IOWA DEPARTMENT OF PUBLIC HEALTH

NON-PORTABLE GAUGING DEVICE REGULATORY GUIDE

IDPH
IOWA Department of PUBLIC HEALTH

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IDPH REGULATORY FOR NON-PORTABLE GAUGING DEVICES

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IDPH REGULATORY GUIDE FOR
NON-PORTABLE GAUGE (FIXED GAUGES)

1. INTRODUCTION

1.1 PURPOSE OF GUIDE

This regulatory guide is provided to describe the type and extent of information needed by the IDPH to evaluate an application for a license to use and possess sealed sources in non-portable gauging devices. An example of a non-portable gauging device is a density gauge that contains a gamma-emitting sealed source, Cesium-137, that measures the density of coal.

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 program.

1.2 APPLICABLE REGULATIONS

Regulations pertaining to this type of license are found in Chapters 38, 39, and 40 of the Radiation Machine 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. Complete Items 1-5 and 13-16 on the form itself. For Items 6 through 12, submit the information on supplementary pages. Each separate sheet or document submitted should be identified with the item in the application to which it refers. All

typed pages, sketches, and drawings should be on 8 1/2 X 11 inch paper to facilitate handling and review, if possible. 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 the IDPH to determine that your equipment, facilities, training, 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 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 the 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 1.b. -- 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 whether a location is for storage, use, or both for sources and devices.

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 - TRAINING AND EXPERIENCE

Provide the following information about the individual or individuals that will be responsible for your radiation safety program. This normally is the Radiation Safety Officer (RSO) and any other personnel who will be physically present and responsible for the services performed under the authority of your license.

A. If installation, initial radiation survey, and maintenance will be performed by the distributor of the gauges or other person specifically licensed to perform these services, the manufacturer training and instruction provided to your employees is satisfactory. Your application should specify that training in the use and operation of the gauges was received, when it was received, and by whom the training was conducted.

    1. The name of each responsible individual.
    2. Dates of training for each individual. Where and by whom the training was conducted.

B. If you wish to perform such operations as installation, initial radiation survey, gauge relocation, and removal from service, the "responsible individual" who performs the operations should have completed a training course of approximately 40 hours in the following topics.

    1. The principles and fundamentals of radiation protection and good safety practices related to the use of radioactive materials.
    2. Radioactivity measurements, use of radiation detection instruments, and monitoring techniques.
    3. Biological effects of radiation.
    4. Procedures for performing services.
    5. Actual practice in performing the services.

    In your application, you should specify the name of each individual who will perform services, the specific services the individual will perform, and the following information on the individual's training:

1. An outline of the training program, including the topics covered and the time spent on each topic.
2. The scope and extent of actual performance of service operations.
3. The name of the firm or person who conducted the course.
4. The qualifications of each instructor in the course.
5. How the person or firm that provided the training determined the competency of individuals to perform the service.
6. Any additional training that will be provided periodically to keep individuals up to date on the servicing of the gauges and any factory modifications of existing equipment.

This training is usually completed in a device manufacturer's training course on the installation and servicing of each specified device requested in the application. If device manufacturer's courses have been submitted to the NRC or an Agreement State for review, simply provide a signed certificate of training that shows satisfactory completion of the specific course. This certificate should identify by model number, the devices upon which the individual is certified to perform the specified services requested in your application.

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 listed in Item 4, submit a complete description of the individual's training and experience in radiation protection and in the handling of gauges. Even if you employ a consultant to assist the RSO, you are 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 radioactive materials 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

1. Identify each radioisotope that will be used in the gauging device.
2. Identify the manufacturer and model number of each sealed source that will be used in the gauging device.
3. Specify the amount of radioactive material that will be in each sealed source.
4. Identify the manufacturer and model number of the gauging device in which the sealed sources will be used.
5. List any survey meter or calibration source not exempted under 39.4(3)"c"(9).

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.

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 gauge other than those listed in Item 6.

ITEM 7. -- PURPOSE FOR WHICH LICENSED MATERIAL WILL BE USED

Specify the purpose for which each sealed source/device combination will be used (e.g., to control the thickness of paper, to measure the density of coal). In order for gauging devices to be used safely, the device should be used only for the purposes for which the gauge was designed and in accordance with manufacturer's recommendations for use.

ITEM 8. -- INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM

Submit a description or chart of the overall organization pertaining to the gauge program that 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

A trained "responsible individual" should always be physically present at your facility when devices are in use. It is not necessary to name each employee who will work under the supervision of a "responsible individual" named in Item 4. Describe your training program for individuals who will work under the supervision of a "responsible individual." As a minimum, such employees should receive training and instructions in:

- Applicable regulations and license conditions;
- Locations where the licensees have posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by 641-40.110;
- The items listed in 40.111; and
- The operation and use of your device(s).

Initial awareness training should also be provided to all employees that may interface with the radiological program. The purpose of this training is to inform personnel of the presence of radioactive material and to address any of their concerns. This training need not be involved but should commensurate with the potential hazard(s).

You should indicate the personnel that will receive the training (use positions rather than individual names, e.g., secretarial staff, maintenance personnel, etc.) and commit to providing training to all appropriate individuals.

You should maintain records of the training program. The records should include the date of program, subjects discussed, and attendees.

ITEM 10. -- FACILITIES AND EQUIPMENT

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

1. A sketch or description of the proposed location of each gauge within your facility.
2. The environmental conditions to which gauges will be exposed (e.g., elevated temperature, corrosive atmosphere, and vibration).
3. If the ambient temperature will exceed the maximum operating temperature specified by the manufacturer, thus creating a need to maintain a lower temperature by means of cooling jackets or similar measures, a description of the cooling system should be provided. In addition,

provide a discussion of how the cooling system will be maintained and the consequences of a failure of the cooling system.

4. If a cooling system is used to maintain the temperature below the maximum operating temperature specified by the manufacturer. Submit a description of the method and procedures for detecting a cooling system failure and your procedures for coping with a cooling system failure.
5. Information on the maintenance of gauges, including (but not limited to) frequency, checks for proper shutter operation, checks that labels are legible and visible, and checks that gauges are protected against corrosive materials or materials at high temperature.

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. If the device distributor or another person specifically licensed to install, survey, maintain, relocate or remove the device will perform those services, you do not need personnel monitoring equipment or radiation detection equipment. Your application should specifically state the name, address, and NRC or Agreement State license number of the person or firm who will provide the services. If you will perform any of the additional services above, provide the information in 11.1 and 11.2.

11.1. -- PERSONNEL MONITORING EQUIPMENT

Personnel monitoring equipment must be used by individuals who receive or are likely to receive occupational exposure in one year from sources external to the body, in excess of 10% of the dose specified in paragraph 641-40.15(1). Individuals under 18 years or declared pregnant women are required to use personnel monitoring equipment if they receive or are likely to receive a dose in excess of 10% of the specified dose in 641-40.21(136C) and 40.22(136C).

If you propose to service the gauges yourself (e.g., install the gauges and perform the initial radiation survey, relocate gauges, ship devices), you should provide personnel monitoring devices for your personnel who perform the operations. Film badges, thermoluminescent dosimeters (TLDs), or optically stimulated dosimeters (OSD) are acceptable. You should:

1. Make a commitment in your application that personnel monitoring devices will be worn by personnel when they are servicing the gauges.
2. Specify the type of personnel monitoring devices that will be used and the frequency of their exchange. The changes should be made at intervals not to exceed 1 month for film badges and 3 months for TLDs and OSDs.
3. Provide the name and address of the company that will provide your personnel monitoring devices.

11.2. -- RADIATION DETECTION INSTRUMENTS

If you plan to perform gauge servicing such as installation, initial radiation survey, maintenance, device relocation, removal, etc., you must have a survey meter, which is calibrated annually and after servicing. Electronic calibrations alone are not acceptable. Battery changes are not considered “servicing.” 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 check source and that you will not use the meter until it is repaired and operable if the meter does not respond properly.

11.3. -- LEAK-TESTING

As a licensee, you must perform tests according to 641-40.32(2). The IDPH requires tests to determine if there is any leakage from the sealed sources in the devices. Normally, leak tests should be performed at 6-month intervals. Some sealed source/device combinations have been authorized for a leak-test interval of 3 years. Information about sealed source/device combinations that have 3-year leak-test intervals may be obtained from suppliers and manufacturers.

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 smears and send them to the kit supplier, who reports the results to you.
3. Perform the entire leak-test sequence yourself, including taking the smears and their measurement.

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

For Option 2, specify the name, address, and license number of the leak test kit supplier. You should state that the test samples will be taken by the individual specified in Item 4 who is responsible for the program. Commit to appendix C.1 or submit your own procedures.

For Option 3, describe the procedure for taking the sample and 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. -- LOCK-OUT PROCEDURES

It is possible that a major portion of an employee's body could receive exposure from the radiation beam from certain devices. For example, the radiation beam of a level gauge could traverse the bin or tank in such a way that an employee entering the bin or tank could receive a radiation exposure.

You must have "lockout" procedures so that personnel will not be subjected to unnecessary exposure. The procedures should specify the means for preventing employees from entering the radiation beam during maintenance, repairs, or other work in, on, or around the bin, tank, or hopper on which the device is mounted. You do not need to submit the procedures. You should state in your application that you will prepare such procedures, that you will provide them to your personnel, and that the procedures will be posted so that personnel can see them. You should specify that the individual who will be responsible for ensuring that the lockout procedures are followed is the "responsible individual" named in Item 4.

11.5. -- PERFORMANCES OF MAINTENANCE

If you have requested authorization to perform non-routine maintenance on your gauges, you should state in your application that you will follow the written procedures provided by the device manufacturer for each service operation requested. In addition review Appendix D and provide all applicable information.

11.6. -- OPERATING AND EMERGENCY PROCEDURES

State on your application that you will provide the operating and emergency procedures to each person responsible for the gauge. Submit the detailed operating and emergency procedures for review. You should cover these topics in your procedures as appropriate:

1. Use of personnel monitoring.
2. Step-by-step procedures for use of the device.
3. Storage of the device. See Item 10.
4. Emergency procedures.
    a. Isolating the gauge and the immediate area.
    b. Radiation surveys around the gauge.
    c. Making sure shutter or other on-off controls are in the "off" position, is possible.
    d. Limiting access to the source housing until a leak test can be performed and source integrity is established.
    e. Keeping personnel informed about the accident or emergency situation.
    f. Obtaining assistance from the gauge manufacturer.
    g. Notifying RSO and IDPH.

11.7. -- INVENTORIES

State that you will conduct inventories at intervals not to exceed six (6) months, to account for all sealed sources and gauges received and possessed under your license. You should maintain records of the inventories for at least five (5) 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.

11.8. -- ANNUAL AUDIT OF RADIATION SAFETY PROGRAM

The annual audit is required by 40.10(3). Currently the IDPH emphasis in inspections is to perform observations of work in progress. As part of their audit programs, applicants should consider performing unannounced audits of their authorized users in the field. The purpose is to determine that proper radiation safety and operating procedures are followed.

It is essential once problems are identified; they are corrected promptly and comprehensibly. The IDPH will review a licensee's audit program and determine if corrective actions are thorough, timely, and sufficient to prevent recurrence. The IDPH will normally exercise discretion and not to cite violations previously identified and corrected by the licensee. The IDPH encourages licensees to regulate their own compliance.

An audit program for a fixed 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)

ITEM 12. -- WASTE MANAGEMENT

641-40.70(136C) specifies the requirements for disposal of licensed material. Because of the nature of the licensed material contained in gauging devices, your only option for disposal is to transfer the

radioactive material to an authorized recipient as specified in paragraph 641-40.70(1)"a". You should state that disposal will be by transfer to a licensee specifically authorized to possess the radioactive material.

Authorized recipients are the original suppliers of the gauges, a commercial firm licensed by the 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 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 A LICENSE

A licensee must receive a license amendment before changing the scope of the program such as changing the Radiation Safety Officer or adding a different gauge. See 641-39.4(35). An application for a license amendment may be prepared either on the application form 229-0514 or in letter form, must be signed by the person delegated in Item 14/15, and must include the appropriate amendment fee. 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. The qualifications of the new responsible individual should be equivalent to those specified in Item 4 of this guide.

5. RENEWAL OF A LICENSE

Licenses are issued for a period of 5 years. An application for the renewal 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 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.

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 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 the IDPH Regulatory Guide for Non-Portable Gauges." 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 5 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 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 health physics practices and in maintaining exposures ALARA.

5. 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 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
1. Total Dose Equivalent: whole body; head and trunk; active blood-forming organs; or gonads	200	400
2. Skin of whole body, extremities	2000	4000
3. 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 in the quarter when the dose was recorded. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the management. **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.

Management will review the justification for and must approve all revisions of investigational levels.

6. 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 or president).

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 Non-Portable Gauges."

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, transportation, and use by 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 the results of audits, identification of deficiencies, and recommendations for change are documented, provided to management for review, and maintained for at least 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 more than 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 Non-Portable Gauges."

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 TEST 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 PROCEDURE FOR ANALYZING TEST SAMPLES
(For Option 3 of Item 11.4)

The samples will be analyzed as follows:

1. Select an instrument that is sufficiently sensitive to detect the levels 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 counter 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 check source that has the same isotope as the sealed source and whose activity is certified by the supplier. 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.

APPENDIX D

INFORMATION NEEDED TO SUPPORT APPLICANT'S REQUEST TO PERFORM NON-ROUTINE OPERATIONS

Non-routine operations include

- installation of the gauge,
- initial radiation survey,
- repair or maintenance involving or potentially affecting components, including electronics, related to the radiological safety of the gauge (e.g., the source, source holder, source drive mechanism, shutter, shutter control, or shielding),
- gauge relocation,
- replacement,
- disposal of sealed sources,
- alignment,
- removal of a gauge from service, and
- any other activities during which personnel could receive radiation doses exceeding IDPH limits.

To ensure that the engineering safety analysis performed and accepted as part of the device registration is not compromised, the use of materials (e.g., lubricants) other than those specified or recommended by the manufacturer or distributor need to be evaluated. A similar analysis should be made for any non-manufacturer/non-distributor supplied replacement components or parts. Licensees also need to ensure that after maintenance or repair is completed, the gauge is tested and functions as designed before the unit is returned to routine use.

If non-routine operations are not performed properly, the gauge may not operate as designed. Without attention to good radiation safety principles, personnel performing these tasks could receive radiation doses exceeding IDPH limits.

Radionuclides and activities in fixed gauges vary widely. For illustrative purposes, in less than one minute, an unshielded Cesium- 137 source with an activity of 100 millicuries can deliver 5 rems (0.05 Sv) to a worker's hands or fingers (i.e., extremities). This assumes that the extremities are one centimeter from the source. However, gauges can contain sources of even higher activities with correspondingly higher dose rates.

The threshold for extremity monitoring is 5.0 rems (0.05 Sv) per year.

Applicants wishing to perform non-routine operations must use personnel with special training. Maintenance personnel must follow appropriate procedures consistent with the manufacturer's or distributor's instructions and recommendations that address radiation safety concerns (e.g., use of radiation survey meter, shielded container for the source, and personnel dosimetry, if required).

Describe the types of work, maintenance, cleaning, and repair that involve:

- Installation, relocation, or alignment of the gauge
- Components, including electronics, related to the radiological safety of the gauge (e.g., the source, source holder, source drive mechanism, shutter, shutter control, or shielding)
- Replacement and disposal of sealed sources
- Removal of a gauge from service
- A potential for any portion of the body to come into contact with the primary radiation beam; or
- Any other activity during which personnel could receive radiation doses exceeding IDPH limits.

The principal reason for obtaining this information is to assist in the evaluation of the qualifications of individuals who will conduct the work and the radiation safety procedures they will follow.

A licensee may initially mount a gauge, without specific IDPH, NRC or another Agreement State authorization, if the SSD Certificate of the gauge explicitly permits mounting of gauges by users. The following conditions must be met:

- The gauge must be mounted according to written instructions provided by the manufacturer or distributor;
- The gauge must be mounted in a location compatible with the "Conditions of Normal Use" and "Limitations and/or Other Considerations of Use" in the certificate of registration issued by NRC or an Agreement State;
- The on-off mechanism (shutter) must be locked in the off position, if applicable, or the source must be otherwise fully shielded;
- The gauge must be received in good condition (package was not damaged); and
- The gauge must not require any modification to fit in the proposed location.
- The source must remain fully shielded and the gauge may not be used until it is installed and made operational by a person specifically licensed by the IDPH, NRC or another Agreement State to perform such operations.

Note: Mounting does not include electrical connection, activation, or operation of the gauge.

- Identify who will perform non-routine operations and their training and experience. Acceptable training would include manufacturer's or distributor's courses for non-routine operations or equivalent.
- Submit procedures for non-routine operations. These procedures should ensure the following:
    - doses to personnel and members of the public are within regulatory limits and ALARA (e.g., use of shielded containers or shielding);
    - the source is secured against unauthorized removal or access or under constant surveillance;
    - appropriate labels and signs are used;
    - manufacturer's or distributor's instructions and recommendations are followed;
    - any non-manufacturer/non-distributor supplied replacement components or parts, or the use of materials (e.g., lubricants) other than those specified or recommended by the manufacturer or distributor are evaluated to ensure that they do not degrade the
    - engineering safety analysis performed and accepted as part of the device registration; and
    - before being returned to routine use, the gauge is tested to verify that it functions as designed and source integrity is not compromised.
- Confirm that individuals performing non-routine operations on gauges will wear both whole body and extremity monitoring devices. As an alternative, commit to completing prospective evaluations demonstrating that unmonitored individuals performing non-routine operations are not likely to receive, in one year, a radiation dose more than 10 percent of the allowable limits.

- Verify possession of at least one survey instrument that meets the criteria in "Radiation Safety Program - Instruments in NUREG-1556, Vol. 4, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Fixed Gauges Licenses,' dated October 1998."

- Describe steps to be taken to ensure that radiation levels in areas where non-routine operations will take place do not exceed 641-Chapter 40 limits. For example, applicants can do the following:

    - commit to performing surveys with a survey instrument (as described above);

    - specify where and when surveys will be conducted during non-routine operations; and

    - commit to maintaining records of the survey (e.g., who performed the survey, date of the survey, instrument used, measured radiation levels correlated to location of those measurements), as required by 641-40.82(136C). Records of the surveys should be retained for three years.

SUMMARY OF REVISIONS

Revision	Section	Description
FG-99	Item 11.8	Auditing Guidance
	Appendix E	Non-routine Procedures Guidance
	Appendix F	Auditing Checklist
12/27/00	All	Revised format. Changed address for Bureau of Radiological Health
03/08/01	Item 9	Revised to clarify the training information requested and the personnel involved.
	All	Revised to FG-01
07/17/01	11.8	Deleted reference to Appendix F and added examples of items that should be in an annual audit.
11/19/01	11.7	Revised inventory record retention from three years to five years.
01/18/02	Section 7	Added information concerning inspections.
12/24/02	Section 9	Deleted Appendix C, which concerned training. Moved the information to Item 9. Re-lettered Appendices D and E to C and D, respectively.
03/13/03	Section 1.2	Replace the website address of the IDPH rules and publications.
05/27/04	11.3 & Appendix C	Corrected references to Appendix D to reflect Appendix C. Updated website.
07/01/05	All	Changed address for the Bureau of Radiological Health
7/9/08	11.5	Corrected an appendix reference
8/11/08	Appendix D	Removed redundant paragraph
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.”