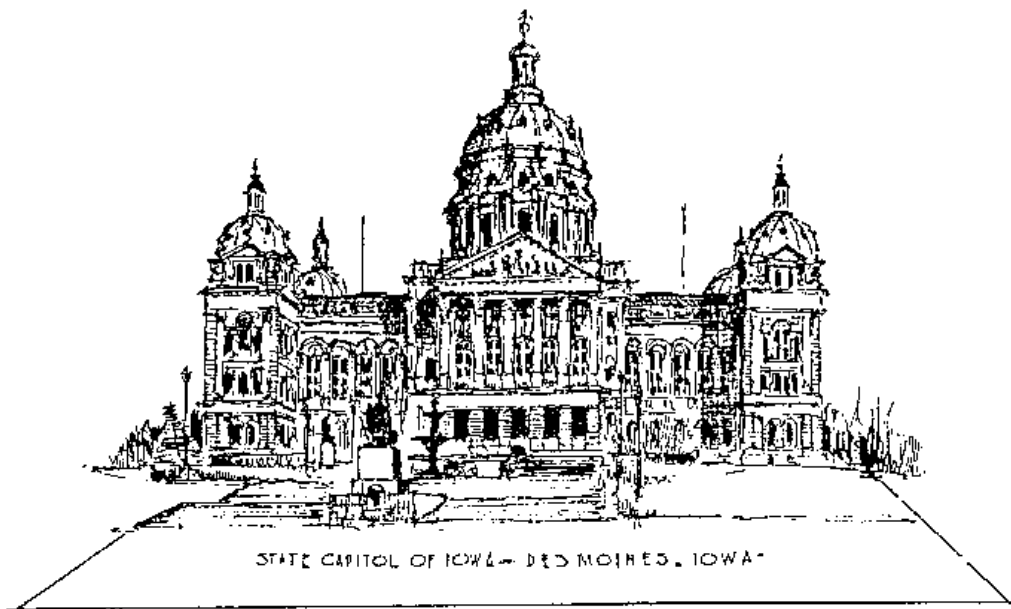


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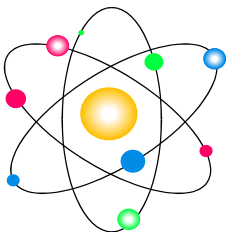
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# IOWA DEPARTMENT OF PUBLIC HEALTH

## GENERALLY LICENSED DEVICE REGULATORY GUIDE



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Iowa Department of Public Health  
Bureau of Radiological Health  
Radioactive Materials Section  
Lucas State Office Building, 5<sup>th</sup> Floor  
321 East 12<sup>th</sup> Street  
Des Moines, Iowa 50319-0075

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## GENERALLY LICENSED DEVICE REGULATORY GUIDE

### 1. INTRODUCTION

#### 1.1 PURPOSE OF GUIDE

This regulatory guide is provided to describe the type and extent of information needed to receive, possess, use, or transfer generally licensed radioactive materials in Iowa.

Individuals or agencies that wish to possess, receive, use or transfer generally licensed devices containing radioactive materials must register those devices with the Iowa Department of Public Health (IDPH). Typically, these devices are designed and manufactured for measuring flow levels, density, or thickness; for analyzing the chemical composition of material; for eliminating or monitoring static; or for calibrating instruments. A generally licensed device must be labeled as such by the manufacturer, and the device must be used and maintained in accordance with the manufacturer's instructions.

You should carefully study this guide and other applicable rules in *Iowa Administrative Code* 641, Chapters 38 through 40 and should then complete the registration form. The IDPH may request additional information to provide reasonable assurance that the applicant has established an adequate radiation protection program.

#### 1.2 APPLICABLE REGULATIONS

Rules pertaining to this type of license are found in the *Iowa Administrative Code* 641, Chapters 38, 39, and 40 of the Radiation Machine and Radioactive Materials Rules. You may go to [www.idph.state.ia.us](http://www.idph.state.ia.us) and click on Health Protection and Environmental Health. Follow the links to the Bureau of Radiological Health. The regulatory guides can be found by further following the links to Radioactive Materials.

#### 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 as low as is reasonably achievable (ALARA)." As a registrant, 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 the use and maintenance of radioactive materials. Management needs to designate one or more responsible persons who will oversee the day-to-day operations of the radiation safety program, including the annual audit of the radiation safety program.

### 2. TYPES OF LICENSES

The Iowa Department of Public Health (IDPH) licenses radioactive materials under either a specific license or a general license. The decision on whether a device must be specifically licensed or generally licensed is based upon an official evaluation of the device's ability to meet or exceed certain safety design criteria. Those who receive, possess, or use devices containing generally licensed radioactive materials must register those devices with the IDPH.

Generally licensed devices may include but are not limited to: gas chromatographs, liquid scintillation detectors, portable gauges, fill level/density gauges, x-ray fluorescent analyzers, static eliminators, and

dewpoint analyzers. It is quite common for firms to have both specifically licensed radioactive materials and registered generally licensed devices included as part of their inventories. The majority of these firms have consolidated the generally licensed materials into their specific licenses to enhance accountability and to minimize costs.

### **3. REGISTRATION**

There are two types of registration -- initial registration and annual renewal of registration. Each type is handled somewhat differently.

#### **3.1 INITIAL REGISTRATION**

The IDPH receives quarterly reports from firms that distribute generally licensed devices containing radioactive materials to facilities in Iowa. Upon receipt of these reports, the IDPH verifies that all recipients have registered to receive, possess, use, or transfer generally licensed radioactive materials. Any of those firms that are not registered are sent an invoice listing all the materials reported to the IDPH. Firms then must verify that the information includes their current inventory of generally licensed devices. A fee of \$250 for annual registration must be sent with the invoice when it is returned to the IDPH. The IDPH will send the annual registration certificate after the information on the invoice is processed.

#### **3.2 REGISTRATION RENEWAL**

The IDPH sends out an annual invoice approximately two months prior to the expiration date of the certificate of registration. This invoice includes the registrant's name and address, contact person, and an inventory of all generally licensed radioactive materials on file with the IDPH. It is the registrant's responsibility to update the information to include all corrections, additions and deletions. The contact person must then sign the form, list his or her telephone number, and return the form to the IDPH with the \$250 registration fee.

Please note that registrations are available for review by the public in the IDPH offices. Do not submit proprietary information unless necessary. If submitting such information is necessary, please specify what the proprietary information involves. Failure to do so may result in unintended disclosure of propriety information. Also, 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 your emergency response plan. Dates of birth, social security numbers, and radiation dose information should be submitted only if specifically requested by the IDPH.

### **4. CONTACT PERSON**

The contact person should be an individual who knows your proposed radioactive materials program and can answer informational questions about the generally licensed devices. This individual -- usually the plant manager, safety officer, or a principal user of the devices -- will serve as the point of contact during the registration and inspection processes. The contact person may be the same individual as the responsible person.

## **5. RESPONSIBLE PERSON**

The responsible person should have independent authority to stop operations that are considered unsafe. The responsible person should also have sufficient time and commitment from management to fulfill certain duties and responsibilities to ensure that radioactive materials are used in a safe manner. Responsibilities should include training, leak testing, inventory, shutter or operations checks (if applicable), annual audits, and disposal of the generally licensed devices.

The responsible person may or may not be the same individual as the contact person. If two or more different individuals are designated, they may share the duties and responsibilities.

## **6. INDIVIDUAL USERS - TRAINING AND EXPERIENCE**

Individuals who use generally licensed devices must follow the manufacturer's instructions for the proper operation, storage, and maintenance of the devices. These instructions appear both in the operator's manuals and on the device labels. Manufacturers often provide this training during installation or servicing of the devices. The registrant should maintain records that document the individual users' training. Although it is not required, annual refresher training on proper operations checks of the device and appropriate radiation safety procedures are valuable tools to maintain safety awareness and to ensure that personnel do not mishandle devices containing radioactive materials.

Individuals who may be considered as users include but are not limited to contact persons, line workers, lead shift workers, maintenance workers, researchers, or others who work in the area where a generally licensed device is installed.

## **7. INVENTORY OF RADIOACTIVE MATERIAL**

A physical inventory of each device containing radioactive materials should be conducted every six (6) months and contain the following information:

1. The type of device (for example, fill level gauge, liquid scintillation detector, static eliminator, dewpoint analyzer, portable thickness gauge, gas chromatograph, calibration sources, etc.)
2. The manufacturer and model number of each device.
3. The serial number of the device.
4. The type and amount of radioactive material that is in each device.
5. The location of the device.
6. The date the inventory was taken.
7. The name or initials of the individual who conducted the inventory.

Routine inventories provide an accurate picture of what radioactive materials your firm has. They also can serve as reminders that the generally licensed devices have other routine requirements such as leak tests and shutter or operations checks. A current inventory also is a tool to verify the accuracy of the information on the annual registration renewal invoice.

## **8. LEAK TESTS**

As a registrant, you must perform tests according to the *Iowa Administrative Code* 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 six (6) month intervals. However, some sealed sources have been authorized for a leak-test interval of thirty-six (36) months. Information about sealed sources that have 36-month leak-test intervals may be obtained from the IDPH, the supplier, or the manufacturer. Any leak test frequency other than six (6) months must be approved by the IDPH.

The options for leak testing are as follows:

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 where you take the smears and send them to the kit supplier, which then reports the results to you; or
3. Perform the entire leak-test sequence yourself, including both taking the smears and analyzing their measurements.

Option 3 is not normally employed by registrants of generally licensed devices because it requires the use of additional radiation measuring equipment and specific procedures. Due to the cost savings and simplicity of the procedures, most registrants of generally licensed devices use Option 2.

If you choose to use Option 3 for leak tests, you must have radiation measuring equipment that is sensitive enough to detect levels down to 0.005 uCi and written procedures for taking and analyzing the samples. An instrument capable of making quantitative measurements should be used; normally, hand-held survey meters will not be considered adequate for these measurements. Include a sample calculation for conversion of the measurement data to microcuries. You should also specify the individual who will make the measurements. This individual should have prior experience in making quantitative radiological measurements, and this experience should be documented in your application. Appendix A lists leak test procedures you can adopt or use as a reference for writing your own procedures.

## **9. SHUTTER OR OPERATIONS CHECKS (IF APPLICABLE)**

Shutter checks or operations checks are required on many devices containing radioactive materials. These checks are to be conducted at the frequency designated by the manufacturer on the device label or in the operation manual. Documentation of the shutter or operations checks should include the following information:

1. The type of device (for example, fill level gauge, static eliminator, dewpoint analyzer, portable thickness gauge, gas chromatograph, or density gauge).
2. The manufacturer and model number of each device.
3. The serial number of each device.
4. The location of each device.
5. The condition of the shutters or operations.
6. The date the shutter or operations check was performed.
7. The name or initials of the individual who conducted the check.
8. Resolution of any problems identified and the date of that resolution.

Results of checks are to be retained for a minimum of three (3) years. Any equipment failure must be reported immediately to the IDPH.

## **10. ANNUAL AUDITS OF THE RADIATION SAFETY PROGRAM**

The annual audit is required by the *Iowa Administrative Code* 641-40.10(3). It is essential that once problems are identified; they are corrected. The IDPH will review a registrant's audit program and determine if corrective actions are thorough, timely, and sufficient to prevent recurrence. The IDPH encourages registrants to regulate their own compliance. Normally violations previously identified and corrected by the registrant will not be cited.

Audits should include personnel training, inventory, leak tests, shutter or operations checks (if appropriate), actual observations of device use, identification of any problems, and resolution of those problems. Any equipment failure must be reported immediately to the IDPH. A copy of a model audit checklist is included as Appendix B. However, this model may need to be modified for your specific operations.

## **11. POSTINGS AND SIGNS**

All device labels must be clean and easily legible. The IDPH recognized that in a manufacturing setting it may not be possible to maintain these conditions. However, it is appropriate to clean labels and check them for legibility any time the devices are inventoried, leak tested, serviced, or checked for operation.

IDPH Form 3, "Notice to Workers," must be posted to permit individuals to observe it on the way to or from the area where generally licensed devices are used or stored. This can be posted on a bulletin board in the employee lounge, on the door to the area where the devices are located, or on the notification bulletin board where other official documents (for example, Occupational Safety and Health Administration or the US Environmental Protection Agency information) are posted.

Also, postings must either include: (1) the certificate of registration, inspection reports, other documents pertaining to the device, or (2) information where these documents can be located.

## **12. TRANSFER OR DISPOSAL**

*Iowa Administrative Code 641-40.70(136C)* specifies the requirements for disposal of licensed material. Because of the nature of the licensed material contained in the devices, disposal of the device is usually by performed an authorized recipient as specified in *Iowa Administrative Code 641-40.70(1)"a"*.

When you dispose of the radioactive material, you should notify the IDPH immediately about what devices were disposed of and where they were sent. This notification may also be done during the registration renewal period. In either case, a copy of the receipt of transfer must be sent to the IDPH.

Authorized recipients are the original manufacturers a commercial firm licensed by the National Regulatory Commission 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 radioactive material.

## **13. REGISTRATION FEES**

An annual registration fee of \$250 must be paid in full as required by the *Iowa Administrative Code 641-38.8(2)"c"* for all generally licensed devices containing radioactive material. Fees for processed registrations are not refundable. Make the check or money order payable to the Iowa Department of Public Health.

Late fees of \$25 a month are assessed starting 30 days after the due date.

## **14. REGISTRATION CORRECTIONS OR UPDATES**

A registration can be corrected or updated by providing the correct information to the IDPH. There is no fee to make these changes. Items about which the IDPH should be informed include receiving or transferring a new device and changes in contact person, responsible person, name of the firm, address, or telephone number.

## APPENDIX A

### PROCEDURES FOR LEAK-TESTING SEALED SOURCES

You may use any of the following procedures to leak-test sealed sources or develop your own procedure. If you do so, you should consider for inclusion all the features in the model procedures and carefully review the requirements of the *Iowa Administrative Code* 641, Chapters 38 through 40. The options are outlined below:

#### 1. CONSULTANT OR COMMERCIAL FACILITY

You can obtain the services of a company licensed to collect and analyze the leak test samples and report the results to you.

#### 2. MODEL PROCEDURE FOR TAKING TEST SAMPLES

This is the most commonly used option for conducting leak tests on generally licensed devices.

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.
4. Test samples are then sent to a company licensed to analyze the lead test samples and report the results to you.

#### 3. MODEL PROCEDURE FOR ANALYZING TEST SAMPLES

This option is rarely used for generally licensed devices because it requires additional radiation measuring equipment and specific written procedures, which must include taking and analyzing test samples. The written procedures may be those outlined below or similar ones that you adopt.

The samples will be analyzed as follows:

1. Select an instrument that is sufficiently sensitive to detect the levels in the *Iowa Administrative Code* 641-40.32. 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 B**

**MODEL ANNUAL AUDIT CHECKLIST**

**AUDITS**

- A. Were previous audits conducted at intervals not to exceed 12 months? [40.10(3)]  N/A  Yes  No
- B. Were records of previous audits maintained? [40.81(136C)]  N/A  Yes  No

**ORGANIZATIONAL STRUCTURE**

- A. If the mailing address or places of use changed, was the IDPH notified?  N/A  Yes  No
- B. If ownership changed or bankruptcy filed, was the IDPH notified?  N/A  Yes  No
- C. Responsible Person  N/A  Yes  No
1. Is the Responsible Person fulfilling his or her duties?  N/A  Yes  No
2. If the designated Responsible Person changed, was the IDPH notified?  N/A  Yes  No
- D. If the designated Contact Person changed, was the IDPH notified?  N/A  Yes  No
- E. Sealed Sources and Devices
1. Have manufacturers or distributor's manuals for operation and maintenance?  N/A  Yes  No
2. Are the actual uses of gauges consistent with the authorized uses?  N/A  Yes  No

**TRAINING AND INSTRUCTION TO WORKERS**

- A. Did all workers receive training in accordance to the manufacturer's recommendations?  N/A  Yes  No
1. Has refresher training provided?  N/A  Yes  No
2. Are records maintained?  N/A  Yes  No
- B. Did individuals who perform non-routine operations receive training before performing the operations?  N/A  Yes  No
- C. Do users know the emergency procedures?  N/A  Yes  No

**INVENTORY**

- A. Is a record kept showing the receipt and transfer of each device or source of radioactive materials?  N/A  Yes  No
- B. Are all devices (sources) physically inventoried every six (6) months?  N/A  Yes  No
- C. Are records of inventory results with appropriate information maintained (i.e. manufacturer name, model, serial number, location of the device (source), type of radioactive materials and activity, date the inventory was conducted, and the name or initials of auditor)?  N/A  Yes  No

**LEAK TESTS**

- A. Was each sealed source leak tested every six (6) months or at other prescribed intervals?  N/A  Yes  No
- B. Are records of results retained with the appropriate information included?  N/A  Yes  No
- C. Were any sources found leaking?  N/A  Yes  No
- D. If any sources were found leaking, was the IDPH notified?  N/A  Yes  No

MAINTENANCE

- A. Are manufacturer or distributor's procedures followed for routine cleaning and lubrication of devices?  N/A  Yes  No
- B. Was each on-off mechanism tested for proper operation every six (6) months or at other prescribed intervals?  N/A  Yes  No
- C. Are repair and maintenance of components related to the radiological safety of the device performed by the manufacturer, distributor or person specifically authorized by the IDPH, NRC or another Agreement State?  N/A  Yes  No
- D. Are labels signs, and postings identifying gauges containing radioactive material, radiation areas, and lockout procedures/warnings clean and legible?  N/A  Yes  No

POSTINGS

- A. Is the IDPH-Form 3 "Notice to Workers" posted?  N/A  Yes  No
- B. Are the IDPH regulations and license documents posted or is a notice posted indicating their location?  N/A  Yes  No

TRANSPORTATION

- A. Do shipping papers contain proper entries? {Shipping name, Hazard Class, Identification Number (UN Number), Total Quantity, Package Type, Nuclide, RQ, Radioactive Material, Physical and Chemical Form, Activity (SI units required), category of label, TI, Shipper's Name, Certification and Signature,  N/A  Yes  No
- B. Are authorized packages used? [49 CFR 173.415, 173.416(b)]  N/A  Yes  No
- C. Are packages properly labeled and marked? [49 CFR 172.301, 172.304, 172.310, 172.324, 49 CFR 172.403, 173.441]  N/A  Yes  No