

Guide for the Preparation of Applications for Licenses for Gas Chromatography Devices



Introduction

This guide describes the type of information required by the department to evaluate an application for a specific license for gas chromatography devices. This type of license is provided under Chapter 246-232 WAC, "Requirements of General Applicability to Licensing of Radioactive Material."

WAC 246-220-007, "Statement of Philosophy," states in part, "...persons engaged in activities under licenses issued by the Washington State Department of Health pursuant to the Atomic Energy Act of 1954, as amended, shall, in addition to complying with the requirements set forth in Chapter 246-221 WAC, make every reasonable effort to maintain radiation exposures, and releases of radioactive materials in effluents to unrestricted areas, As Low As is Reasonably Achievable" (ALARA). Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures as Low as is Reasonably Achievable," provides the department position on this important subject. License applicants should give consideration to the ALARA philosophy, as described in Regulatory Guide 8.10, in the development of plans for work with licensed radioactive material.

License Fees

An application fee is required for radioactive materials licenses. Refer to the application cover letter to determine the amount of fee that must accompany the application. Review of the application will not begin until the proper fee is received by Washington State Department of Health.

Filing an Application

Complete Form RHF-1GC, "Application for Radioactive Material License-Gas Chromatograph." All items on the application form should be completed in sufficient detail for the Division of Radiation Protection to determine if the applicant's equipment, facilities, and radiation protection program are adequate to protect health and minimize danger to life and property.

Since the space provided on Form RHF-1GC is limited, the applicant should append additional sheets to provide complete information, if necessary. Each separate sheet or document submitted with the application should be identified by a heading indicating the appropriate item number (on Form RHF-1GC) and its purpose (e.g., radiation safety instructions).

The application must be completed **in duplicate**. The original copy and fee, are to be mailed to Washington State Department of Health in accordance with the directions contained in the application cover letter. One copy of the application with all attachments must be retained by the applicant, since the license will require, as a condition, that the licensee follow the statements and representations set forth in the application and any supplements to it.

Contents of an Application

Most items of Form RHF-1GC are self-explanatory. The following comments apply to the indicated numbered items on the form.

Item 1a. Name and Mailing Address. Specify the applicant corporation, or other legal entity by name and mailing address of the principal office. Individuals should be designated as the applicant only if the use of the radioactive material is not connected with the individual's employment with a corporation or other legal entity. If the applicant is an individual, the individual must be specified by full name and address, including state and zip code.

Item 1b. Street Address. Specify the street address of the location of use if the address differs from the one given in Item 1a. If use is to be at more than one location, the specific address of each should be given. Describe the extent of use and the facilities and equipment at each location. A post office box address is not acceptable. No license can be issued unless the applicant lists an in-state permanent address, even if all uses of radioactive materials will be at temporary job sites.

Item 4a. Authorized Users. Specify the names of the persons who will directly supervise the use of radioactive material or who will use radioactive material without supervision.

Item 4b. Training and Experience. Complete Form RHF-1GC, Appendix A, for the Radiation Safety Officer and each authorized user, unless this information has been previously submitted as part of a license application. Designate which license the information was filed under.

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. 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.

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 instructions 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 one or two days. In your application, you must 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 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.

Item 5a. Radiation Safety Officer. Specify the name of the person who will be designated as the Radiation Safety Officer or Radiation Protection Officer (include training certificates). This person will be responsible for implementing the radiation safety program and must therefore be readily available to the users in case of difficulty.

Appendix B "Duties of the Radiation Safety Officer for Gas Chromatograph Licensee" must be signed, dated and returned with the application.

Items 6, 7, 8 and 9. Material to be Possessed.

- 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 used in each foil source, plated source, or other sealed source. It is not necessary to designate the number of sources that you may want to possess at any one time. It is the Department's practice to provide flexibility in the number of identical sources that you may possess. However, a decommissioning - funding plan may be required for possession of an unusually large number of sources. You should check with the department if this is foreseeable.
- D. Identify the manufacturer and model number of the detector cell that will be used in the gas chromatography device.

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

Item 11. Radiation Detection Instruments. You do not need to have a survey meter for routine use of gas chromatography devices.

If you wish to perform the maintenance and repair operations and if the operations involve a sealed source other than Nickel 63, you should have a survey meter that can measure the appropriate radiation levels. In your application, you should state that you will have a calibrated, operable survey meter.

Item 12. Calibration of Detection Instruments (for in-house calibrations)

- A. Describe the instrument calibration methods and procedures for the calibration of contamination monitoring instruments, as well as any other measuring instruments and systems used in the radiation protection program, such as measuring instruments used to assay sealed source leak test samples (see Item 15) and contamination samples.
- B. An adequate calibration of instruments usually cannot be performed with built-in check sources. Such check sources are, however, ideal for instrument standardization. Electronic calibrations that do not involve a source of radiation are generally not adequate to determine the proper functioning and response of all components of an instrument.
- C. Daily or other frequent checks (standardization) of contamination monitoring instruments should be performed. Additionally, a determination should be made annually and after each repair or battery change to verify that the minimum sensitivity of the instrument is appropriate for energies of the radionuclides of concern. This determination should be made using sources which are traceable to the National Institute of Standards and Technology (NIST).
- D. Description of calibration procedures must include, as a minimum:
 - 1. The name of the manufacturer and the model number of each of the standards to be used.
 - 2. The nuclide and quantity of radioactive material contained in each of the standard sources.
 - 3. A statement of the accuracy of each of the standard sources. The source accuracy should be, as a minimum \pm five percent of the stated value and traceable to a primary standard, such as that maintained by the NIST.
 - 4. Step-by-step calibration procedures and, if appropriate, associated radiation safety procedures.
 - 5. The name and pertinent experience of each person who will perform the instrument calibrations.

If survey meter calibrations will be done by a calibration agency you must provide their name, address and their radioactive materials license number.

Item 13. Personnel Monitoring. WAC 246-221-090 specifies when personnel monitoring is required. For routine use of gas chromatography devices you do not need to use personnel monitoring devices. You do not need them in maintenance and repair operations if the radiation source in your gas chromatography device is in gaseous form or is Nickel 63.

If your program includes maintenance and repair operations involving other sealed sources, personnel monitoring devices should be used by persons performing these operations. In your application, state that personnel will be provided with either film badges or thermoluminescent dosimeters (TLDs) for use while performing service operations. Specify names of organizations furnishing dosimetry services, and state the frequency of exchange for personnel monitoring devices. The exchanges should be at intervals not to exceed three months.

Item 14. Facilities. Attach to the application a diagram and description of the gas chromatography facilities, source and/or detector cell storage areas. If there is more than one location of use, describe in detail the facilities and equipment for each site. The rooms, laboratories, or areas in which the devices are located should be locked when an authorized person is not physically present.

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

Item 15. Leak Test Program. 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 six-month intervals. Leak testing of alpha-particle-emitting sources containing more than 10 microcuries of an alpha emitter is required at three-month intervals. If a commercial firm is to perform the leak tests, the name, address, and license number of the firm must be submitted. If the tests are to be performed using a commercial kit, the name of the manufacturer or distributor and processor of the kit must be given. If the applicant intends to perform leak tests without the use of a commercial kit, the following information must be submitted:

1. Qualifications of personnel who will perform the leak tests.
2. Procedures and materials to be used in taking test samples.
3. The type, manufacturer's name, model number, and radiation detection and measurement characteristics of the instrument to be used for assay of test samples.
4. Instrument calibration procedures, including calibration source characteristics, make, and model number.
5. The method, including a sample calculation, to be used to convert instrument readings to units of activity; e.g., microcuries.

Item 16. Waste Disposal. Because of the nature of the licensed material contained in your device, your only option for disposal is to transfer the material to an authorized recipient. You should state that disposal will be by transfer of the radioactive material to a licensee specifically authorized to possess it.

Authorized recipients are the original supplier of the device, a commercial firm licensed by NRC or an Agreement State to accept radioactive waste from other persons, or another specific licensee authorized to possess the licensed material. No one else is authorized to dispose of your licensed material.

Item 17. Appendix C. "Radiation Protection Program for Gas Chromatographs / Standard Emergency Procedures for Gas Chromatographs" must be completed, signed, dated and returned with the application.

Item 18. License Fee Required. Consult application cover letter for determination of the required license fee. List fee category in Subitem 18a. Mark "License fee enclosed" in Subitem 18b. All new applications and renewals require a license fee. Review of your license application cannot begin until the license fee has been received by the Department of Health. There is no fee for normal amendments.

Item 19. Certificate. Item 19 must be completed on all applications. The form must be dated and signed by management on new applications (not the Radiation Safety Officer, unless management files with the department a statement authorizing the RSO to sign all applications and radiation safety program commitments). The Radiation Safety Officer may sign renewal applications and amendment requests.

Amendments to Licenses

Licensees are required to conduct their programs in accordance with statements, representations, and procedures contained in the license application and the supporting documents. The license must therefore be amended if the licensee plans to make any changes in facilities, equipment (including monitoring and survey instruments), procedures, personnel named on the license, or radioactive material to be used, before the changes are implemented.

Applications for license amendments may be filed either on the application form or in letter form, and must be signed by an appropriate representative of management or the Radiation Safety Officer. The application must identify the license by number and must clearly describe the exact nature of the change, addition, or deletion. References to previously submitted information and documents must be clear and specific and should identify the pertinent information by date, page, and paragraph.

Renewal of Licenses

Renewal applications must be filed on Form RHF-1GC, appropriately supplemented, and must contain complete and up-to-date information about the applicant's current program. The Division of Radiation Protection informs licensees three months prior to the expiration date on the license. Renewal application forms accompany each renewal notice. The completed application and any attachments must be submitted to the department at least 30 days prior to the expiration date. This will ensure that the license does not expire until final action on the application has been taken by the department as provided for in WAC 246-235-050.

In order to facilitate the review process, the application for renewal should be submitted without reference to previously submitted documents and information. If such references cannot be avoided, they must be clear and specific and should identify the pertinent information by date, page, and paragraph.