma, or neutron), the sensitivity range (milliroentgens per hour or counts per minute), and the type of use. The type of use would normally be monitoring, surveying, assaying, or measuring.

If the applicant proposes to calibrate their survey instruments, they must submit a detailed description of planned calibration procedures. State the frequency and describe the methods and procedures for the calibration of survey and monitoring instruments. If other instruments and systems are used in the radiation protection program, such as measuring instruments used to assay sealed-source leak-test samples (see Item 13), contamination samples (e.g., air samples, surface "wipe" samples), and bioassay samples (see Item 11), submit adequate procedures for each instrument. All calibration procedures should be comparable to the model calibration program published in Appendix I in NUREG-1556, Volume 7, Revision 1.

If the applicant intends to contract out the calibration of instruments, the name, address, and license number of the firm should be specified together with the frequency of calibration. The applicant should contact the firm that will perform the calibrations to determine if they are licensed with the Department, the NRC, or an Agreement State for calibration services.

Quantitative measurement instruments used to monitor the adequacy of containment and contamination control such as those used for measuring leak test, air effluent, bioassay, work area, and equipment contamination samples should usually be calibrated prior to each use. The

procedures and frequency for calibration of such instruments should be comparable to the model radiation survey meter calibration program published in Appendix I in NUREG-1556, Volume 7, Revision 1.

Item 11. Personnel Monitoring Devices

180 NAC 4-022 states the conditions requiring individual monitoring of external and internal occupational dose.

Personnel dosimeters that require processing to determine the radiation dose to a worker must be evaluated by a dosimetry processor accredited by the National Voluntary Laboratory Accreditation Program (NVLAP), per 180 NAC 4-021.04.

If personnel monitoring equipment will be used, provide the name of the organization furnishing the monitors and the type of monitor (optically stimulated luminescent dosimeter (OSLD), thermoluminescent dosimeter (TLD), film badge, etc). Specify the frequency for exchanging dosimeters. If pocket chambers or pocket dosimeters will be used, state the useful range of the device, in milliroentgens, the frequency of reading, and the procedures for maintaining and calibrating the devices.

If personnel monitoring will not be used, the applicant should submit calculations or documentation from radiation surveys demonstrating that it is unlikely that any individual will receive a dose equal to or greater than that indicated in 180 NAC 4-022.

Further information on personnel monitoring can be found in NUREG 1556, Volume 7, Revision 1, Sections 8.10.4 and 8.10.5.

Item 12. Facilities and Equipment

Describe the facilities and equipment for each site in detail. The proposed facilities and equipment for each operation should be adequate to protect health and minimize danger to life and property. In the application, the following should be included, as appropriate:

a) Physical Plant, Laboratory, and Working Areas

Include information about fume hoods, glove boxes, waste receptacles, special sinks, ventilation and containment systems, effluent filter systems, and all related equipment. Submit a drawing or sketch showing the location of all such equipment. Specify on the sketches all restricted areas where radioactive material will be stored or handled. In those programs where radioactive material may become airborne or may be included in airborne effluents, the drawing or sketch should also include a schematic description of the ventilation system annotated to show airflow rates, differential pressures, air and effluent treatment equipment, and air and effluent monitoring instruments. Drawings or sketches should be drawn to a specified scale, or dimensions should be included on each drawing or sketch. Each drawing or sketch should be labeled to specify the location of the facilities and equipment depicted with respect to the address(es) given in Item 1.(b) of Form NRH-5.

b) Equipment and Storage

Identify containers, devices, protective clothing, auxiliary shielding, general laboratory equipment, remote handling devices, and all related equipment used to store or handle radioactive material. Describe special provisions for shielding and containment to minimize personnel exposure. Storage containers and facilities should provide both shielding and security for materials.

c) Respirators

If respiratory protective equipment will be used to limit the inhalation of airborne radioactive material, the provisions of 180 NAC 4-028 should be followed and appropriate information should be submitted.

Item 13. Radiation Protection Program

a) Survey Program

The Department regulations require radiation surveys to determine the hazards of the radiation levels in a facility (See 180 NAC 4-021). A survey should include the evaluation of external exposure to personnel, concentrations of airborne radioactive material in the facility, and radioactive effluents from the facility. Although a theoretical calculation is often used to demonstrate compliance with regulations regarding airborne or external radiation, it cannot always be used in lieu of a physical survey.

For operations involving materials in gas, liquid, or finely divided forms, a survey program equivalent to the program outlined in Appendix M in NUREG-1556, Volume 7, Revision 1 should be submitted to the Department.

For operations involving only sealed sources, a survey program should include evaluation and/or measurement of radiation levels for storage and use configurations. When sources are used in devices having "on" and "off" positions, both positions should be evaluated at the time of installation. Supplemental surveys should be performed following any changes in operation, shielding, or use.

b) Bioassay Procedures

Bioassays are a method to determine the amount of radioactive material in an individual's body. Bioassays are normally required for individuals who use millicurie quantities of hydrogen 3, iodine 125, or iodine 131 depending on the type of work, equipment, and procedures followed. Other materials may also be used in physical or chemical forms and under conditions that present an opportunity for uptake by the body through ingestion, inhalation, or absorption. A bioassay program to determine and control the uptake of radioactive material should be considered and discussed in relation to each such material, procedures, etc.

The criteria to be used in determining the need for bioassays, the type and frequency of bioassays that will be performed, and the bioassay procedures should be specified and described in detail. NRC Regulatory Guide 8.20, "Applications of Bioassay for Radioiodine," and NRC Regulatory Guide 8.32, "Criteria for Establishing a Tritium Bioassay Program," may be consulted. If a commercial bioassay service is to be used, the name and address of the firm should be provided.

Bioassays may not be substituted for other elements of a safety program such as air monitoring and dispersion control (hoods, glove boxes, etc.) and for well thought out and well executed handling procedures.

c) Records Management Program

Describe provisions for keeping and reviewing records of surveys; materials inventories; personnel exposures; receipt, use, and disposal of materials, etc. Recordkeeping requirements for radiation surveys, protection programs, and occupational dose are located in 180 NAC 4-046 through 4-056. Identify persons responsible for keeping and reviewing records.

d) Emergency Procedures

Submit a copy of your emergency procedures. These instructions should be addressed to all persons in all laboratory or facility areas where radioactive materials will be used. The emergency procedures should list appropriate actions to take when radioactive material accidents occur, including spills, fires, release or loss of material, or accidental contamination of personnel. Specifically, these instructions should:

- Outline immediate actions to be taken in order to prevent or limit the contamination of personnel and areas, e.g., the shutting down of ventilation equipment, evacuation of contaminated and potentially contaminated areas, containment of any spills of radioactive material
- Provide the telephone numbers of individuals to be notified in case of emergency
- Instruct personnel in proper entry, decontamination, and recovery operations for contaminated facilities. (Note: Only properly trained individuals should attempt decontamination and recovery operations).

A model emergency preparedness program can be found in Appendix L of NUREG-1556, Volume 7, Revision 1.

e) Sealed Source Leak Test Procedures

Sealed sources containing more than 100 microcuries of a beta or gamma emitter or more than 10 microcuries of an alpha emitter must be leak tested at 6 month intervals. If a commercial firm is to perform the leak tests, provide the name, address, and license number of the firm. If the tests are to be performed using a commercial "kit," the name of the kit manufacturer or distributor and the kit model designation should be given. If the applicant intends to perform his own leak tests without the use of a commercial kit, a leak testing program similar to the program outlined in Appendix N of NUREG-1556, Volume 7, Revision 1.

Item 14. Waste Disposal

The procedures for disposing of radioactive material waste should be described. Under Title 180, a licensee may dispose of waste in the following ways:

- a) Transfer to a person properly licensed to receive such waste in conformance with 180 NAC 4-039.01, item 1. The name of the firm (which should be contacted in advance to determine any limitations that the firm may have on acceptance of waste) should be given.
- b) Release into a sanitary sewer in conformance with 180 NAC 4-041. Depending on water usage, releases of up to 1 curie per year are permitted.
- c) Release into air or water in concentrations in conformance with 180 NAC 4-014. Possible exposure to persons offsite limits the amount that may be released.
- d) Treatment or disposal by incineration in conformance with 180 NAC 4-042. This must be specifically approved by the Department.
- e) Other methods specifically approved by the Department pursuant to 180 NAC 4-040.

Further information and guidance regarding the disposal of radioactive materials can be found in Section 8.11 in NUREG-1556, Volume 7, Revision 1.

Item 15. Citizenship Attestation

All applicants must complete a citizenship attestation. Check the first box if the application is for a corporation or other separate legal entity, otherwise check the second box. If the second box is checked, continue to the next section under the "United States Citizenship Attestation Form." Check the appropriate box and sign. Continue to item 16.

Item 16. Certification

If you are an individual applicant acting in a private capacity, you are required to sign the form. Otherwise, your application should be dated and signed by a representative of the corporation or legal entity who is authorized to sign official documents and to certify that the application contains information that is true and correct to the best of your knowledge and belief. Unsigned applications will be returned for proper signature.

5) AMENDMENTS TO A LICENSE

After you are issued a license, you must conduct your program in accordance with:

- The statements, representations, and procedures contained in your application;
- The terms and conditions of the license; and
- Title 180 NAC.

Title 180 NAC does not allow you to implement changes on the basis of a submission requesting an amendment to your license.

An application for a license amendment may be prepared either on the application Form NRH-5, an equivalent form, or in letter form and should be submitted to the address specified in Section II of this guide.

Your application should identify your license by number and should clearly describe the exact nature of the changes, additions, or deletions. References to previously submitted information and documents should be clear and specific and should identify the pertinent information by date, page, and paragraph. For example,

if you wish to change the responsible individual, your application for a license amendment should specify the new individual's name, training, and experience.

6) RENEWAL OF A LICENSE

Licenses are issued for a period of up to five years. You must send an application for renewal to the address specified in Section II of this guide. You are required to submit an entirely new application for renewal as if it were an application for a new license without referring to previously submitted information.

a) Timely Filing

If you file your application for license renewal at least 30 days before the expiration date of your license, your present license will automatically remain in effect until the Department takes final action on your renewal application.

However, if you file an application less than 30 days before the expiration date and the Department cannot process it before that date, you would be without a valid license when your license expires.

b) License Termination

If you do not wish to renew your license, you must dispose of all licensed radioactive material you possess and send a notification of disposition of the materials with a request for license termination (See 180 NAC 3-019 and 3-025) before the expiration date.

If you cannot dispose of all the licensed radioactive material in your possession before the expiration date, you must request a license renewal for storage only of the radioactive material. The renewal is necessary to avoid violating Department regulations that do not allow you to possess licensable material without a valid license.