



REGULATORY GUIDE 3.6

GUIDE FOR THE PREPARATION OF APPLICATION FOR LICENSES FOR THE USE OF SEALED SOURCES IN GAS CHROMATOGRAPHY DEVICES

1. INTRODUCTION

PURPOSE AND SCOPE

The purpose of this regulatory guide is to provide assistance to applicants and licensees in preparing applications for new licenses, license amendments, and license renewals for the use of sealed sources in gas chromatography devices.

This regulatory guide is intended to provide you, the applicant and licensee, with information that will enable you to have an understanding of specific regulatory requirements and licensing policies as they apply to gas chromatography devices. The information in this guide is not a substitute for training in radiation safety.

After you have been issued a license, you must conduct your program in accordance with (1) the statements, representations, and procedures contained in your application, (2) the terms and conditions of the license, and (3) Title 180, "Control of Radiation". The information you provide in your application should be clear, specific, and accurate.

APPLICABLE REGULATIONS

The applicable chapter in Title 180 NAC, "Control of Radiation" to gas chromatography devices are in 180 NAC 10, "Notices, Instructions and Reports to Workers; Inspections"; 180 NAC 4, "Standards for Protection Against Radiation"; 180 NAC 3-011 "General Requirements for the Issuance of Specific Licenses." Other pertinent regulations are 180 NAC 3-016 through 3-022, 3-025 through 3-028, 3-30, 180 NAC 13, "Transportation of Radioactive Material"; 180 NAC 15, "Training and Experience Requirements for Use of Radiation Sources"; 180 NAC 17, "Enforcement of Radiation Control Act and Rights to Hearing Procedures for Licensees and Registrants; Penalties" and 180 NAC 18, "Fees for Certificates of Registration, Radioactive Material(s) Licenses, Environmental Surveillance and Implementation, Emergency Planning, Emergency Response and Implementation and other Regulatory Services."

It is your responsibility as an applicant and as a licensee to have copies of, to read, and to abide by each regulation. As a licensee, you are subject to all applicable provisions of the regulations as they pertain to gas chromatography devices.

This guide identifies the information needed to complete Form NRH-5 for applications for a license for the use of sealed sources and devices in gas chromatography devices.

NEBRASKA DEPARTMENT OF HEALTH & HUMAN SERVICES, 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 68509-5026. 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.

(Rev 4) 02-2013

2. LICENSE FEES

An 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. Review of the application will not begin until the proper fee is received by the Department. The check or money order should be made payable to the Nebraska Department of Health and Human Services .

In the case of an application for renewal or amendment, a fee should NOT be submitted with the application. All current licensees will be billed annually according to the expiration month of their current license.

3. FILING AN APPLICATION

An application for radioactive material license should be completed on Form NRH-5 provided by the Department. Complete Items 1 through 5, and 16 on the form. For Items 6 through 14, submit additional information on supplementary pages if needed. Each separate sheet or document submitted with the applications should be identified and keyed to the item number on the application to which it refers. You should complete all items in the application in sufficient detail for the Department to determine that your equipment, facilities, training and experience, and radiation safety program are adequate to protect health and to minimize danger to life and property.

The forms should be completed in duplicate. Retain one copy for yourself, because the license will require that you possess and use radioactive material in accordance with the statements and representations in your application and in any supplements to it.

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

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

Individuals should be designated as the applicant only 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. Otherwise, the applicant, should be the corporation or other legal entity applying for the license.

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

Specify 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, Anytown, State). A Post Office Box address is not acceptable. Also, specify whether a location is one at which operations will be conducted or whether the location is only for storage of sources and devices. If operations will be conducted at temporary job sites, specify. 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. Person to be Contacted About Application

Name the individual who knows your program and can answer questions about the application. Also, please note the telephone number at which the individual may be contacted. If the contact changes, notify the Department. 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)

Persons who will use the device that are competent in operating procedures and manufacturer's instructions.

Item 5. Individuals Responsible for Radiation Safety Program

All licensees must have a Radiation Safety Officer (RSO) or Radiation Protection Officer (RPO) designated by and responsible to the corporation's management for the coordination of the radiation protection program. A statement should be included with the application outlining the named individual's duties and responsibilities. The radiation protection officer is expected to coordinate the safe use of radioactive materials and to ensure compliances with Title 180 and conditions of the license.

If you do not propose to perform any maintenance or repair on the gas chromatography device, no specific training and experience in the use and handling of radioactive materials is necessary for individuals who will use it or supervise its use, provided they follow the manufacturer's direction of use. No special training or experience is needed to perform leak tests using a leak-test kit or to clean detector cells used in gas chromatography devices provided the source or foil is not removed from the detector cell and the licensee follows the directions of the manufacturer for leak testing and cleaning of detector cells.

If you propose to perform any operations that involve removal of sources from the device or maintenance and repair of a device that involves the source, only a "responsible individual" may perform these operations. This "responsible individual" must have received instruction and training in the principles and practices of radiation safety, the use of radiation detection instruments, and the performance of these operations. Such training may normally be accomplished in 1 or 2 days. In your application, you should provide the following information:

- A. The specific operations you wish to perform.
- B. The name of each "responsible individual" who will perform the operations.
- C. An outline of the instruction and training each "responsible individual" has received in the principles and practices of radiation safety, the use of radiation detection instruments, and the operations that will be performed, including actual practice in performing the operations. The amount of time spent on each topic in the training should be specified.
- D. The name and affiliation of the person who provided the instruction and training and this person's qualifications to conduct the operations.

Typical duties of the radiation safety officer would be:

To assure that radioactive materials possessed under the license conform to the materials listed on the license.

To assure that radioactive materials are used only by individuals authorized by the license.

To assure that radioactive materials are properly secured against unauthorized removal at all times when they are not in use.

To serve as a point of contact and give assistance in case of emergency to assure that proper authorities are notified promptly in case of accident or damage to radioactive devices.

To assure that the terms and conditions of the license, such as periodic leak tests, are met and that the required records are maintained.

Item 6. Radioactive Material Data

- A. Identify the radioisotope that will be used in the gas chromatography device.
- B. Identify the manufacturer and model number of the foil source, plated source, or sealed source that will be used in the gas chromatography device.
- C. Specify the amount of radioactive material that will be in each foil source, plated source, or other sealed source.
- D. Identify the manufacturer and model number of the detector cell that will be used in the gas chromatography device. Also specify the purpose for which the gas chromatography device will be used.

The information specified above is available from the manufacturer of the gas chromatography device.

Items 7 and 8. Training and Experience

These items must be completed for each individual named in Items 4 and 5, use supplemental sheets if necessary.

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

180 NAC 4-005 specifies that you, as the licensee, must make such surveys as are necessary to evaluate the extent of radiation hazards that may be present and to comply with regulatory requirements. In order to perform appropriate surveys, you need to have operable, calibrated instruments.

You do not need to have a survey meter for routine use of gas chromatography devices, nor do you need to have one if you perform maintenance and repair operations as described in Item 5 if the radiation source is gaseous or nickel-63.

If you wish to perform the maintenance and repair operations described in Item 5 and the operations involve the sealed source, you should have a survey meter that can measure the radiation levels to which personnel would be subjected during these operations. The survey meter should be capable of measuring radiation levels up to 1 roentgen per hour.

In your application, you should state that you will have a calibrated, operable survey meter that is capable of measuring radiation levels up to 1 roentgen per hour. Specify the manufacturer and model number of the survey meter.

In order to perform appropriate surveys, instruments must be operable and calibrated with an appropriate radiation source. State that the survey meter will (1) be calibrated so that the readings are $\pm 20\%$ of the actual values over the range of the instrument, (2) have a calibration chart or graph that shows the results of the calibration, the date of the last calibration, and the due date for the next calibration affixed to it, and (3) be calibrated at intervals not to exceed 1 year and after servicing. Also state that calibration records will be kept for a minimum of 2 years after each calibration and identify who will calibrate the instrument. If a person or firm outside your organization will perform the calibration, identify each person or firm by name and U.S. Nuclear Regulatory Commission or Agreement State license number. If the person or firm is not a licensee, provide a copy of the procedure used for instrument calibration for Department review.

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 to compare to the 180 NAC 4-005, 4-011 and 4-012 dose limits must be processed and evaluated at a dosimetry

processor per 180 NAC 4-021.03, that is accredited under the National Voluntary Laboratory Accreditation Program (NVLAP).

For routine use, e.g., normal operation for the intended purpose, of gas chromatography devices, you do not need to use personnel monitoring devices, nor do you need to use them in the maintenance and repair operations described in Item 5 if the radiation source in your gas chromatography device is in gaseous form or is nickel-63.

If your program includes the maintenance and repair operations described in Item 5 and these operations involve the sealed source, personnel monitoring devices should be used by persons performing these operations. In your application, you should state that personnel will be provided with either film badges or thermoluminescent dosimeters (TLDs) or optically stimulated luminescent dosimeters (OSLDs) for use while performing service operations; you should be at intervals not to exceed 1 month for film badges and 3 months for TLDs or OSLDs.

Item 12. Facilities and Equipment

180 NAC 3-011.02 states that an application will be approved if, among other things, the applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to the public health and safety or property. Therefore, you should provide information about your equipment and facilities (e.g. sketch of facility). Also, 180 NAC 4-031 states that (1) radioactive material of radiation shall be secured against unauthorized removal from the place of storage and (2) radioactive material in an unrestricted area and not in storage shall be tended under the constant surveillance and immediate control of the licensee or registrant.

The room, laboratory, or area in which the device is located should be (1) accessible only to persons authorized to use the device and (2) locked when an authorized person is not physically present. You should state that the room, laboratory, or area will be locked when an authorized person is not present.

The room, laboratory, or area cannot be considered a restricted area if it is accessible to unauthorized persons.

Item 13. Radiation Protection Procedures

Procedures should be established to ensure compliance with the provisions of 180 NAC 10, "Notices, Instructions and Reports to Workers, Inspections," and 180 NAC 4, "Standards for Protection Against Radiation." The applicant must submit a copy of the written radiation safety and emergency procedures provided to the users of radioactive material.

Leak Tests: As a licensee, you must perform such tests as the Department deems appropriate or necessary pursuant to 180 NAC 1-006. The Department has deemed it necessary for tests to be made to determine whether or not there is any leakage from the radioactive source in the gas chromatography device. There are some source/device combinations that have leak-test intervals up to 3 years. Information on source/device combinations that have 3-year leak-test intervals may be obtained from suppliers and manufacturers. Unless a specific request for the 3-year leak-test interval is included in the application, a 6-month interval will be specified in licenses.

Tests to determine whether there is any leakage are not required for sources containing radioactive material in gaseous form.

The measurement of the leak-test sample should be quantitative and should be sufficiently sensitive to detect 0.005 microcurie of radioactivity.

The options for leak-testing are:

- A. Engage the services of a consultant or commercial facility to take samples, evaluate the samples, and report the results to you.
- B. Use a commercial leak-test kit. You take the smear and send it to the kit supplier, who reports the results to you.
- C. You perform the entire leak-test sequence yourself, including taking the smears and making the measurements.

For Option 1, specify the name, address, and license number of the consultant or commercial organization.

For Option 2, specify the kit model number and the name, address, and license number of the kit supplier. In your application, you should state that the test samples will be taken by the individual specified in Item 5 who is responsible for the program.

For Option 3, specify how and by whom the test sample will be taken, the instrumentation that will be used for measurement, and the individual who will make the measurement and his or her qualifications. An instrument capable of making quantitative measurements should be used. Hand-held survey meters will not normally be considered adequate for measurements. Include a sample calculation for conversion of the measurement data to microcuries.

Maintenance and Repair

If you have requested authorization to perform the maintenance and repair operations described in Item 5, you should state in your application that you will follow the written procedures provided by the device manufacturer for each such operation requested. If you will follow a procedure other than that provided by the device manufacturer, you should submit the procedure you propose to use for each operation requested.

Item 14. Waste Disposal

180 NAC 4-039 specifies the general requirements for disposal of radioactive material. Because of the nature of the radioactive material contained in your devices, your only option for disposal is to transfer the material to an authorized recipient as specified in 180 NAC 4-039.01, item 1. You should state that disposal will be by transfer of the radioactive material to a license specifically authorized to possess it.

Authorized recipients are the original supplier of the device, a commercial firm licensed by the Department, U.S. Nuclear Regulatory Commission or an Agreement State to accept radioactive waste from other persons, or another specific licensee authorized to dispose of your radioactive material.

Item 15. Citizenship Attestation must be completed by all applicants. 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 (1) the statements, representations, and procedures contained in your application, (2) the terms and conditions of the license, and (3) Title 180.

It is your obligation to keep your license current. You should anticipate the need for a license amendment insofar as possible. If any of the information provided in your application is to be modified or changed, submit an application for a license amendment. In the meantime, you must comply with the terms and conditions of your license until it is actually amended; Title 180 do 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 or in letter form and should be submitted to the address specified in Section 3 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" specified in Item 5, your application for a license amendment should specify the new responsible individual's name, training, and experience. The qualifications of the new responsible individual should be equivalent to those specified in Item 5 of this guide.

6. RENEWAL OF A LICENSE

Licenses are issued for a period of up to 5 years. You must send an application for renewal to the address specified in Section 3 of this guide. You may be 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.

As an alternative, you may be permitted to:

- A. Review your current license to determine whether the information about the sealed sources and devices accurately represents your current and anticipated program. Identify any additions, deletions, or other changes and then prepare information appropriate for the required additions or changes.
- B. Review the documents you have submitted in the past to determine whether the information in them is up to date and accurately represents your facilities, equipment, personnel, radiation safety procedures, locations of use, and so on. The documents you consider to represent your current program should be identified by date. Any out-of-date or superseded documents should be identified, and changes should be made in the documents as necessary to reflect your current program.
- C. Review Title 180 NAC to ensure that any changes in the regulations are appropriately covered in your program description.
- D. After you have completed your review, submit a letter to the Department requesting renewal of your license and providing the information in Items 1, 2, and 3 as necessary.
- E. Include the name and telephone number of the person to be contacted about your renewal application and include your current mailing address if it is not indicated correctly on your license.

If you file your application for license renewal at least 30 days before the expiration date of the 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.

If you do not wish to renew your license, you must dispose of all licensed radioactive material you possess in a manner authorized by 180 NAC 4 and send a notification of disposition and a completed NRH-60 of the materials to the Department before the expiration date of your license with a request that your license be terminated.

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.

