IOWA DEPARTMENT OF PUBLIC HEALTH

GAS CHROMATOGRAPHS AND X-RAY FLOURESCENCE ANALYZERS REGULATORY GUIDE

IDPH
IOWA Department of PUBLIC HEALTH

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IDPH REGULATORY GUIDE FOR GAS CHROMATOGRAPHS AND X-RAY FLUORESCENCE ANALYZERS

IDPH REGULATROY GUIDE FOR
GAS CHROMATOGRAPH DEVICES AND
X-RAY FLUORESCENCE ANALYZERS

1. INTRODUCTION

1.1 PURPOSE OF GUIDE

This regulatory guide is designed to describe the type and extent of information needed by the IDPH 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 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 Iowa Rules and should then complete the application form, IDPH Form 299-0514. The IDPH may request additional information when necessary to provide reasonable assurance that the applicant has established an adequate radiation protection.

1.2 APPLICABLE REGULATIONS

Regulations pertaining to this type of license are found in Chapters 38, 39, and 40 of the Radiation Machines and Radioactive Materials Rules. To view these rules you may go to https://idph.iowa.gov/radioactivematerials/rules.

1.3 AS LOW AS IS REASONABLY ACHIEVABLE (ALARA) PHILOSOPHY

Paragraph 641-40.1(3) states "...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 by-product material program to ensure the continued safe use of by-product material. The RSO is also responsible for the day-to-day operations of the radiation safety program.

A model ALARA management program is contained in Appendix A to this guide. Applicants are required to consider the ALARA philosophy in the development of plans for radioactive materials.

2. FILING AN APPLICATION

You should apply for a license by completing an "Application for Radioactive Materials License" found on the IDPH website at https://idph.iowa.gov/radioactivematerials/forms. You should complete Items 1 through 5, and 14/15 on the form itself. For Items 6 through 12, submit the required information on supplementary pages. Identify each sheet or document with the item number on the application. All

typed papers, 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, fold them to 8 1/2 x 11 inches.

You should complete all items in the application in enough detail for the IDPH to determine that your equipment, facilities, training, 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 public in the IDPH 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 propriety 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 IDPH.

Retain a copy of your application because the license will be issued based on the statements and representations in your application and any supplements to it as well as the requirements in the regulations. The statements and representations become enforceable as if they were regulations.

3. CONTENTS OF AN APPLICATION

This portion of the guide explains, item by item, the information requested on the IDPH Application for Radioactive Materials License. The appendices to this guide serve to

- provide additional information on certain subject areas;
- provide a model procedure the applicant may adopt in response to an item on the application form; or
- provide an outline the applicant may use to develop a procedure for review by the IDPH staff.

If you have specific questions after careful review of this guide, contact the IDPH material licensing staff at Iowa Department of Public Health, Radioactive Materials Section, Lucas State Office Building, 5th Floor, 321 East 12th Street, Des Moines, Iowa 50319-0075, email iowaram@idph.iowa.gov, or call program staff listed on the website at https://idph.iowa.gov/radioactivematerials/contacts.

ITEM 1.a. -- APPLICANT'S NAME AND MAILING ADDRESS

The applicant should be the corporation or other legal entity applying for the license.

The address specified here should be your mailing address for correspondence. 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 1b. -- LOCATIONS OF USE

You should specify each location of storage or use by the street address, city, and state or other descriptive address (such as 5 miles east on Highway 10, Anytown, Iowa) to allow us to easily locate your facilities. A post office box address is not acceptable. Also specify if there is a location for storage of sources and devices. If you will conduct operations at temporary job sites, you may specify "temporary job sites in Iowa." If a device will be used in a permanent facility or facilities, you should give the specific address of each location.

ITEM 2. -- PERSON TO BE CONTACTED ABOUT APPLICATION

You should provide the name and telephone number of the individual who knows your proposed radioactive materials program and can answer informational questions only about the application. This individual, usually the RSO or a principal user of radioactive materials, will serve as the point of contact during the review of the application and during the period of the license. If this individual is not your full-time paid employee, specify your relationship with this individual. Notify the IDPH if this individual changes. Unless the contact person is the RSO, a contact change is for information only. It would not be considered an application for a license amendment.

Any requests from the IDPH concerning additional commitments, procedures, or for changes to the application will be addressed to the CEO or President with a copy to the RSO. The CEO can designate a different person if the authorization to make commitments on behalf of the licensee if the CEO or President provides that authorization in writing to IDPH.

ITEM 3. -- LICENSE INFORMATION

For a new license, amendment to a license or renewal of an existing license, check the appropriate block. Provide the license number where indicated for amendments or renewals.

ITEM 4. -- INDIVIDUAL USERS - THEIR TRAINING AND EXPERIENCE

Unless you propose to perform maintenance or repairs, no specific training is necessary. However, individuals who will use it or supervise its 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 a one or two-day training from the manufacturer or equivalent. In your application, you should provide the following information:

1. The specific operations you wish to perform.
2. The name of each "responsible individual" who will perform the operations.
3. 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.
4. The name and affiliation of the person who provided the instruction and training and this person's qualifications to conduct the operations.

ITEM 5. -- 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 B. You should commit to Appendix B or its equivalent.

ITEM 6. -- RADIOACTIVE MATERIAL

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

1. Identify each radioisotope.
2. Identify the manufacturer and model number of each foil source, plated source or sealed source.
3. Specify the amount of radioactive material that will be in each foil source, plated source or sealed source.
4. 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 calibration and reference sources exempted in 39.4(22)"g".

NOTE: It is the practice of IDPH 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 6.

ITEM 7. -- PURPOSE 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 8. -- INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM

Submit a description of the overall organization pertaining to the radiation safety program, which specifies the name and title of each individual who has responsibility for management or supervision of the program.

ITEM 9. -- TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

Describe your training program for individuals who work near the devices described in Item 6. This includes all employees (clerical, delivery, security, and housekeeping) except those described in Item 4. Training should cover regulations, in-house work rules, and the location of posted notices and copies of regulations and the license.

ITEM 10. -- FACILITIES AND EQUIPMENT

641-39.4(25)"b" states that 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:

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

2. 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 (1) accessible only to persons authorized to use the device and (2) locked when an authorized person is not physically present.

3. The security measures to be taken when stored in the field. State that
   (a) 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.
   (b) 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 11. -- RADIATION SAFETY PROGRAM

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

11.1. -- PERSONNEL MONITORING EQUIPMENT

641-40.37(1)"a" specifies that personnel monitoring equipment by used by individuals who are likely to receive a dose in excess of 10% of the limit specified in paragraph 641-40.15(1). Individuals under 18 years of age and declared pregnant women are required to use personnel monitoring equipment if they are likely to receive in one year from sources external to the body a dose in excess of 10% of any of the applicable limits in 641-40.21(136C) or 641-40.22(136C).

For routine use (i.e., normal operation for the intended purpose) of gas chromatograph devices or x-ray fluorescence analyzers, you do not need to use personnel monitoring devices. Personnel monitoring devices are not required for maintenance and repair operations described in Item 11.4 if the radiation source in your gas chromatograph device or x-ray fluorescence analyzer is in gaseous form or is Nickel-63.

If your program includes the maintenance and repair operations described in Item 11.4 and these operations involve the sealed source other than gaseous or Nickel-63, 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, thermoluminescent dosimeters (TLDs), or optically stimulated dosimeters (OSDs) for use while performing service operations. Provide the name and address of the supplier and the frequency of exchange for the personnel monitoring devices. The exchanges should be at intervals not to exceed one month for film badges and three months for TLDs and OSDs.

11.2. -- RADIATION DETECTION INSTRUMENTS

1. You do not need to have a survey meter for routine use of gas chromatograph devices or x-ray fluorescence analyzers. Survey meters are not necessary if you perform maintenance and repair operations as described in Item 11.4 if the radiation source is gaseous or Nickel-63.

2. If you wish to perform the maintenance and repair operations described in Item 11.4 and the operations involve the sealed source other than gaseous or Nickel-63, you should have a survey meter. The meter should be capable of measuring the radiation levels to which personnel would be subjected during these operations and of measuring radiation levels of at least one (1) roentgen per hour. Provide the type and range of the meter and the name and address of the company who will calibrate the meter. State that before using the survey meter, you will check the response of the instrument with a dedicated check source. Confirm that if the meter does not respond properly, you will not use the meter until it is repaired and operable.

Survey meters must be calibrated annually and after servicing or repair. Electronic calibrations alone are not acceptable. Battery changes are not considered “servicing”.

11.3. -- LEAK TESTING

As a licensee, you must perform leak test according to 641-40.32(2). The IDPH requires test to determine whether or not there is any leakage from the radioactive source in the device. There are some source/device combinations that have leak-test intervals up to three (3) years. Information on the leak check frequency for your source/device combinations may be obtained from suppliers and manufacturers. Provide the frequency recommended by the supplier.

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

The options for leak testing are:

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 reports the results to you.
3. Perform the entire leak-test sequence yourself, including the smears and measurement.

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

For Option 2, specify the kit model number and the name, address, and license number of the kit supplier and company who will analyze the samples. Commit to Appendix C.1 or submit your own procedures.

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. Commit to Appendix C or submit your own procedures.

11.4. -- 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.

11.5. -- TRANSPORTATION OF DEVICES 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. The general requirements for shipping and packaging radioactive material are in Subpart I of 49 CFR Part 173 of the DOT regulations. The address to write for a copy of these regulations is:

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.

11.6. -- 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 IDPH for review. You should cover these topics in your procedures:

1. Use of personnel monitoring. All personnel who use the device should wear their personal dosimeters when they are performing device maintenance or repair.
2. Use of the device. Systematic procedures for the use of the device.
3. Storage of the device. See the commitment in Item 10.
4. Transportation. Procedures for transporting devices to and from work sites.
5. Emergency procedures. Actions that workers should take. Include individuals to be notified and their telephone numbers.

ITEM 11.7. -- INVENTORIES

State that you will conduct inventories at intervals not to exceed six (6) months to account for all sealed sources and devices received and possessed under your license. You should maintain records of the inventories for at least three (3) years from the date of the inventory. The record of the test should include

- the radionuclide and amount of material in each source;
- the manufacturer's name,
- model number and serial number of each device,
- location of each device, and
- date of inventory.

ITEM 11.8. -- ANNUAL AUDIT OF RADIATION SAFETY PROGRAM

The annual audit is required by 40.10(3). This will be reviewed during inspections.

ITEM 12. -- WASTE MANAGEMENT

641-40.70(136C) specifies that general requirements for disposal of licensed material (i.e., the radioactive source). Because of the nature of the licensed material contained in devices, your only option for disposal is to transfer the material to an authorized recipient as specified in paragraph 641-40.70(1)"a". 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 13. -- LICENSE FEES

1. An application fee paid in full is required by 641-38.8(2) for all new licenses and amendments. Fee information is available in the above rule or our web site at www.idph.state.ia.us. An application received without a fee or with an inadequate fee may be returned to you. Fees for processed applications are not refundable. Make check or money order payable to the IDPH.

2. An annual fee will be assessed based on the license category and is due by September 1st of each year. IDPH sends a billing invoice in July of each year for the annual fee.

3. Review 39.4(26) “Financial Assurance and Recordkeeping for Decommissioning.” Submit financial assurance as described or provide information that exempts the facility.

ITEM 14/15 -- CERTIFICATION

The application must be signed by a senior partner, the president, director or chief executive officer. Identify the title of the office held by the individual who signs the application.

If the senior partner, president, director, or chief executive officer wishes another person other than himself to sign the application, a delegation of authority must be enclosed. The delegation of authority should state that the person signing the application has authority to commit the facility to the conditions of the application and any amendments submitted later.

4. AMENDMENTS TO LICENSE

A licensee must receive a license amendment before changing the scope of the program such as changing the Radiation Safety Officer or adding to the staff of authorized users. See 641-39.4(35). An application for an amendment must be filed either on IDPH Form 299-0514 or as a letter. The request must be signed by the person delegated in Item 14/15. The appropriate fee must be included.

You may not place into effect any amendment until you have received written verification from the IDPH that the amendment has been approved.

5. 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 the IDPH as provided for in paragraph 641-39.4(34). 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 IDPH regulations that do not allow you to possess licensable material without a valid license.

6. IMPLEMENTATION

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

7. INSPECTIONS

IDPH conducts initial inspections of new radiological programs between six months and one year after licensed material is received and operations have begun. Subsequent routine inspections of licenses are normally scheduled after the initial inspection. The routine inspections are scheduled at intervals corresponding to frequency, which is indicated in the IDPH Radioactive Materials Fee Schedule.

APPENDIX A

MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURE ALARA

You may use the text as it appears here, saying on your application, "We will establish and implement the model ALARA program that was published in Appendix A to IDPH Regulatory Guide for Gas Chromatographs and X-Ray Analyzers" and submit a signed copy of section 5 of this appendix.

If you prefer, you may develop your own ALARA program for IDPH review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of Iowa Rules. Say on your application, "We have developed an ALARA program for your review that is appended as Appendix A," and submit your program and a signed copy of section number 6 of this appendix.

ALARA PROGRAM

1. MANAGEMENT COMMITMENT

a. We, the management of this facility, are committed to the program described herein for keeping individual and collective doses as low as is reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution.

b. We will perform a formal annual review of the radiation safety program, including ALARA considerations. This will include reviews of operating procedures and past dose records, inspections, etc., and consultations with the radiation safety staff or outside consultants.

c. Modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures unless the cost, in our judgment, is considered unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been recommended but not implemented, and we will be prepared to describe the reasons for not implementing them.

d. In addition to maintaining doses to individuals as far as below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

2. RADIATION SAFETY OFFICER COMMITMENT

a. Annual and Quarterly Review

(1) Annual review of the radiation safety program. The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific methods of use may be conducted on a more frequent basis.

(2) Quarterly review of occupational exposures. The RSO will review at least quarterly the external radiation doses of authorized users and workers to determine that their doses are ALARA in accordance with the provisions of section 4 of this appendix.

b. Education Responsibilities for ALARA Program

The RSO will schedule briefing and educational sessions to ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the

ALARA philosophy. They should also be informed that management and the RSO are committed to implementing the ALARA concept.

c. Cooperative Efforts for Development of ALARA Procedures

Radiation workers will be given opportunities to participate in formulating the procedures that they will be required to follow.

(1) The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.

(2) The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those programs.

(3) Workers will be instructed in recourses available if they feel that ALARA is not being promoted on the job.

d. Reviewing Instances of Deviation from Good ALARA Practices:

The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will implement changes in the program to maintain doses ALARA.

3. AUTHORIZED USERS COMMITMENT

a. New methods of Use Involving Potential Radiation Doses

(1) The authorized user will consult the RSO during the planning stage before using radioactive materials for new uses.

(2) The authorized user will review each planned use of radioactive materials to ensure that uses will be kept ALARA. Trial runs may be helpful.

b. Authorized User's Responsibility to Supervised Individuals

(1) The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.

(2) The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

4. ESTABLISHMENT OF INVESTIGATIONAL LEVELS IN ORDER TO MONITOR INDIVIDUAL OCCUPATIONAL EXTERNAL RADIATION DOSES[1]

This institution hereby establishes investigational levels for occupational external radiation doses which, when exceeded, will initiate review or investigation by the RSO. The investigational levels that we have adopted are listed in Table 1. These levels apply to the exposure of individual workers.

[1] IDPH emphasizes that the investigational levels in this program are not new dose limits but serve as check points above which the results are considered sufficiently important to justify investigations.

TABLE 1 Investigational Levels		
	Investigational Levels (mrems per calendar quarter) Level I	Level II
Total Dose Equivalent: whole body; head and trunk; active blood-forming organs; or gonads	200	400
Skin of whole body, extremities	2000	4000
Lens of eyes	600	1200

The RSO will review and record on IDPH Form, "Current Occupational External Radiation Exposures," or an equivalent form (e.g., dosimeter processor's report) results of personnel monitoring not less than once in any calendar quarter as required by 641-40.100. The following actions will be taken at the investigational levels as stated in Table 1:

a. Personnel dose less than Investigational Level I.

   Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's dose is less than Table 1 values for the investigational Level I.

b. Personnel doses equal to or greater than Investigation Level I but less than Investigational Level II.

   The RSO will review the dose of each individual whose quarterly dose equals or exceeds Investigational Level I and will report the results of the reviews to management as soon as completed. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required. The RSO and management will, however, review each such dose in comparison with those of others performing similar tasks as an index of ALARA program quality.

c. Personnel dose equal to or greater than Investigational Level II.

   The RSO will investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation and any actions taken will be presented to the management following completion of the investigation. The report should include a copy of the individual's Form IDPH 588-2834 “Occupational Exposure Record for Monitoring Period” and 588-2833 “Cumulative Occupational Exposure History” or its equivalent.

d. Re-establishment of investigational levels to levels above those listed in Table I.

In cases where a worker's or a group of workers' doses need to exceed an investigation level, a new, higher investigational level may be established with good ALARA practices. Justification for new investigational level will be documented.

The RSC will review the justification for and must approve or disapprove all revisions of investigational levels.

5. SIGNATURE OF CERTIFYING OFFICIAL[1] Sign and submit as part of Appendix A.

I hereby certify that this institution has implemented the ALARA Program as set forth above.

_____
Signature

_____
Name (Print or type)

_____
Title

[1] The person who is authorized to make commitments for the administration of the institution (e.g., CEO, president, etc.).

APPENDIX B

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 RSO that was published in Appendix B to the IDPH Regulatory Guide for Gas Chromatographs and X-Ray 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 Iowa Rules. Say on your application, "We have developed an RSO procedure for your review that is appended as Appendix B," 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:

1. Ensure that licensed material is limited to the kinds, quantities and forms listed on the license.
2. Ensure that individuals using the material are properly trained; designated by the RSO; have received refresher training at least annually; and are informed of all changes in regulatory requirements and deficiencies identified during annual audits or IDPH inspections.
3. Ensure that personnel monitoring devices are used as required and reports of personnel exposure are reviewed in a timely manner.
4. Ensure that material is properly secured against unauthorized removal at all times when material is not in use.
5. Ensure that proper authorities are notified in case of accident, damage, fire, or theft.
6. Ensure that audits are performed at least annually to ensure that:
    a. The licensee is abiding by IDPH and DOT regulations and the terms and conditions of the license (e.g., periodic leak tests, inventories, use limited to trained, approved users),
    b. The licensee's radiation protection program content and implementation achieve occupational doses and doses to members of the public that are ALARA, and
    c. 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 IDPH requirements.
7. Ensure that 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.
8. Ensure that 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).
9. Ensure that all incidents, accidents, and personnel exposure to radiation in excess of ALARA levels or Chapter 40 limits are investigated and reported to IDPH within the required time limits.
10. Ensure that licensed material is transported in accordance with all applicable DOT requirements.
11. Ensure that licensed material is disposed of properly.
12. Ensure that the facility has up-to-date copies of IDPH's regulations, completing a review of new or amended IDPH regulations, and revising licensee procedures, as needed, to comply with IDPH regulations.
13. Ensure that the license is amended whenever there are changes in licensed activities, responsible individuals, or information or commitments provided to IDPH in the licensing process.

APPENDIX C

MODEL PROCEDURE FOR LEAK-TESTING SEALED SOURCES

You may use the following model procedure to leak-test sealed sources. If you follow the model procedure you may say on your application, "We will establish and implement the model procedure for leak-testing sealed sources that was published in Appendix (C.1 and/or C.2) to the IDPH Regulatory Guide for Gas Chromatographs and X-Ray 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 Iowa Rules. Say on your application, "We have developed a leak-test procedure for your review that is appended as Appendix C," and submit your leak-test procedure.

C.1. 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.

C.2. MODEL PROCEDURES FOR ANALYZING LEAK TEST SAMPLES
(for Option 3 in Item 11.3)

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 microcurie or greater, notify the RSO. The source must be withdrawn from use to be repaired or disposed of in accordance with IDPH 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 record for five (5) years.

Revision	Section	Description
12/26/00	ALL	Reformat text. Changed address for Bureau of Radiological Health
01/18/02	Section 7	Added information concerning inspections.
03/13/03	Section 1.2	Change address for web access to IDPH rules and publications.
07/01/05	ALL	Changed address for the Bureau of Radiological Health
09/07/10	Sections 3.13 & 7	Removed references to renewal and inspection fees. Added reference to annual fee.
10/7/20	Item 1, Appendix A	Updated IDPH website and contact information. Changed ALARA note from per “month” to per “calendar quarter.”