MINNESOTA DEPARTMENT OF HEALTH

REGULATORY GUIDE FOR GAS CHROMATOGRAPHS AND X-RAY FLUORESCENCE ANALYZERS

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INTRODUCTION

This regulatory guide is designed to describe the type and extent of information needed by the MDH to evaluate an application for license to use and possess gas chromatograph devices and x-ray fluorescence analyzers. An example of a gas chromatograph device is a device that contains a Hydrogen-3 or Nickel-63 foil source. Fluorescence analyzers normally contain Iron-55, Cadmium-109, Americium-241 or Curium-244.

The information in this guide is not a substitute for training in radiation safety or for developing and implementing an effective radiation safety program. You should carefully study this guide and all the regulations identified in the Minnesota Rules and should then complete the application form. The MDH may request additional information when necessary to provide reasonable assurance that the applicant has established an adequate radiation protection program.

AS LOW AS REASONABLY ACHIEVABLE (ALARA) PHILOSOPHY

Every reasonable effort should be made to maintain radiation exposures and releases of radioactive material in effluents to unrestricted areas as low as is reasonably achievable (ALARA). As an applicant, you should consider the ALARA philosophy in the development of work plans involving radioactive materials.

The success of an ALARA program depends on the cooperation of each person who works at your facility. Management should make a formal policy commitment to the ALARA philosophy and implement that commitment with adequate resources.

The Radiation Safety Officer (RSO) and management are required to audit the radiological program to ensure the continued safe use of radioactive material. The RSO is also responsible for the day-to-day operations of the radiation safety program.

FILING AN APPLICATION

You should apply for a license by completing the “Application for a Minnesota Radioactive Materials License.” Complete Items 1 through 4 on the form itself. For Items 5 through 11, submit the information on supplementary pages. Identify and key each sheet or document with the item number on the application. All typed pages, sketches, and, if possible, drawings should be on 8 1/2 X 11 inch paper to facilitate handling and review. If larger drawings are necessary, they should be folded to 8 1/2 X 11 inches. You should complete all items in the application in sufficient detail for MDH to determine that your equipment, facilities, training and experience, and radiation safety program are adequate to protect the health and safety of the public as well as your employees.

Please note that license applications are available for review by the general public in the MDH offices. Do not submit proprietary information unless necessary. If submittal of such information is necessary, please clearly specify the proprietary information. Failure to do so may result in disclosure of this information to the public or substantial delays in processing your application.

Do not submit personal information about your individual employees unless it is necessary. For example, the training and experience of individuals should be submitted to demonstrate their ability to manage radiation safety programs or to work safely with radioactive materials. Home addresses and home

telephone numbers should be submitted only if they are part of an emergency response plan. Dates of birth, social security numbers, and radiation dose information should be submitted only if specifically requested by MDH.

Submit one copy of your application to:

Radioactive Materials Unit
Minnesota Department of Health
625 Robert Street North
PO Box 64975
St. Paul, MN 55164-0975

Retain one copy for yourself, as the license will be issued based on the statements and representations in your application, its supplements, and the requirements in the regulations. The statements and representations you make as if they were regulations will bind you.

The following comments apply to the indicated items on the Application for a Minnesota Radioactive Materials License.

Item 1: License Action Type

Check box A for a new license request.

Check box B for an amendment to an existing license and provide the license number. See "Amendments and Renewals to a License," section of this document.

Check box C for a renewal of an existing license and provide the license number.

Item 2: Name and Mailing Address of Applicant

List the legal name of the applicant's corporation or other legal entity with direct control over use of the radioactive material; a division or department within a legal entity may not be a licensee. An individual may be designated as the applicant only if the individual is acting in a private capacity and the use of the radioactive material is not connected with employment in a corporation or other legal entity. Provide the mailing address where correspondence should be sent.

Timely Notification of Transfer of Control

Licensees must provide full information and obtain MDH's prior written consent before transferring control of the license, directly or indirectly, or, as some licensees call it, "transferring the license." Transfers of control may be the results of mergers, contractual agreements, buyouts, or majority stock transfers. Although it is not MDH's intent to interfere with the business decisions of licensees, it is necessary for licensees to obtain prior MDH written consent. This is to ensure the following:

- Radioactive materials are possessed, used, or controlled only by persons who have valid MDH licenses.
- Materials are properly handled and secured.
- Persons using these materials are competent and committed to implementing appropriate radiological controls.
- A clear chain of custody is established to identify who is responsible for final disposal of radiography devices.
- Public health and safety are not compromised by the use of such materials.

Item 3: Address(es) Where Licensed Material Will Be Used or Possessed

Applicants must provide a specific address for each location where radioactive material will be used, stored, or dispatched. Specify the street address, city, and state or other descriptive address (such as on Highway 10, 5 miles east of the intersection of Highway 10 and State Route 234, Anytown, Minnesota) for each permanent storage or use facility. A Post Office Box address is insufficient because MDH needs a specific address to allow an MDH inspector to find the use and/or storage location. In addition, the applicant should state whether a location will be used only for storage of devices.

Item 4: Person to Be Contacted About This Application

Identify the individual who can answer questions about the application and include his or her telephone number. This is typically the proposed radiation safety officer (RSO) or knowledgeable management official. The MDH will contact this individual if there are questions about the application.

Notify MDH if the contact person or telephone number changes. This notice is for information only and does not require a license amendment or a fee.

Items 5 through 11 should be submitted on separate sheets of paper.

Item 5: Radioactive Material

For each gas chromatograph device or fluorescence analyzer, provide the following:

- Identify each radioisotope.
- Identify the manufacturer and model number of each foil source, plated source or sealed source.
- Specify the amount of radioactive material that will be in each foil source, plated source or sealed source.
- Identify the manufacturer and model number of the device in which the sealed sources will be used.

You should consult with your proposed supplier for this information to be sure that your sources and devices conform to the sealed source and device designations registered with the US Nuclear Regulatory Commission (NRC) or an Agreement State. You do not have to list exempt calibration and reference sources.

NOTE: It is the practice of MDH to provide flexibility in the number of identical sealed source/device combinations you may want to possess at any one time. Therefore, it is not necessary for you to specify the number of identical source/device combinations. You will need to amend your license before you obtain a device other than those listed in Item 5.

Item 6: Purpose(s) for Which Licensed Material Will Be Used

Specify the purpose for which the gas chromatograph or fluorescence analyzer device you want to possess will be used. For example, a gas chromatograph is normally used for analyzing organic and non-organic compounds. In order for devices to be used safely, the device should be used only for the purposes for which it was designed and in accordance with the manufacturer's recommendations for use.

Item 7: Individual(s) Responsible for Radiation Safety Program

Radiation Safety Officer (RSO)
State the name and title of the person designated by, and responsible to, the applicant's management as RSO. If the RSO is not one of the proposed authorized users, submit a complete description of the individual's training and experience in radiation protection and the handling of the devices. Even if the licensee employs a consultant to assist the RSO, the licensee is still responsible for the radiation safety program as required by the license.

The RSO needs independent authority to stop operations that are considered unsafe. The RSO also needs sufficient time and commitment from management to fulfill certain duties and responsibilities to ensure that the devices are used only by authorized individuals and in a safe manner. The RSO's duties and responsibilities should include those areas listed in Appendix A. You should commit to Appendix A or its equivalent.

Authorized Users
Unless you propose to perform maintenance or repairs, no specific training is necessary. However, individuals who will use devices or supervise their use should review the operating manual. No special training or experience is needed to perform leak tests using a leak test kit or to clean detector cells used in gas chromatograph devices provided the source or foil is not removed from the detector cell. Proposed users should not be named. *State that no maintenance or repair will be performed and that all users will follow the instructions in the operating manual.*

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 through a one- or two-day training from the manufacturer or equivalent. In your application, you should provide the following information:

- The specific operations you wish to perform.
- The name of each responsible individual who will perform the operations.
- 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.
- The name and affiliation of the person who provided the instruction and training and this person's qualifications to conduct the operations.

Item 8: Training for Individuals Working In or Frequenting Restricted Areas

Describe your training program for individuals who work near the devices. This includes all employees (clerical, delivery, security, and housekeeping). Training should cover regulations, in-house work rules, and the location of posted notices and copies of regulations and the license.

Item 9: Facilities and Equipment

An application will be approved if, among other things, the applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property. Therefore, you should provide the following information concerning your equipment and facilities:

- A description of where the device will be stored when not in use or at field locations.

- The security measures taken during storage and use when not at field locations. You should state that the room, laboratory, or area in which the device is located will be (a) accessible only to persons authorized to use the device and (b) locked when an authorized person is not physically present.
- The security measures to be taken when stored in the field. State that
    - the device will be locked in the trunk of a car, hidden from view while in a locked van. A restricted area does not include areas used as residential quarters, motel rooms, or occupied offices because they are accessible to unauthorized persons.
    - the device will be physically watched by an authorized user at all times when the device is not in storage. It is not acceptable for a device to be left lying unattended at the place of use during lunch or breaks because the device would then be accessible to unauthorized persons.

Any change to permanent storage locations cannot be made unless approved by an amendment to the license.

Item 10: Radiation Safety Program

You, as the licensee, are responsible for the conduct of your radiation safety program and for all actions of your employees. The elements of a radiation safety program are contained in the appendices. Review each appendix carefully. (Some of these appendices have been addressed in the proceeding text and need not be re-addressed.) Commit to the specific appendix, submit your own procedures using the appendix as a guide, or indicate "not applicable."

Leak Testing of Sealed Sources

Each sealed source must be tested for leakage at intervals not to exceed 6 months. The leak test should be performed at 6-month intervals. The instrumentation should be sufficiently sensitive to detect 0.005 microcuries of radioactivity.

The following options are available for leak testing:

1. Engage the services of a consultant or commercial facility to take samples, evaluate the samples, and report the results to you.

2. Use a commercial leak test kit. You take the smear and send the smear to the kit supplier, who will report the results to you.

3. Perform the entire leak test sequence yourself, including the smears and measurements.

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

For Option 2, specify 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 individuals specified in Item 8 who are responsible for your radiation safety program. Commit to Appendix C.1.

For Option 3, indicate how the test sample will be taken. Specify the instrumentation that will be used for measurement. 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. You should also specify the individual who will make the measurement and his or her qualifications. The individual should have prior experience in making quantitative measurements, and this experience should be documented in your application.

Maintenance
If you wish to request authorization to perform the maintenance and repair operations, you should state in your application what maintenance you wish to perform. Commit to following 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.

You should state that any maintenance you will perform (such as cleaning) will always be done with the radioactive source in the safe shielded position. You may not do any maintenance unless the source is safely shielded.

To take the radioactive source out of the device, you must have special training and procedures, use a radiation survey meter, and take appropriate radiation safety precautions. If you plan to remove the source from the device for exchange or maintenance, your license must specifically authorize those procedures.

Radiation Detection Equipment
You do not need to have a radiation survey meter during routine use. If you plan to perform servicing that requires removal of the source from its shielded position, you must have a survey meter that is calibrated annually.

State that you do not intend to service the devices, or provide information concerning the survey meters available for use.

Personnel Monitoring Equipment
Personnel monitoring equipment is not normally required for gas chromatographs or x-ray fluorescent analyzer users. If you propose to service the gauges yourself, you should provide personnel monitoring devices for your personnel who will perform the operations. Film badges, thermoluminescent dosimeters (TLDs), or optically stimulated dosimeters (OSD) are acceptable.

Inventories
State that you will conduct inventories at intervals not to exceed six (6) months, to account for all sealed sources received and possessed under your license. You should maintain records of the inventories for at least three years from the date of the inventory. The records should include the radionuclide and amount of material in each source, the manufacturer's name, model number and serial number of each gauge, the location of each, and the date of the inventory.

Annual Audits
Licensees must review the content and implementation of their radiation protection programs at intervals not to exceed 12 months to ensure compliance with MDH rules and the terms and conditions of the license. Records of audits and other reviews of program content are maintained for three years.

As part of your audit programs, you should consider performing unannounced audits of your authorized users. The purpose is to determine that proper radiation safety and operating procedures are followed.

Once problems are identified, it is essential that they are corrected promptly and comprehensibly. MDH will review a licensee's audit program and determine if corrective actions are thorough, timely, and

sufficient to prevent recurrence. MDH will normally exercise discretion and not cite violations previously identified and corrected by the licensee. The licensees are encouraged to regulate their own compliance.

An audit program for a portable gauge should include a review of:

- ✓ leak test records and procedures
- ✓ inventory records
- ✓ training
- ✓ the operating and emergency procedures
- ✓ survey instrument calibration records and procedures (if applicable)

You, as the licensee, are responsible for the content and implementation of your radiation safety program and for all actions of your employees.

Operating and Emergency Procedures

You should state on your application that you will provide the operating and emergency procedures to each person who uses the device. Submit the detailed operating and emergency procedures to the MDH for review. You should cover these topics in your procedures:

- Use of personnel monitoring - all personnel who use the device should wear their personal dosimeters if they are performing device maintenance or repair.
- Use of the device - systematic procedures for the use of the device.
- Storage of the device.
- Transportation - procedures for transporting devices to and from work sites.
- Emergency procedures - actions that workers should take in the event of an emergency. (Include individuals to be notified and their telephone numbers.)

Transportation to Field Locations

It is your obligation to obtain a copy of the DOT regulations on transportation of radioactive materials. The requirements for package labeling are in subpart E of 49 CFR Part 172 of the DOT regulations. General requirements for shipping and packaging radioactive material are in Subpart I of 49 CFR Part 173 of the DOT regulations. A copy of these regulations can be obtained by writing to the following address:

US Government Bookstore
120 Bannister Road
Kansas City, MO 64137
(816) 765-2256

You should state in your application that packaging and transport of the device will be carried out in accordance with the applicable DOT regulations.

Item 11: Waste Management

The only option for disposal of the licensed material contained in portable gauges 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 suppliers of the device, a commercial firm licensed by an Agreement State or the NRC 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 12: License Fee

If this is an application for a new license, the full fee must be included with this application. An application received without a fee or with an inadequate fee may be returned to you or delayed in processing. Fees for processed applications are not refundable. Make check or money order payable to the Minnesota Department of Health.

For license renewals, the fee is due on the date your license expires.

Item 13: Certification

Individuals acting in a private capacity are required to sign and date the *Application for Radioactive Materials License*. Otherwise, representatives of the corporation or legal entity filing the application should date and sign the form. Representatives signing an application must be authorized to make binding commitments and to sign official documents on behalf of the applicant. Signing the application acknowledges management's commitment and responsibilities for the radiation protection program. NRC will return all unsigned applications for proper signature. When the application references commitments, those items become part of the licensing conditions and regulatory requirements.

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) the MDH rules.

It is your obligation to keep your license current. You should anticipate the need for a license amendment as far in advance as possible. If any of the information provided in your application is to be modified or changed, submit a signed application for a license amendment and include the appropriate amendment fee.

The licensee may not place into effect any amendment until receiving written verification from MDH that the amendment has been approved.

An application for a license amendment may be prepared either on the *Application for Radioactive Materials License* or in letter format. The 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 should specify the new individual's name, training, and experience.

RENEWAL OF A LICENSE

An application for the renewal of a license should be filed at least 30 days before the expiration date. This will ensure that the license does not expire before the final action on the application has been taken by MDH. The application for the renewal should not reference material that was previously submitted.

If you do not wish to renew your license and 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 MDH rules that do not allow you to possess licensable material without a valid license.

IMPLEMENTATION

The information in this regulatory guide is *guidance*, not requirement. The Minnesota Department of Health reviews each application to ensure that users of byproduct material are capable of complying with MDH rules. This guide provides one set of methods approved by MDH for meeting the regulations and represents the minimum acceptable standards.

INSPECTIONS

MDH conducts initial inspections of new radiological programs between six and 12 months after licensed material is received and operations have begun. Subsequent routine inspections of licenses are scheduled after the initial inspection. The routine inspections are scheduled at intervals corresponding to frequency indicated in NRC Inspection Manual Chapter 2800.

APPENDIX A
DUTIES AND RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER (RSO)

You may use the following model procedure to make commitments for your RSO. If you follow the model procedure, you may say on your application, "We will establish and implement the model procedure for Radiation Safety Officer Duties published in Appendix A to the MDH Regulatory Guide for Gas Chromatographs and X-Ray Fluorescence Analyzers."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of the Minnesota Rules. Say on your application, "We have developed an RSO procedure for your review that is appended as Appendix A," and submit your procedure.

MODEL PROCEDURE

The RSO is responsible for implementing the radiation safety program and ensuring that radiation safety activities are performed in accordance with approved procedures and regulatory requirements. The RSO's duties and responsibilities include ensuring the following:

- Licensed material is limited to the kinds, quantities and forms listed on the license.
- Individuals using the material are properly trained, designated by the RSO, and are informed of all changes in regulatory requirements and deficiencies identified during annual audits or MDH inspections.
- Material is properly secured against unauthorized removal at all times when material is not in use.
- Proper authorities are notified in case of accident, damage, fire, or theft.
- Audits are performed at least annually to ensure that:
    - The licensee is abiding by MDH and DOT regulations and the terms and conditions of the license (e.g., periodic leak tests, inventories, use limited to trained and approved users),
    - The licensee's radiation protection program content and implementation achieve occupational doses and doses to members of the public that are ALARA, and
    - The licensee maintains required records with all required information (e.g., records of personnel exposure; receipt, transfer, and disposal of licensed material; user training) sufficient to comply with MDH requirements.
- Results of audits, identification of deficiencies, and recommendations for change are documented, provided to management for review, and maintained for at least three (3) years. Ensure prompt action is taken to correct deficiencies.
- Audit results and corrective actions are communicated to all personnel who use licensed material (regardless of their location or the license under which they normally work).
- Licensed material is transported in accordance with all applicable DOT requirements.
- Licensed material is disposed of properly.
- The facility has up-to-date copies of MDH's regulations, completing a review of new or amended MDH regulations, and revising licensee procedures, as needed, to comply with MDH regulations.
- The license is amended whenever there are changes in licensed activities, responsible individuals, or information or commitments provided to MDH in the licensing process.

APPENDIX B
LEAK TESTING SEALED SOURCES

You may use the following model procedure to leak test sealed sources. If you follow the model procedure you may state on your application, "We will establish and implement the model procedure for leak testing sealed sources published in Appendix B to the MDH Regulatory Guide for Gas Chromatographs and X-Ray Fluorescence Analyzers."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of Minnesota Rules. State on your application, "We have developed a leak test procedure for your review that is appended as Appendix B," and submit your leak test procedure.

MODEL PROCEDURE FOR TAKING SAMPLES

1. Make a list of all sources to be tested. This should include at least the isotope, the activity on a specified date, and the physical form.

2. If you will be testing sources stronger than a few millicuries, set out a survey meter, preferably with a speaker, so you can monitor your exposure rate.

3. Prepare a separate wipe sample for each source. A cotton swab, injection prep pad, filter paper, or tissue paper is suitable. Number each wipe so you will know for which source it is to be used. Samples should be taken as follows:

    a. For small sealed sources, it may be easier to wipe the entire accessible surface area. Pay particular attention to seams and joints. However, do not wipe the port of beta applicators.

    b. For larger sealed sources and devices (survey meter calibrator), take the wipe near the radiation port and on the activating mechanism.

    c. If you are testing radium sources, you should also check for radon leakage. This can be done by submerging the source in a vial of fine-grained charcoal or cotton for a day. Then remove the source and analyze the absorbent sample as described below. A survey should be done to be sure that sources are adequately shielded during the leak test period.

MODEL PROCEDURES FOR ANALYZING LEAK TEST SAMPLES

The samples will be analyzed as follows:

1. Select an instrument that is sufficiently sensitive to detect the levels listed in 40.32. For beta sources, a proportional flow counter, liquid scintillation counter, or thin-end-window GM survey meter may be appropriate. For gamma sources, a GM instrument or a scintillation detector with either a ratemeter or scaler may be appropriate. Dose calibrators used in nuclear medicine are not sufficiently sensitive.

2. To estimate the detection efficiency of the analyzer used to assay the wipe samples, assay a certified check source that has the same isotope as the sealed. If one is not available, it will be necessary to use a certified check source with a different isotope that has a similar spectrum. If calculations demonstrate that the instrument is not sufficiently sensitive to detect 0.005 microcuries, a different instrument must be used.

3. Assay the wipe sample. It must be in the same geometry relative to the detector as was the certified check source.

4. Record the wipe sample in counts per minute. Then calculate and record the estimated activity in microcuries on the wipe sample.

5. Continue the same analysis procedure for all wipe samples.

6. If the wipe sample activity is 0.005 microcuries or greater, notify the RSO. The source must be withdrawn from use to be repaired or disposed of in accordance with MDH rules.

7. Record model number and serial number (if assigned) of each source tested, radionuclide and estimated activity, measured activity of each test sample in microcuries, description of method used to test each sample, date of test, and signature of RSO. Maintain these records for three years.

SUMMARY OF REVISIONS

REVISION	SECTION	DESCRIPTION
5-6-2005	Item 10	Remove 'kit model number'
9/16/05	Title page and filing an application	Address and section name change